

Full text of "Legislative history of the Toxic Substances Control Act, together with a section-by-section index"

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[COMMITTEE PRINT]

LEGISLATIVE HISTORY OF THE TOXIC
SUBSTANCES CONTROL ACT

TOGETHER WITH

A SECTION-BY-SECTION INDEX

PREPARED BY THE

ENVIRONMENT AND NATURAL RESOURCES
POLICY DIVISION

OF THE

LIBRARY OF CONGRESS

FOR THE

HOUSE COMMITTEE ON
INTERSTATE AND FOREIGN COMMERCE

Printed for the use of the
Committee on Interstate and Foreign Commerce

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DECEMBER 1976

Printed for the use of the
Committee on Interstate and Foreign Commerce

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LETTER OF TRANSMITTAL

The Library of Congress,
Congressional Research Service,
Washington[^] D.C., November 15[^] 1976.

Hon. PLYMOUTH O. Stammers,

Chairman, Committee on Interstate and Foreign Commerce[^] U.S.
House of Representatives[^] Washington[^] B.C.

Dear [^]Mr. Chairman : In response to your request, we have prepared a legislative history of the Toxic Substances Control Act, Public Law 94-469.

This document contains the major bills, reports, and debates which comprise the action of the 94th Congress concerning the act. Appendices contain a report of the Council on Environmental Quality which originally proposed this legislation and a bibliography of Congressional documents concerning Toxic Substances Control legislation

from 1971 to 1976. A section-by-section index is included to permit easier access to provisions of concern.

The history should be of considerable aid to legislators, public officials, industries, and the general public who are affected by this act and who wish to understand the Congressional intent of Public Law 94-469.

The author of this report was John E. Plodgett, Analyst, of the Environment and Natural Resources Policy Division.

We hope this document will serve your Committee's needs for a history of Congressional action on this act.
Sincerely,

Norman Beckman,

Acting Director.

(Ill)

FOREWORD

This committee print compiles the significant documents and debates comprising the legislative history of S. 3149, the Toxic Substances Control Act, signed into law (Public Law 94-469) on October 11, 1976.

Congressional activity concerning this act extends back to 1971, when the Council on Environmental Quality published a report "Toxic Substances." This report is reprinted as an appendix. The major Congressional documents and debates of the full period of action on toxic substances control - 1971 to 1976 - are listed in the bibliography.

In the debates, references to specific sections are in boldface type; these refer to the section numbers of the bill under consideration. A table at the beginning of the index correlates the section numbers of the major bills and of the act (all of which are identical except for the last few sections).

John E. Plodgett,
Analyst, Environment and Natural

Resources Policy Division.

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CHAPTER I

TOXIC substance control act-
public LAW 94-469

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PUBLIC LAW 94-469- OCT. 11, 1976 90 STAT. 2003

Public Law 94-469
94th Congress ,

An Act

To regulate commerce and protect human health and the environment by Oct. 11, 1976
requiring testing and necessary use restrictions on certain chemical substances, rg 31 40
1

and for other purposes. ^ ' ^

Be it enacted by the Senate and House of Representatives of the
United States of America in Congress assembled^ Toxic Substances

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS. (USC 28)^

This Act may be cited as the "Toxic Substances Control Act". note.

TABLE OF CONTENTS

Sec. 1. Short title and table of contents.

Sec. 2. Findings, policy, and intent.

Sec. 3. Definitions.

Sec. 4. Testing of chemical substances and mixtures.

Sec. 5. Manufacturing and processing notices.

Sec. 6. Regulation of hazardous chemical substances and mixtures.

Sec. 7. Imminent hazards.

Sec. 8. Reporting and retention of information.

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Sec. 10. Research, development, collection, dissemination, and utilization of data.

Sec. 11. Inspections and subpoenas.

Sec. VI. Exports.

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Sec. 17. Specific enforcement and seizure.

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Sec. 21. Citizens' petitions.

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Sec. 27. Development and evaluation of test methods.

Sec. 28. State programs.

Sec. 29. Authorization for appropriations.

Sec. 30. Annual report.

Sec. 31. Effective date.

SEC. 2. FINDINGS, POLICY, AND INTENT.

(a) Findings.— The Congress finds that— 15 USC 2601.

(1) human beings and the environment are being exposed each year to a large number of chemical substances and mixtures;

(2) among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment; and

(3) the effective regulation of interstate commerce in such chemical substances and mixtures also necessitates the regulation of intrastate commerce in such chemical substances and mixtures.

(b) Policy. - It is the policy of the United States that -

(1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environ-

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ment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures ;

(2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and

(3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.

(c) Intent of Congress. - It is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this Act.

SEC. 3. DEFINITIONS.

15 use 2602. As used in this Act:

(1) the term "Administrator" means the Administrator of the Environmental Protection Agency.

(2) (A) Except as provided in subparagraph (B), the term "chemical substance" means any organic or inorganic substance of a particular molecular identity, including -

(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and

(ii) any element or uncombined radical.

(B) Such term does not include -

(i) any mixture,

(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide,

(iii) tobacco or any tobacco product,

(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act,

42 use 2011 of 1954 and regulations issued under such Act),

(v) any article the sale of which is subject to the tax imposed

26 use 4181. by section 4181 of the Internal Revenue Code of 1954 (deter-

mined without regard to any exemptions from such tax provided

26 use 4182, by section 4182 or 4221 or any other provision of such Code) , and

(vi) any food, food additive, drug, cosmetic, or device (as such

terms are defined in section 201 of the Federal Food, Drug, and

21 use 321. Cosmetic Act) when manufactured, processed, or distributed in

commerce for use as a food, food additive, drug, cosmetic, or device.

The term "food" as used in clause (vi) of this subparagraph includes poultry and poultry products (as defined in sections 4(e) and 4(f)

21 use 453. of the Poultry Products Inspection Act) , meat and meat food prod-

21 use 601. ucts (as defined in section of the Federal Meat Inspection Act), and eggs and egg products (as defined in section 4 of the Egg Prod-21 use 1033. ucts Insnection Act) .

(3) The term "commerce" means trade, traffic, transportation, or other commerce (A) between a place in a State and any place outside

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PUBLIC LAW 94-469- OCT. 11, 1976 90 STAT. 2005

of sucli State, or (B) which affects trade, traffic, transportation, or commerce described in clause (A) .

(4) The terms "distribute in commerce"* and "distribution in commerce" when used to describe an action taken with respect to a chemical substance or mixture or article containing a substance or mixture mean to sell, or the sale of, the substance, mixture, or article in commerce ; to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of, the substance, mixture, or article ; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.

(5) The term "environment" includes water, air, and land and the interrelationship which exists among and between w^ater, air, and land and all living things.

(6) The tenn "health and safety study" means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act.

(7) The term 'Snanufacture" means to import into the customs territory of the United States (as defined in general headnote 2 of

the Tariff Schedules of the United States), prepuce, or manufacture. 19 USC 1202.

(8) The term "mixture" means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction ; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical

substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.

(9) The term "new chemical substance" means any chemical substance which is not included in the chemical substance list compiled and published under section 8(b). Post, p. 2027.

(10) The term "process" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce –

(A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or

(B) as part of an article containing the chemical substance or mixture.

(11) The term "processor" means any person who processes a chemical substance or mixture.

(12) The term "standards for the development of test data" means a prescription of –

(A) the–

(i) health and environmental effects, and

(ii) information relating to toxicity, persistence, and other characteristics which affect health and the environment,

for which test data for a chemical substance or mixture are to be developed and any analysis that is to be performed on such data, and

(B) to the extent necessary to assure that data respecting such effects and characteristics are reliable and adequate –

(i) the manner in which such data are to be developed,

(ii) the specification of any test protocol or methodology to be employed in the development of such data, and

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90 STAT. 2006

PUBUC LAW 94^469- OCT. 11, 1976

15 use 2603.

Rules.

Standards for
development of
test data.
Data, submittal to
Administrator.

(iii) such other requirements as are necessary to provide
such assurance.

(13) The term "State" means any State of the United States, the
District of Columbia, the Commonwealth of Pueiix) Rico, the Virgin
Islands, Guam, the Canal Zone, American Samoa, the Northern
Mariana Islands, or any other territory or possession of the United
States.

(14) The term "United States", when used in the geographic sense,
means all of the States.

SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.

(a) Testing Requirements. - If the Administrator finds that -

(1) (A)(i) the manufacture, distribution in commerce, proc-
essing, use, or disposal of a chemical substance or mixture, or that
any combination of such activities, may present an unreasonable
ri k of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data ; or

(B) (i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data ; and

(2) in the case of a mixture, the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture ;

the Administrator shall by rule require that testing be conducted on such substance or mixture to develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.

(b) (1) Testing Requirement Rule. – A rule under subsection (a) shall include –

(A) identification of the chemical substance or mixture for which testing is required under the rule,

(B) standards for the development of test data for such sub-

stance or mixture, and

(C) with respect to chemical substances which are not new chemical substances and to mixtures, a specification or the period (which period may not be of unreasonable duration) within

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which the persons required to conduct the testing shall submit to the Administrator data developed in accordance with the standards referred to in subparagraph (B).

In determining the standards and period to be included, pursuant to subparagraphs (B) and (C), ^{an} a rule under subsection (a), the Administrator's considerations shall include the relative costs of the various test protocols and methodologies which ma^{ay} be required under the rule and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule. Any such rule may require the submission to the Administrator of preliminary data during the period prescribed under subparagraph (C).

(2) (A) The health and environmental effects for which standards for the development of test data may be prescribed include carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment. The characteristics of chemical substances and mixtures for which such standards may be prescribed include persistence, acute toxicity, subacute toxicity, chronic toxicity, and any other characteristic which may present such a risk. The methodologies that may be prescribed in such standards include epidemiologic studies, serial or hierarchical tests, in vitro tests, and whole animal tests, except that before prescribing epidemiologic studies of employees, the Administrator shall consult with the Director of the National Institute for Occupational Safety and Health.

(B) From time to time, but not less than once each 12 months, the Review of Administrator shall review the adequacy of the standards for development of data prescribed in rules under subsection (a) and shall, if necessary, institute proceedings to make appropriate revisions of such standards.

(3) (A) A rule under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph (B)

to conduct tests and submit data to the Administrator on such substance or mixture, except that the Administrator may permit two or more of such persons to designate one such person or a qualified individual party to conduct such tests and submit such data on behalf of the persons making the designation.

(B) The following persons shall be required to conduct tests and submit data on a chemical substance or mixture subject to a rule under subsection (a) :

(i) Each person who manufactures or intends to manufacture such substance or mixture if the Administrator makes a finding described in subsection (a) (1) (A) (ii) or (a) (1) (B) (ii) with respect to the manufacture of such substance or mixture.

(ii) Each person who processes or intends to process such substance or mixture if the Administrator makes a finding described in subsection (a) (1) (A) (ii) or (a) (1) (B) (ii) with respect to the processing of such substance or mixture.

(iii) Each person who manufactures or processes or intends to manufacture or process such substance or mixture if the Administrator makes a finding described in subsection (a) (1) (A) (ii) or (a) (1) (B) (ii) with respect to the distribution in commerce, use, or disposal of such substance or mixture.

(4) Any rule under subsection (a) requiring the testing of and submission of data for a particular chemical substance or mixture shall expire at the end of the reimbursement period (as defined in subsection (c)(3)(B)) which is applicable to test data for such substance or mixture unless the Administrator repeals the rule before such date;

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90 STAT. 2008

PUBLIC LAW 94-469- OCT. 11, 1976

Oral presentation
and written

submissions.
TranscripL
Publication.

Application.

Fair and
equitable
reimbursement

Rules.

and a rule under subsection (a) requiring the testing of and submission of data for a category of chemical substances or mixtures shall expire with respect to a chemical substance or mixture included in the category at the end of the reimbursement period (as so defined) which is applicable to test data for such substance or mixture unless the Administrator before such date repeals the application of the rule to such substance or mixture or repeals the rule.

(5) Rules issued under subsection (a) (and any substantive amendment thereto or repeal thereof) shall be promulgated pursuant to section 553 of title 5, United States Code, except that (A) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions; (B) a transcript shall be made of any oral presentation; and (C) the Administrator shall make and publish with the rule the findings described in paragraph (1) (A) or (1)(B) of subsection (a) and, in the case of a rule respecting a mixture, the finding described in paragraph (2) of such subsection.

(c) Exemption. - (1) Any person required by a rule under subsection (a) to conduct tests and submit data on a chemical substance or mixture may apply to the Administrator (in such form and manner as the Administrator shall prescribe for an exemption from such requirement.

(2) If, upon receipt of an application under paragraph (1), the Administrator determines that -

(A) the chemical substance or mixture with respect to which such application was submitted is equivalent to a chemical substance or mixture for which data has been submitted to the Administrator in accordance with a rule under subsection (a) or for which data is being developed pursuant to such a rule, and

(B) submission of data by the applicant on such substance or mixture would be duplicative of data which has been submitted to the Administrator in accordance with such rule or which is being developed pursuant to such rule,

the Administrator shall exempt, in accordance with paragraph (3) or (4), the applicant from conducting tests and submitting data on such substance or mixture under the rule with respect to which such application was submitted.

(3) (A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the existence of previously submitted test data and if such exemption is granted during the reimbursement period for such test data (as prescribed by subparagraph (B)), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator) -

(i) to the person who previously submitted such test data, for a portion of the costs incurred by such person in complying with the requirement to submit such data, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General

and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) For purposes of subparagraph (A), the reimbursement period Reimbursement for any test data for a chemical substance or mixture is a period - period.

(i) beginning on the date such data is submitted in accordance with a rule promulgated under subsection (a) , and

(ii) ending -

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and which is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later.

(4) (A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the fact that test data is being developed by one or more persons pursuant to a rule promulgated under subsection (a), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator) -

(i) to each such person who is developing such test data, for a portion of the costs incurred by each such person in complying with such rule, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to the costs of complying with such rule, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and

the Federal Trade Commission, consider the factors described in the second sentence of paragraph (3) (A). An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) If any exemption is granted under paragraph (2) on the basis of the fact that one or more persons are developing test data pursuant to a rule promulgated under subsection (a) and if after such exemption is granted the Administrator determines that no such person has complied with such rule, the Administrator shall (i) after providing written notice to the person who holds such exemption and an opportunity for a hearing, by order terminate such exemption, and (ii) notify in writing such person of the requirements of the rule with respect to which such exemption was granted.

(d) Notice. - Upon the receipt of any test data pursuant to a rule Publication in under subsection (a), the Administrator shall publish a notice of the Federal Register, receipt of such data in the Federal Register within 15 days of its receipt. Subject to section 14, each such notice shall (1) identify the chemical substance or mixture for which data have been received; (2) list the uses or intended uses of such substance or mixture and the

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90 STAT. 2010

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Post, p. 2034.

Committee to
make

recommendations
to

Administrator.

Recommendations, list of chemical substances and mixtures.

Publication in Federal Register; transmitt^{^^} to Administrator.

List revision, publication in Federal Register.

information required by the applicable standards for the development of test data; and (3) describe the nature of the test data developed. Except as otherwise provided in section 14, such data shall be made available by the Administrator for examination by any person.

(e) Priority List. - (1) (A) There is established a committee to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of a rule under subsection (a). In making such a recommendation with respect to any chemical substance or mixture, the committee shall consider all relevant factors, including -

(i) the quantities in which the substance or mixture is or will be manufactured,

(ii) the quantities in which the substance or mixture enters or will enter the environment,

(iii) the number of individuals who are or will be exposed to the substance or mixture in their places of employment and the duration of such exposure,

(iv) the extent to which human beings are or will be exposed to the substance or mixture,

(v) the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to present an unreasonable risk of injury to health or the environment,

(vi) the existence of data concerning the effects of the substance or mixture on health or the environment,

(vii) the extent to which testing of the substance or mixture may result in the development of data upon which the effects of the substance or mixture on health or the environment can reasonably be determined or predicted, and

(viii) the reasonably foreseeable availability of facilities and personnel for performing testing on the substance or mixture.

The recommendations of the committee shall be in the form of a list of chemical substances and mixtures which shall be set forth, either by individual substance or mixture or by groups of substances or mixtures, in the order in which the committee determines the Administrator should take action under subsection (a) with respect to the substances and mixtures. In establishing such list, the committee shall give priority attention to those chemical substances and mixtures which are known to cause or contribute to or which are suspected causing or contributing to cancer, gene mutations, or birth defects. The committee shall designate chemical substances and mixtures on the list with respect to which the committee determines the Administrator should, within 12 months of the date on which such substances and mixtures are first designated, initiate a proceeding under subsection (a). The total number of chemical substances and mixtures on the list which are designated under the preceding sentence may not, at any time, exceed 50.

(B) As soon as practicable but not later than nine months after the effective date of this Act, the committee shall publish in the Federal Register and transmit to the Administrator the list and designations required by subparagraph (A) together with the reasons for the committee's inclusion of each chemical substance or mixture on the list. At least every six months after the date of the transmission to the Administrator (if the list pursuant to the preceding sentence, the committee shall make such revisions in the list as it determines to be necessary and shall transmit them to the Administrator together with the committee's reasons for the revisions. Upon receipt of any such revision,

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90 STAT. 2011

the Administrator shall publish in the Federal Register the list with such revision, the reasons for such revision, and the designations made under subparagraph (A) . The Administrator shall provide reasonable Comments, opportunity to any interested person to file with the Administrator written comments on the committee's list, any revision of such list by the committee, and designations made by the committee, and shall make such comments available to the public. Within the 12-month Publication in period beginning on the date of the first inclusion on the list of a Federal Register, chemical substance or mixture designated by the committee under subparagraph (A) the Administrator shall with respect to such chemical substance or mixture either initiate a rulemaking proceeding under subsection (a) or if such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not initiating such a proceeding.

(2) (A) The committee established by paragraph (1) (A) shall consist of eight members as follows :

(i) One member appointed by the Administrator from the Environmental Protection Agency.

(ii) One member appointed by the Secretary of Labor from officers or employees of the Department of Labor engaged in the Secretary's activities under the Occupational Safety and Health Act of 1970.

(iii) One member appointed by the Chairman of the Council on Environmental Quality from, the Council or its officer's or

(iv) One member appointed by the Director of the National Institute for Occupational Safety and Health from officers or employees of the Institute.

(v) One member appointed by the Director of the National Institute of Environmental Health Sciences from officers or employees of the Institute.

(vi) One member appointed by the Director of the National Cancer Institute from officers or employees of the Institute.

(vii) One member appointed by the Director of the National Science Foundation from officers or employees of the Foundation.

(viii) One member appointed by the Secretary of Commerce from officers or employees of the Department of Commerce.

(B) (i) An appointed member may designate an individual to serve on the committee on the member's behalf. Such a designation may be made only with the approval of the applicable appointing authority and only if the individual is from the entity from which the member was appointed..

(ii) No individual may serve as a member of the committee for more than four years in the aggregate. If any member of the committee leaves the entity from which the member was appointed, such member may not continue as a member of the committee, and the member's position shall be considered to be vacant. A vacancy in the committee shall be filled in the same manner in which the original appointment was made. \

(iii) Initial appointments to the committee shall be made not later than the 60th day after the effective date of this Act. Not later than the 90th day after such date the members of the committee shall hold a meeting for the selection of a chairperson from among their number.

(C) (i) No member of the committee, or designee of such member, shall accept employment or compensation from any person subject to any requirement of this Act or of any rule promulgated or order issued thereunder, for a period of at least 12 months after termination of service on the committee.

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(ii) No person, while serving as a member of the committee, or designee of such member, may own any stocks or bonds, or have any pecuniary interest, of substantial value in any person engaged in the manufacture, processing, or distribution in commerce of any chemical substance or mixture subject to any requirement of this Act or of any rule promulgated or order issued thereunder.

(iii) The Administrator, acting through attorneys of the Environmental Protection Agency, or the Attorney General may bring an action in the appropriate district court of the United States to restrain any violation of this subparagraph.

(D) The Administrator shall provide the committee such administrative support services as may be necessary to enable the committee to carry out its function under this subsection.

(f) Required Actions. – Upon the receipt of –

(1) any test data required to be submitted under this Act, or

(2) any other information available to the Administrator, which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects, the Administrator shall, within the 180-day period beginning on the date of the receipt of such data or information, initiate appropriate action under section 5, 6, or 7 to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding that such risk is not unreasonable. For good cause shown the Administrator may extend such period for an

Publication in additional period of not more than 90 days. The Administrator shall Federal Register, publish in the Federal Register notice of any such extension and the reasons therefor. A finding by the Administrator that a risk is not unreasonable shall be considered agency action for purposes of judicial review under chapter 7 of title 5, United States Code. This subsection shall not take effect until two years after the effective date of this Act.

(g) Petition for Standards for the Development of Test Data. – A person intending to manufacture or process a chemical substance

for which notice is required under section 5(a) and who is not required

under a rule under subsection (a) to conduct tests and submit data on such substance may petition the Administrator to prescribe standards for the development of test data for such substance. The Admin-

istrator shall by order either grant or deny any such petition within 60 days of its receipt. If the petition is granted, the Administrator shall prescribe such standards for such substance within 75 days of Publication in the date the petition is granted. If the petition is denied, the Administrator shall publish, subject to section 14, in the Federal Register the reasons for such denial.

SEC. 5. MANUFACTURING AND PROCESSING NOTICES.

15 use 2604. (a) In General. - (1) Except as provided in subsection (h), no person may -

(A) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 8 (b) , or

(B) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2) , is a significant new use,

unless such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of subsection (b).

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(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including -

(A) the projected volume of manufacturing and processing of a chemical substance,

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and

duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(b) Submission of Test Data. – (1) (A) If (i) a person is required by subsection (a) (1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit test data for such substance pursuant to a rule promulgated under section 4 before the submission of such notice, such person shall submit to the Administrator such data in accordance with such rule at the time notice is submitted in accordance with subsection (a) (1).

<B) If- . .

(i) a person is required by subsection (a)(1) to submit a notice to the Administrator, and

(ii) such person has been granted an exemption under section 4(c) from the requirements of a rule promulgated under section 4 before the submission of such notice,

such person may not, before the expiration of the 90 day period which begins on the date of the submission in accordance with such rule of the test data the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(B).

(2) (A) If a person –

(i) is required by subsection (a) (1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (4), and

(ii) is not required by a rule promulgated under section 4 before the submission of such notice to submit test data for such substance,

such person shall submit to the Administrator data prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).

(B) Data submitted pursuant to subparagraph (A) shall be data which the person submitting the data believes show that –

(i) in the case of a substance with respect to which notice is required under subsection (a) (1) (A), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(B), the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.

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Post, p. 2034.

Oral

presentation.

Transcript.

Publication.

Publication in
Federal Register.

(3) Data submitted under paragraph (1) or (2) shall be made available, subject to section 14, for examination by interested persons.

(4) (A) (i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment.

(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present

Administrator shall consider all relevant factors, including –

(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and

(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.

(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under subsection (a) (2), would constitute a significant new use of such substance.

(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of title 5, United States Code, except that (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, (ii) a transcript shall be kept of any oral presentation, and (iii) the Administrator shall make and publish with the rule the finding described in subparagraph (A).

(c) Extension of Notice Period. – The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b) before which the manufacturing or processing of a chemical substance subject to such subsection may begin. Subject to section 14, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

(d) Content of Notice ; Publications in the Federal Register. –

(1) The notice required by subsection (a) shall include –

(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 8(a) (2), and

(IB) in such form and manner as the Administrator may prescribe, any test data in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and (C) a description of any other data concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertain-

Such a notice shall be made available, subject to section 14. for examination by interested persons.

(2) Subject to section 14, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a

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notice under subsection (a) or of data under subsection (b), the Administrator shall publish in the Federal Register a notice which -

(A) identifies the chemical substance for which notice or data has been received ;

(B) lists the uses or intended uses of such substance; and

(C) in the case of the receipt of data under subsection (b), describes the nature of the tests performed on such substance and any data which was developed pursuant to subsection (b) or a rule under section 4.

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of (A) each chemical substance for which notice has been received under subsection (a) and for which the notification period prescribed by subsection (a) , (b) , or (c) has not expired, and (B) each chemical substance for which such notification period has expired since the last publication in the Federal Register of such list.

(e) Regulation Pending Development of Information. - (1) (A)
If the Administrator determines that -

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a) ; and

(ii) (I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

the Administrator may issue a proposed order, to take effect on the Proposed order, expiration of the notification period applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c), to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities.

(B) A proposed order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c), and (ii) unless the Administrator has, on or before the issuance of the proposed order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which

underlies such order.

(C) If a manufacturer or processor of a chemical substance to be subject to a proposed order issued under subparagraph (A) files with the Administrator (within the 30-day period beginning on the date such manufacturer or processor received the notice required by subparagraph (B) (ii)) objections specifying with particularity the provisions of the order deemed objectionable and stating the grounds therefor, the proposed order shall not take effect.

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Injunction, (2) (A) (i) Except as provided in clause (ii), if with respect to a application. chemical substance with respect to which notice is required by subsection (a), the Administrator makes the determination described in paragraph (1) (A) and if -

(I) the Administrator does not issue a proposed order under paragraph (1) respecting such substance, or

(II) the Administrator issues such an order respecting such substance but such order does not take effect because objections were filed under paragraph (1) (C) with respect to it,

the Administrator, through attorneys of the Environmental Protection Agency, shall apply to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer or processor, as the case may be, of such substance is found, resides, or transacts business for an injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance (or to prohibit or limit any combination of such activities) .

(ii) If the Administrator issues a proposed order under paragraph (1) (A) respecting a chemical substance but such order does not take effect because objections have been filed under paragraph (1) (C) with respect to it, the Administrator is not required to apply for an injunction under clause (i) respecting such substance if the Administrator determines, on the basis of such objections, that the determinations under paragraph (1) (A) may not be made.

(B) A district court of the United States which receives an application under subparagraph (A) (i) for an injunction respecting a chemical substance shall issue such injunction if the court finds that -

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a) ; and

(ii) (I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance.

(C) Pending the completion of a proceeding for the issuance of an injunction under subparagraph (B) respecting a chemical substance, the court may, upon application of the Administrator made through attorneys of the Environmental Protection Agency, issue a temporary restraining order or a preliminary injunction to prohibit the manufacture, processing, distribution in commerce, use, or disposal of such a substance (or any combination of such activities) if the court finds that the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance may expire before such proceeding can be completed.

(D) After the submission to the Administrator of test data sufficient to evaluate the health and environmental effects of a chemical substance subject to an injunction issued under subparagraph (B) and the evaluation of such data by the Administrator, the district court of the United States which issued such injunction shall, upon petition, dissolve the injunction unless the Administrator has initiated a pro-

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ceeding for the issuance of a rule under section 6(a) respecting the substance. If such a proceeding has been initiated, such court shall continue the injunction in effect until the effective date of the rule promulgated in such proceeding or, if such proceeding is terminated without the promulgation of a rule, upon the termination of the proceeding, whichever occurs first.

(f) Protection Against Unreasonable Risks. – (1) If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance with respect to which notice is required by subsection (a), or that any combination of such activities, presents or will present an unreasonable risk of injury to health or environment before a rule promulgated under section 6 can protect against such risk, the Administrator shall, before the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.

(2) The Administrator may issue a proposed rule under section Proposed rule 6(a) to apply to a chemical substance with respect to which a finding

was made under paragraph (1) –

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 6(a), or

(C) any combination of the requirements referred to in subparagraph (B).

Such a proposed rule shall be effective upon its publication in the Federal Register. Section 6(d)(2)(B) shall apply with respect to such rule.

(3) (A) The Administrator may –

(i) issue a proposed order to prohibit the manufacture, processing, or distribution in commerce of a substance with respect to

which a finding was made under paragraph (1), or

(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance.

A proposed order issued under clause (i) respecting a chemical substance shall take effect on the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacture or processing of such substance.

(B) If the district court of the United States to which an application has been made under subparagraph (A) (ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with respect to which such application was made, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 6 can protect against such risk, the court shall issue an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance or to prohibit any combination of such activities.

Publication in
Federal Register.

Proposed order.

Injunction
application.

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(C) The provisions of subparagraphs (B) and (C) of subsection (e) (1) shall apply with respect to an order issued under clause (i) of subparagraph (A) ; and the provisions of subparagraph (C) of subsection (e) (2) shall apply with respect to an injunction issued under subparagraph (B).

(D) If the Administrator issues an order pursuant to subparagraph (A) (i) respecting a chemical substance and objections are filed in accordance with subsection (e) (1) (C), the Administrator shall seek an injunction under subparagraph (A) (ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment.

(g) Statement of Reasons for Not Taking Action. - If the Administrator has not initiated any action under this section or section 6 or 7 to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, with respect to which notification or data is required by subsection (a) (1) (B) or (b), before the expiration of the notification period applicable to the manufacturing or processing of such substance, the Administrator shall publish a statement of the Administrator's reasons for not initiating

Publication in such action. Such a statement shall be published in the Federal Register, before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

(h) Exemptions. - (1) The Administrator may, upon application, exempt any person from any requirement of subsection (a) or (b) to permit such person to manufacture or process a chemical substance for test marketing purposes -

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, and

(B) under such restrictions as the Administrator considers appropriate.

(2) (A) The Administrator may, upon application, exempt any person from the requirement of subsection (b) (2) to submit data for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that -

(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which data has been submitted to the Administrator as required by subsection (b) (2), and

(ii) submission of data by the applicant on such substance would be duplicative of data which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from the requirement to submit such data on such substance. No exemption which is granted under this subparagraph with respect to the submission of data for a chemical substance may take effect before the beginning of the reimbursement period applicable to such data.

Fair and (B) If the Administrator exempts any person, under subpara<rraph

equitable (A), from Submitting data required under subsection fb) (2) for a

reimbursement. chemical substance because of the existence of previously submitted data and if such exemption is granted during the reimbursement period for such data, then (unless such person and the persons referred to in

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clauses (i) and (ii) agree on the amount and method of reimbui-se-ment) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator) -

(i) to the person who previously submitted the data on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b) (2) to submit such data, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator

shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.

(C) For purposes of this paragraph, the reimbursement period for Reimbursement any previously submitted data for a chemical substance is a period – period.

(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such data to the Administrator, and

(ii) ending –

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later.

(3) The requirements of subsections (a) and (b) do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of –

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of

the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment. A rule promulgated under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with paragraphs (2) and (3) of section 6(c).

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Publication in
Federal Register.
Comments.

Publication in
Federal Register.

15 use 2605.

(5) The Administrator may, upon application, make the requirements of subsections (a) and (b) inapplicable with respect to the manufacturing or processing of any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure.

(6) Immediately upon receipt of an application under paragraph (1) or (5) the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

(i) Definition. – For purposes of this section, the terms "manufacture" and "process" mean manufacturing or processing for commercial purposes.

SEC. 6. REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND MIXTURES.

(a) Scope of Regulation. – If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment, the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary to protect adequately against such risk using the least burdensome requirements :

(1) A requirement (A) prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

(2) A requirement –

(A) prohibiting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or

(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions

with respect to its use, distribution in commerce, or disposal or with i-pect to any combination of such activities. The form and content of such warnings and instructions shall be prescribed by the Administrator.

(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.

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(5) A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.

(6) (A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.

(B) A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

(7) A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such unreasonable risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such risk of injury, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

Any requirement (or combination of requirements) imposed under

this subsection may be limited in application to specified geographic areas.

(b) Quality Control. – If the Administrator has a reasonable basis to conclude that a particular manufacturer or processor is manufacturing or processing a chemical substance or mixture in a manner which unintentionally causes the chemical substance or mixture to present or which will cause it to present an unreasonable risk of injury to health or the environment –

(1) the Administrator may by order require such manufacturer or processor to submit a description of the relevant quality control procedures followed in the manufacturing or processing of such chemical substance or mixture ; and

(2) if the Administrator determines –

(A) that such quality control procedures are inadequate to prevent the chemical substance or mixture from presenting such risk of injury, the Administrator may order the manufacturer or processor to revise such quality control procedures to the extent necessary to remedy such inadequacy ; or

(B) that the use of such quality control procedures has resulted in the distribution in commerce of chemical substances or mixtures which present an unreasonable risk of injury to health or the environment, the Administrator may order the manufacturer or processor to (i) give notice of such risk to processors or distributors in commerce of any such substance or mixture, or to both, and, to the extent reasonably ascertainable, to any other person in possession of or exposed to any such substance, (ii) to give public notice of such risk, and (iii) to provide such replacement or repurchase of any such substance or mixture as is necessary to adequately protect health or the environment.

A determination under subparagraph (A) or (B) of paragraph (2) Hearing, shall be made on the record after opportunity for hearing in accordance with section 654 of title 5, United States Code. Any manufacturer

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Statement,
publication.

5 use 556, 557.
Notice,
publication.
Written data,
views, arguments,
submittal.
Hearing.
Final rule.

Informal
hearings.

or processor subject to a requirement to replace or repurchase a chemical substance or mixture may elect either to replace or repurchase the substance or mixture and shall take either such action in the manner prescribed by the Administrator.

(c) Promulgation of Subsection (a) Rules. - (1) In promulgating any rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement with respect to -

(A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture.

(B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,

(C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and

(D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy,

small business, technological innovation, the environment, and public health.

If the Administrator determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not promulgate a rule under subsection (a) to protect against such risk of injury unless the Administrator finds, in the Administrator's discretion, that it is in the public interest to protect against such risk under this Act. In making such a finding the Administrator shall consider (i) all relevant aspects of the risk, as determined by the Administrator in the Administrator's discretion, (ii) a comparison of the estimated costs of complying with actions taken under this Act and under such law (or laws), and (iii) the relative efficiency of actions under this Act and under such law (or laws) to protect against such risk of injury.

(2) When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of title 5, United States Code (without regard to any reference in such section to sections 556 and 557 of such title), and shall also (A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule; (B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available; (C) provide an opportunity for an informal hearing in accordance with paragraph (H) ; (D) promulgate, if appropriate, a final rule based on the matter in the rulemaking record (as defined in section 19(a)), and (E) make and publish with the rule the finding described in subsection (a).

(3) Informal hearings required by paragraph (2) (C) shall be conducted by the Administrator in accordance with the following requirements :

(A) Subject to subparagraph (B), an interested person is entitled -

(i) to present such person's position orally or by documentary submissions (or both), and

(ii) if the Administrator determines that there are disputed issues of material fact it is necessary to resolve, to present such rebuttal submissions and to conduct (or have conducted under subparagraph (B) (ii)) such cross-examina-

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tion of persons as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to such issues.

(B) The Administrator may prescribe such rules and make such Rules, rulings concerning procedures in such hearings to avoid unnecessary costs or delay. Such rules or rulings may include (i) the imposition of reasonable time limits on each interested person's

oral presentations, and (ii) requirements that any cross-examination to which a person may be entitled under subparagraph (A) be conducted by the Administrator on behalf of that person in such manner as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to disputed issues of material fact.

(C) (i) Except as provided in clause (ii), if a group of persons each of whom under subparagraphs (A) and (B) would be entitled to conduct (or have conducted) cross-examination and who are determined by the Administrator to have the same or similar interests in the proceeding cannot agree upon a single representative of such interests for purposes of cross-examination, the Administrator may make rules and rulings (I) limiting the representation of such interest for such purposes, and (II) governing the manner in which such cross-examination shall be limited.

(ii) "Whenever any person who is a member of a group with respect to which the Administrator has made a determination under clause (i) is unable to agree upon group representation with the other members of the group, then such person shall not be denied under the authority of clause (i) the opportunity to conduct (or have conducted) cross-examination as to issues affecting the person's particular interests if (I) the person satisfies the Administrator that the person has made a reasonable and good faith effort to reach agreement upon group representation with the other members of the group and (II) the Administrator determines that there are substantial and relevant issues which are not adequately presented by the group representative.

(D) A verbatim transcript shall be taken of any oral presentation made, and cross-examination conducted in any informal transcript,

hearing under this subsection. Such transcript shall be available to the public.

(4) (A) The Administrator may, pursuant to rules prescribed by the Compensation Administrator, provide compensation for reasonable attorneys' fees, expert witness fees, and other costs of participating in a rulemaking proceeding for the promulgation of a rule under subsection (a) to any person -

(i) who represents an interest which would substantially contribute to a fair determination of the issues to be resolved in the proceeding, and

(ii) if-

(I) the economic interest of such person is small in comparison to the costs of effective participation in the proceeding by such person, or

(II) such person demonstrates to the satisfaction of the Administrator that such person does not have sufficient resources adequately to participate in the proceeding without compensation under this subparagraph.

In determining for purposes of clause (i) if an interest will substantially contribute to a fair determination of the issues to be resolved in

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a proceeding, the Administrator shall take into account the number and complexity of such issues and the extent to which representation of such interest will contribute to widespread public participation in the proceeding and representation of a fair balance of interests for the resolution of such issues.

(B) In determining whether compensation should be provided to a person under subparagraph (A) and the amount of such compensation, the Administrator shall take into account the financial burden which will be incurred by such person in participating in the rulemaking proceeding. The Administrator shall take such action as may be necessary to ensure that the aggregate amount of compensa-

tion paid under this paragraph in any fiscal year to all persons who, in rulemaking proceedings in which they receive compensation, are persons who either -

(i) would be regulated by the proposed rule, or

(ii) represent persons who would be so regulated,

may not exceed 25 per centum of the aggregate amount paid as compensation under this paragraph to all persons in such fiscal year.

(5) Paragraph (1), (2), (3), and (4) of this subsection apply to the promulgation of a rule repealing, or making a substantive amendment to, a rule promulgated under subsection (a).

(d) Effective Date. - (1) The Administrator shall specify in any rule under subsection (a) the date on which it shall take effect, which date shall be as soon as feasible.

Publication in (2) (A) The Administrator may declare a proposed rule under sub-

Federal Register, section (a) to be effective upon its publication in the Federal Register

and until the effective date of final action taken, in accordance with subparagraph (B), respecting such rule if -

(i) the Administrator determines that -

(I) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before such effective date; and

(II) making such proposed rule so effective is necessary to protect the public interest ; and

(ii) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under clause (i) (I), a court has in an action under section 7 granted relief with respect to such risk associated with such substance or mixture.

Such a proposed rule which is made so effective shall not, for purposes of judicial review, be considered final agency action.

Notice. (B) If the Administrator makes a proposed rule effective upon its

publication in the Federal Register, the Administrator shall, as expe-

ditionally as possible, give interested persons prompt notice of such action, j) provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c), for a hearing on such rule, and either promulgate such rule (as proposed or with modifications) or revoke it; and if such a hearing is requested, the Administrator shall commence the hearing within five days from the date such request is made unless the Administrator and the person making the request agree upon a later date for the hearing to begin, and after the hearing is concluded the Administrator shall, within ten days of the conclusion of the hearing, either promulgate such rule (as proposed or with modifications) or revoke it.

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(e) POLYCHLORINATED BIPHENYLS. - (1) Within six months after the effective date of this Act the Administrator shall promulgate rules to -

(A) prescribe methods for the disposal of poly chlorinated biphenyls, and

(B) require polychlorinated biphenyls to be marked with clear and adequate warnings, and instructions with respect to their processing, distribution in commerce, use, or disposal or with respect to any combination of such activities.

Requirements prescribed by rules under this paragraph shall be consistent with the requirements of paragraphs (2) and (3).

(2) (A) Except as provided under subparagraph (B), effective one year after the effective date of this Act no person may manufacture, process, or distribute in commerce or use any polychlorinated biphenyl in any manner other than in a totally enclosed manner.

(B) The Administrator may by rule authorize the manufacture, processing, distribution in commerce or use (or any combination of

such activities) of any polychlorinated biphenyl in a manner other than in a totally enclosed manner if the Administrator finds that such manufacture, processing, distribution in commerce, or use (or combination of such activities) will not present an unreasonable risk of injury to health or the environment.

(C) For the purposes of this paragraph, the term "totally enclosed manner" means any manner which will ensure that any exposure of human beings or the environment to a polychlorinated biphenyl will be insignificant as determined by the Administrator by rule.

(3) (A) Except as provided in subparagraphs (B) and (C) -

(i) no person may manufacture any polychlorinated biphenyl after two years after the effective date of this Act, and

(ii) no person may process or distribute in commerce any polychlorinated biphenyl after two and one-half years after such date.

(B) Any person may petition the Administrator for an exemption from the requirements of subparagraph (A), and the Administrator may grant by rule such an exemption if the Administrator finds that-

(i) an unreasonable risk of injury to health or environment would not result, and

(ii) good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for such polychlorinated biphenyl.

An exemption granted under this subparagraph shall be subject to such terms and conditions as the Administrator may prescribe and shall be in effect for such period (but not more than one year from the date it is granted) as the Administrator may prescribe.

(C) Subparagraph (A) shall not apply to the distribution in commerce of any polychlorinated biphenyl if such polychlorinated biphenyl was sold for purposes other than resale before two and one half years after the date of enactment of this Act.

(4) Any rule under paragraph (1), (2)(B), or (3) (B) shall be promulgated in accordance with paragraphs (2), (3), and (4) of subsection (c).

(5) This subsection does not limit the authority of the Administrator, under any other provision of this Act or any other Federal law,

to take action respecting any polychlorinated biphenyl.

Rules.

"Totally enclosed manner."

Petition for exemption.

Terms and conditions.

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SEC. 7. IMMINENT HAZARDS.

Civil action. (a) Actions AUTHORIZED AND REQUIRED. - (1) The Administrator

may commence a civil action in an appropriate district court of the United States -

(A) for seizure of an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture,

(B) for relief (as authorized by subsection (b)) against any person who manufactures, processes, distributes in commerce, or uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing such a substance or mix-

ture, or

(C) for both such seizure and relief.

A civil action may be commenced under this paragraph notwithstanding the existence of a rule under section 4, 5, or 6 or an order under section 5, and notwithstanding the pendency of any administrative or judicial proceeding under any provision of this Act.

(2) If the Administrator has not made a rule under section 6(a) immediately effective (as authorized by subsection 6(d) (2) (A) (i)) with respect to an imminently hazardous chemical substance or mixture, the Administrator shall commence in a district court of the United States with respect to such substance or mixture or article containing such substance or mixture a civil action described in subparagraph (A) , (B) , or (C) of paragraph (1) .

Jurisdiction. (b) Relief Authorized. - (1) The district court of the United

States in which an action under subsection (a) is brought shall have jurisdiction to grant such temporary or permanent relief as may be necessary to protect health or the environment from the unreasonable risk associated with the chemical substance, mixture, or article involved in such action.

(2) In the case of an action under subsection (a) brought against a person who manufactures, processes, or distributes in commerce a chemical substance or mixture or an article containing a chemical substance or mixture, the relief authorized by paragraph (1) may include the issuance of a mandatory order requiring (A) in the case of purchasers of such substance, mixture, or article known to the defendant, notification to such purchasers of the risk associated with it; (B) public notice of such risk; (C) recall; (D) the replacement or repurchase of such substance, mixture, or article; or (E) any combination of the actions described in the preceding clauses.

(3) In the case of an action under subsection (a) against a chemical substance, mixture, or article, such substance, mixture, or article may be proceeded against by process of libel for its seizure and condemnation. Proceedings in such an action shall conform as nearly as possible to proceedings in rem in admiralty.

(c) Venue and Consolidation. - (1) (A) An action under subsection (a) against a person who manufactures, processes, or distributes a chemical substance or mixture or an article containing a chemical substance or mixture may be brought in the United States District Court for the District of Columbia or for any judicial district in which any of the defendants is found, resides, or transacts business ; and process in such an action may be served on a defendant in any other district

in which such defendant resides or may be found. An action under subsection (a) against a chemical substance, mixture, or article may be brought in any United States district court within the jurisdiction of which the substance, mixture, or article is found.

(B) In determining the judicial district in which an action may be brought under subsection (a) in instances in which such action may

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be brought in more than one judicial district, the Administrator shall take into account the convenience of the parties.

(C) Subpoenas requiring attendance of witnesses in an action brought under subsection (a) may be served in any judicial district.

(2) Whenever proceedings under subsection (a) involving identical chemical substances, mixtures, or articles are pending in courts in two or more judicial districts, they shall be consolidated for trial by order of any such court upon application reasonably made by any party in interest, upon notice to all parties in interest,

(d) Action Under Section 6. - Where appropriate, concurrently with the filing of an action under subsection (a) or as soon thereafter as may be practicable, the Administrator shall initiate a proceeding for the promulgation of a rule under section 6(a).

(e) Representation. - Notwithstanding any other provision of law, in any action under subsection (a), the Administrator may direct attorneys of the Environmental Protection Agency to appear and represent the Administrator in such an action.

(f) Definition. - For the purposes of subsection (a), the term "imminently hazardous chemical substance or mixture" means a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment. Such a risk to health or the environment shall be considered imminent if it is shown that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture, or that any combination of such activities, is likely to result in such injury to health or the environment before a final rule under section 6 can protect against such risk.

SEC. 8. REPORTING AND RETENTION OF INFORMATION.

(a) Reports. – (1) The Administrator shall promulgate rules Rules, under which– 15 USC 2607.

(A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B)(ii)) shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require, and

(B) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process –

(i) a mixture, or

(ii) a chemical substance in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product,

shall maintain records and submit to the Administrator reports but only to the extent the Administrator determines the maintenance of records or submission of reports, or both, is necessary for the effective enforcement of this Act.

The Administrator may not require in a rule promulgated under this paragraph the maintenance of records or the submission of reports with respect to changes in the proportions of the components of a mixture unless the Administrator finds that the maintenance of such records or the submission of such reports, or both, is necessary for the effective enforcement of this Act. For purposes of the compilation

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of the list of chemical substances required under subsection (b), the Administrator shall promulgate rules pursuant to this subsection not later than 180 days after the effective date of this Act.

(2) The Administrator may require under paragraph (1) maintenance of records and reporting with respect to the following insofar as known to the person making the report or insofar as reasonably ascertainable:

(A) The common or trade name, the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required.

(B) The categories or proposed categories of use of each such substance or mixture.

(C) The total amount of each such substance and mixture manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.

(D) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture.

(E) All existing data concerning the environmental and health effects of such substance or mixture.

(F) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure.

(G) In the initial report under paragraph (1) on such Substance or mixture, the manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such manner or method.

To the extent feasible, the Administrator shall not require under paragraph (1), any reporting which is unnecessary or duplicative.

(3) (A) (i) The Administrator may by rule require a small manufacturer or processor of a chemical substance to submit to the Administrator such information respecting the chemical substance as the Administrator may require for publication of the first list of chemical substances required by subsection (b).

(ii) The Administrator may by rule require a small manufacturer or processor of a chemical substance or mixture –

(I) subject to a rule proposed or promulgated under section 4, 5(b) (4) , or 6, or an order in effect under section 5(e), or

(II) with respect to which relief has been granted pursuant to a civil action brought under section 5 or 7,

to maintain such records on such substance or mixture, and to submit to the Administrator such reports on such substance or mixture, as the Administrator may reasonably require. A rule under this clause requiring reporting may require reporting with respect to the matters referred to in paragraph (2) .

Standards. (B) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the manufacturers and processors which qualify as small manufacturers and processors for purposes of this paragraph and paragraph (1) .

(b) Inventory. - (1) The Administrator shall compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States. Such list shall at least include each chemical substance which any person reports, imder section 5 or

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subsection (a) of this section, is manufactured or processed in the United States. Such list may not include any chemical substance which was not manufactured or processed in the United States within three years before the effective date of the rules promulgated pursuant to the last sentence of subsection (a) (1). In the case of a chemical substance for which a notice is submitted in accordance with section 5, such chemical substance shall be included in such list as of the earliest date (as determined by the Administrator) on which such substance was manufactured or processed in the United States. The Administrator shall first publish such a list not later than 315 days after the effective date of this Act. The Administrator shall not include in such list any chemical substance which is manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product.

(2) To the extent consistent with the purposes of this Act, the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.

(c) Records. – Any person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture. Records of such adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. Any other record of such adverse reactions shall be retained for a period of five years from the date the information contained in the record was first reported to or known by the person maintaining the record. Records required to be maintained under this subsection shall include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source. Upon request of any duly designated representative of the Administrator, each person who is required to maintain records under this subsection shall permit the inspection of such records and shall submit copies of such records.

(d) Health and Safety Studies. – The Administrator shall promulgate rules under which the Administrator shall require any person

who manufactures, processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce any chemical substance or mixture (or with respect to paragraph (2), any person who has possession of a study) to submit to the Administrator –

(1) lists of health and safety studies (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person, or (C) reasonably ascertainable by such person, except that the Administrator may exclude certain types or categories of studies from the requirements of this subsection if the Administrator finds that submission of lists of such studies are unnecessary to carry out the purposes of this Act; and

(2) copies of any study contained on a list submitted pursuant to paragraph (1) or otherwise known by such person.

(e) Notice to Administrator of Substantial Risks. – Any person who manufactures, processes, or distributes in commerce a chemical

substance or mixture and who obtains information which reasonably

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supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

(f) Definitions.- For purposes of this section, the terms "manufacture" and "process" mean manufacture or process for commercial purposes.

SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.

15 use 2608. (a) Laws Not Administered by the Administrator. - (1) If

the Administrator has reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment and determines, in the Administrator's discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator,

Report- the Administrator shall submit to the agency which administers such

law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency -

(A) (i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and

(ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk ; and

(B) to respond to the Administrator with respect to the matters described in subparagraph (A) .

Publication in Any report of the Administrator shall include a detailed statement of Federal Register, the information on which it is based and shall be published in the Federal Register. The agency receiving a request under such a report shall make the requested determination, issue the requested order, and make the requested response within such time as the Administrator specifies in the request, but such time specified may not be less than 90 days from the date the request was made. The response of an agency shall be accompanied by a detailed statement of the findings and conclusions of the agency and shall be published in the Federal Register.

(2) If the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which such report was made either -

(A) issues an order declaring that the activity or combination of activities specified in the description of the risk described in the report does not present the risk described in the report, or

(B) initiates, within 90 days of the publication in the Federal Register of the response of the agency under paragraph (1) , action under the law (or laws) administered by such agency to protect against such risk associated with such activity or combination of activities,

the Administrator may not take any action under section 6 or 7 with respect to such risk.

(3) If the Administrator has initiated action under section 6 or 7 with respect to a risk associated with a chemical substance or mixture which was the subject of a report made to an agency under paragraph (1), such agency shall before taking action under the law (or laws)

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administered by it to protect against such risk consult with the Administrator for the purpose of avoiding duplication of Federal action against such risk.

(b) Laws Administered by the Administrator. – The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

(c) Occupational Safety AND Health. – In exercising any authority under this Act, the Administrator shall not, for purposes of section

4(b)(1) of the Occupational Safety and Health Act of 1970, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

(d) Coordination. – In administering this Act, the Administrator shall consult and coordinate with the Secretary of Health, Education, and Welfare and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes. The Administrator shall, in the report required by section 30, report, annually to the Congress on actions taken to coordinate with such other Federal departments, agencies, or instrumentalities, and on actions taken to coordinate the authority under this Act with the authority granted under other Acts referred to in subsection (b).

SEC. 10. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA.

(a) Authority. – The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare

and with other heads of appropriate departments and agencies, conduct such research, development, and monitoring as is necessary to carry out the purposes of this Act. The Administrator may enter into contracts and may make grants for research, development, and monitoring under this subsection. Contracts may be entered into under this subsection without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 14 U.S.C. 5).

(b) Data Systems. - (1) The Administrator shall establish, administer, and be responsible for the continuing activities of an interagency committee which shall design, establish, and coordinate an efficient and effective system, within the Environmental Protection Agency, for the collection, dissemination to other Federal departments and agencies, and use of data submitted to the Administrator under this Act.

(2) (A) The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare and other heads of appropriate departments and agencies design, establish, and coordinate an efficient and effective system for the retrieval of toxicological and other scientific data which could be useful to the Administrator in carrying out the purposes of this Act. Systematized retrieval shall be developed for use by all Federal and other departments and agencies

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with responsibilities in the area of regulation or study of chemical substances and mixtures and their effect on health or the environment.

(B) The Administrator, in consultation and cooperation with the Secretary of Health, Education, and Welfare, may make grants and enter into contracts for the development of a data retrieval system described in subparagraph (A). Contracts may be entered into under this subparagraph without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5) .

(c) Screening Techniques. - The Administrator shall coordinate, with the Assistant Secretary for Health of the Department of Health, Education, and Welfare, research undertaken by the Administrator and directed toward the development of rapid, reliable, and economical screening techniques for carcinogenic, mutagenic, teratogenic, and ecological effects of chemical substances and mixtures.

(d) Monitoring. - The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare, establish and be responsible for research aimed at the development, in cooperation with local, State, and Federal agencies, of monitoring techniques and instruments which may be used in the detection of toxic chemical substances and mixtures and which are reliable, economical, and capable of being implemented under a wide variety of conditions.

(e) Basic Research. – The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare, establish research programs to develop the fundamental scientific basis of the screening and monitoring techniques described in subsections (c) and (d), the bounds of the reliability of such techniques, and the opportunities for their improvement.

(f) Training. – The Administrator shall establish and promote programs and workshops to train or facilitate the training of Federal laboratory and technical personnel in existing or newly developed screening and monitoring techniques.

(g) Exchange of Research and Development Results. – The Administrator shall, in consultation with the Secretary of Health, Education, and Welfare and other heads of appropriate departments and agencies, establish and coordinate a system for exchange among Federal, State, and local authorities of research and development results respecting toxic chemical substances and mixtures, including a system to facilitate and promote the development of standard data format and analysis and consistent testing procedures.

SEC. 11. INSPECTIONS AND SUBPOENAS.

15 use 2610. (a) In General. – For purposes of administering this Act, the

Administrator, and any duly designated representative of the Administrator, may inspect any establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce and any conveyance being used to transport chemical substances, mixtures, or such articles in connection with distribution in commerce. Such an inspection may only be made upon the presentation of appropriate credentials and of a written notice to the owner, operator, or agent in charge of the premises or conveyance to be inspected. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness and shall be conducted at reasonable times, within reasonable limits, and in a reasonable manner.

(b) Scope. – (1) Except as provided in paragraph (2), an inspection conducted under subsection (a) shall extend to all things within

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the premises or conveyance inspected (including records, files, papers, processes, controls, and facilities) bearing on whether the requirements of this Act applicable to the chemical substances or mixtures within such premises or conveyance have been complied with.

(2) No inspection under subsection (a) shall extend to -

(A) financial data,

B) sales data (other than shipment data) ,

C) pricing data,

(D) personnel data, or

(E) research data (other than data required by this Act or under a rule promulgated thereunder) ,

unless the nature and extent of such data are described with reasonable specificity in the written notice required by subsection (a) for such inspection.

(c) Subpoenas. - In carrying out this Act, the Administrator may by subpoena require the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, and other information that the Administrator deems necessary. Witnesses shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. In the event of contumacy, failure, or refusal of any person to obey any such subpoena, any district court of the United States in which venue is proper shall have jurisdiction to order any such person to comply with such subpoena. Any failure to obey such an order of the court is punishable by the court as a contempt thereof.

SEC. 12. EXPORTS.

(a) In General. - (1) Except as provided in paragraph (2) and 15USC2611. subsection (b), this Act (other than section 8) shall not apply to any

chemical substance, mixture, or to an article containing a chemical substance or mixture, if -

(A) it can be shown that such substance, mixture, or article is being manufactured, processed, or distributed in commerce for export from the United States, unless such substance, mixture, or article was, in fact, manufactured, processed, or distributed in commerce, for use in the United States, and

(B) such substance, mixture, or article (when distributed in commerce), or any container in which it is enclosed (when so distributed), bears a stamp or label stating that such substance, mixture, or article is intended for export.

(2) Paragraph (1) shall not apply to any chemical substance, mixture, or article if the Administrator finds that the substance, mixture, or article will present an unreasonable risk of injury to health within the United States or to the environment of the United States. The Administrator may require, under section 4, testing of any chemical substance or mixture exempted from this Act by paragraph (1) for the purpose of determining whether or not such substance or mixture presents an unreasonable risk of injury to health within the United States or to the environment of the United States.

(b) Notice. - (1) If any person exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under section 4 or 5(b), such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of the availability of the data submitted to the Administrator under such section for such substance or mixture.

(2) If any person exports or intends to export to a foreign country a chemical substance or mixture for which an order has been issued

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under section 5 or a rule has been proposed or promulgated under section 5 or 6, or with respect to which an action is pending, or relief has been granted under section 5 or 7, such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of such rule, order, action, or relief.

SEC. 13. ENTRY INTO CUSTOMS TERRITORY OF THE UNITED STATES.

15 use 2612. (a) General. - (1) The Secretary of the Treasury shall refuse entry into the customs territory of the United States (as defined in

19 use 1202. general headnote 2 to the Tariff Schedules of the United States) of any chemical substance, mixture, or article containing a chemical substance or mixture offered for such entry if -

(A) it fails to comply with any rule in effect under this Act, or

(B) it is offered for entry in violation of section 5 or 6, a rule or order under section 5 or 6, or an order issued in a civil action brought under section 5 or 7.

Notification. (2) If a chemical substance, mixture, or article is refused entry

under paragraph (1), the Secretary of the Treasury shall notify the consignee of such entry refusal, shall not release it to the consignee, and shall cause its disposal or storage (under such rules as the Secretary of the Treasury may prescribe) if it has not been exported by the consignee within 90 days from the date of receipt of notice of such refusal, except that the Secretary of the Treasury may, pending a review by the Administrator of the entry refusal, release to the consignee such substance, mixture, or article on execution of bond for the amount of the full invoice of such substance, mixture, or article (as such value is set forth in the customs entry), together with the duty thereon. On failure to return such substance, mixture, or article for any cause to the custody of the Secretary of the Treasury when demanded, such consignee shall be liable to the United States for liquidated damages equal to the full amount of such bond. All charges for storage, cartage, and labor on and for disposal of substances, mixtures, or articles which are refused entry or release under this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future entry made by such owner or consignee.

(b) Rules. - The Secretary of the Treasury, after consultation with the Administrator, shall issue rules for the administration of subsection (a) of this section.

SEC. 14. DISCLOSURE OF DATA.

15 use 2613. (a) In General. - Except as provided by subsection (b), any

information reported to, or otherwise obtained by, the Administrator (or any representative of the Administrator) under this Act, which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b) (4) of such section, shall, notwithstanding the provisions of any other section of this Act, not be disclosed by the Administrator or by any officer or employee of the United States, except that such information -

(1) shall be disclosed to any officer or employee of the United States-

(A) in connection with the official duties of such officer or employee under any law for the protection of health or the environment, or

(B) for specific law enforcement purposes ;

(2) shall be disclosed to contractors with the United States and employees of such contractors if in the opinion of the Administra-

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tor such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States entered into on or after the date of enactment of this Act for the performance of work in connection with this Act and under such conditions as the Administrator may specify ;

(3) shall be disclosed if the Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment ; or

(4) may be disclosed when relevant in any proceeding under this Act, except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding.

In any proceeding under section 552(a) of title 5, United States Code, to obtain information the disclosure of which has been denied because of the provisions of this subsection, the Administrator may not rely on section 55*2(1)} (3) of such title to sustain the Administrator's action.

(b) Data From Health and Safety Studies. - (1) Subsection (a) does not prohibit the disclosure of -

(A) any health and safety study which is submitted under this Act with respect to -

(i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution, or

(ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5, and

(B) any data reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

This paragraph does not authorize the release of any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

(2) If a request is made to the Administrator under subsection (a) of section 552 of title 5, United States Code, for information which is described in the first sentence of paragraph (1) and which is not information described in the second sentence of such paragraph, the Administrator may not deny such request on the basis of subsection (b) (4) of such section.

(c) **Test; notification and Release of Confidential Data.** - (1) In submitting data under this Act, a manufacturer, processor, or distributor in commerce may (A) designate the data which such person believes is entitled to confidential treatment under subsection (a), and (B) submit such designated data separately from other data submitted under this Act. A designation under this paragraph shall be made in writing and in such manner as the Administrator may prescribe.

(2) (A) Except as provided by subparagraph (B), if the Administrator proposes to release for inspection data which has been designated under paragraph (1)(A), the Administrator shall notify, in writing and by certified mail, the manufacturer, processor, or distributor in commerce who submitted such data of the intent to release such data. If the release of such data is to be made pursuant to a request made under section 552(a) of title 5, United States Code, such notice shall be given immediately upon approval of such request by the Administrator. The Administrator may not release such data until

the expiration of 30 days after the manufacturer, processor, or distributor in commerce submitting such data has received the notice required by this subparagraph.

Notification. (B) (i) Subparagraph (A) shall not apply to the release of information under paragraph (1), (2), (3), or (4) of subsection (a), except that the Administrator may not release data under paragraph (3) of subsection (a) unless the Administrator has notified each manufacturer, processor, and distributor in commerce who submitted such data of such release. Such notice shall be made in writing by certified mail at least 15 days before the release of such data, except that if the Administrator determines that the release of such data is necessary to protect against an imminent, unreasonable risk of injury to health or the environment, such notice may be made by such means as the Administrator determines will provide notice at least 24 hours before such release is made.

(ii) Subparagraph (A) shall not apply to the release of information described in subsection (b)(1) other than information described in the second sentence of such subsection.

(d) Criminal Penalty for Wrongful Disclosure. - (1) Any officer or employee of the United States or former officer or employee of the United States, who by virtue of such employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a), and who knowing that disclosure of such material is prohibited by such subsection, willfully discloses the material in any manner to any person not entitled to receive it, shall be guilty of a misdemeanor and fined not more than \$5,000 or imprisoned for not more than one year, or both. Section 1905 of title 18, United States Code, does not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported or otherwise obtained under this Act.

(2) For the purposes of paragraph (1), any contractor with the United States who is furnished information as authorized by subsection (a) (2), and any employee of any such contractor, shall be considered to be an employee of the United States.

(e) Access by Congress. - Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this Act shall be made available, upon written request of any duly authorized committee of the Congress, to such committee.

SEC. 15. PROHIBITED ACTS.

15 use 2614. It shall be unlawful for any person to -

(1) fail or refuse to comply with (A) any rule promulgated or order issued under section 4, (B) any requirement prescribed by section 5 or 6, or (C) any rule promulgated or order issued under section 5 or 6 ;

(2) use for commercial purposes a chemical substance or mixture which such person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 or 6, a rule or order under section 5 or 6, or an order issued in action brought under section 5 or 7 ;

(3) fail or refuse to (A) establish or maintain records, (B) submit reports, notices, or other information, or (C) permit access to or copying of records, as required by this Act or a rule thereunder; or

(4) fail or refuse to permit entry or inspection as required by section 11.

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SEC. 16. PENALTIES.

(a) Civil. - (1) Any person who violates a provision of section 15 15 USC 2615. shall be liable to the United States for a civil penalty in an amount

not to exceed \$25,000 for each such violation. Each day such a violation continues shall, for purposes of this subsection, constitute a separate violation of section 15.

(2) (A) A civil penalty for a violation of section 15 shall be assessed Hearing, by the Administrator by an order made on the record after opportunity (provided in accordance with this subparagraph) for a hearing

in accordance with section 554 of title 5, United States Code. Before issuing such an order, the Administrator shall give written notice to the person to be assessed a civil penalty under such order of the Administrator's proposal to issue such order and provide such person an opportunity to request, within 15 days of the date the notice is received by such person, such a hearing on the order.

(B) In determining the amount of a civil penalty, the Administrator shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Administrator may compromise, modify, or remit, with or without conditions, any civil penalty which may be imposed under this subsection. The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(3) Any person who requested in accordance with paragraph (2) Petition for (A) a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for

judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 30-day period beginning on the date the order making such assessment was issued.

(4) If any person fails to pay an assessment of a civil penalty -

(A) after the order making the assessment has become a final order and if such person does not file a petition for judicial review of the order in accordance with paragraph (3), or

(B) after a court in an action brought under paragraph (3) has entered a final judgment in favor of the Administrator,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 30-day period referred to in paragraph (3) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(b) Criminal. - Any person who knowingly or willfully violates any provision of section 15 shall, in addition to or in lieu of any civil penalty which may be imposed under subsection (a) of this section for such violation, be subject, upon conviction, to a fine of not more than \$25,000 for each day of violation, or to imprisonment for not more than one year, or both.

SEC. 17. SPECIFIC ENFORCEMENT AND SEIZURE.

(a) Specific Enforcement. – (1) The district courts of the United States shall have jurisdiction over civil actions to –
(A) restrain any violation of section 15,

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(B) restrain any person from taking any action prohibited by section 5 or 6 or by a rule or order under section 5 or 6,

(C) compel the taking of any action required by or under this Act, or

(D) direct any manufacturer or processor of a chemical substance or mixture manufactured or processed in violation of section 5 or 6 or a rule or order under section 5 or 6 and distributed in commerce, (i) to give notice of such fact to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (ii) to give public notice of such risk of injury, and (iii) to either replace or repurchase such substance or mixture, whichever the person to which the requirement is directed elects.

(2) A civil action described in paragraph (1) may be brought –

(A) in the case of a civil action described in subparagraph (A) of such paragraph, in the United States district court for the judicial district wherein any act, omission, or transaction constituting a violation of section 15 occurred or wherein the defendant is found or transacts business, or

(B) in the case of any other civil action described in such paragraph, in the United States district court for the judicial district wherein the defendant is found or transacts business.

In any such civil action process may be served on a defendant in any judicial district in which a defendant resides or may be found. Subpoenas requiring attendance of witnesses in any such action may be served in any judicial district.

(b) Seizure. – Any chemical substance or mixture which was manu-

factured, processed, or distributed in commerce in violation of this Act or any rule promulgated or order issued under this Act or any article containing such a substance or mixture shall be liable to be proceeded against, by process of libel for the seizure and condemnation of such substance, mixture, or article, in any district court of the United States within the jurisdiction of which such substance, mixture, or article is found. Such proceedings shall conform as nearly as possible to proceedings in rem in admiralty.

SEC. 18. PREEMPTION.

15 use 2617. (a) Effect on State Law. - (1) Except as provided in paragraph

(2) , nothing in this Act shall affect the authority of any State or political subdivision of a State to establish or continue in effect regulation of any chemical substance, mixture, or article containing a chemical substance or mixture.

(2) Except as provided in subsection (b) -

(A) if the Administrator requires by a rule promulgated under section 4 the testing of a chemical substance or mixture, no State or political subdivision may, after the effective date of such rule, establish or continue in effect a requirement for the testing of such substance or mixture for purposes similar to those for which testing is required under such rule ; and

(B) if the Administrator prescribes a rule or order under section 5 or 6 (other than a rule imposing a requirement decriDed in subsection (a) (6) of section 6) which is applicable to a chemical substance or mixture, and which is designed to protect against a risk of injury to health or the environment associated with such substance or mixture, no State or political subdivision of a State may, after the effective date of such requirement, establish or continue in effect, any requirement which is applicable to such substance or mixture, or an article containing such substance or mix-

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Petition.
15 use 2618.

ture, and which is designed to protect against such risk unless such requirement (i) is identical to the requirement prescribed by the Administrator, (ii) is adopted under the authority of the Clean Air Act or any other Federal law, or (iii) prohibits the use of such substance or mixture in such State or political subdivision (other than its use in the manufacture or processing of other substances or mixtures).

(b) Exemption. – Upon application of a State or political subdivision of a State the Administrator may by rule exempt from subsection (a)(2), under such conditions as may be prescribed in such rule, a requirement of such State or political subdivision designed to protect against a risk of injury to health or the environment associated with a chemical substance, mixture, or article containing a chemical substance or mixture if –

(1) compliance with the requirement would not cause the manufacturing, processing, distribution in commerce, or use of the substance, mixture, or article to be in violation of the applicable requirement under this Act described in subsection (a)(2), and
 ^2) the State or political subdivision requirement (A) provides a significantly higher degree of protection from such risk than the requirement under this Act described in subsection (a)(2) and (B) does not, through difficulties in marketing, distribution, or other factors, unduly burden interstate commerce.

SEC. 19. JUDICIAL REVIEW.

(a) In Gener.\l. – (1)(A) Not later than 60 days after the date of the promulgation of a rule under section 4(a), 5(a) (2), 5(b) (4), 6(a), 6(e), or 8, any person may file a petition for judicial review of such rule with the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which such person resides or in which such person's principal place of business is located. Courts of appeals of the Ignited States shall have exclusive jurisdiction of any action to obtain judicial review (other tlian in an enforcement proceeding) of such a rule if any district court of the United States would liave had jurisdiction of such action but for this subparagraph.

(R) Courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of an order issued under subparagraph (A) or (B) of sectioft 6(b)(1) if any district court of the United States

would have had jurisdiction of such action but for this subparagraph.

(2) Copies of any petition filed under paragraph (1)(A) shall be transmitted forthwith to the Administrator and to the Attorney General by the clerk of the court with which such petition was filed. The provisions of section 2112 of title 28, United States Code, shall apply to the filing of the rulemaking record of proceedings on which the Administrator based the rule being reviewed under this section and to the transfer of proceedings between United States courts of appeals.

(3) For purposes of this section, the term "rulemaking record" means -

(A) the rule being reviewed under this section ;

(B) in the case of a rule under section 4(a) , the finding required by such section, in the case of a rule under section 5(b) (4), the finding required by such section, in the case of a rule under section 6(a) the finding required by section 5(f) or 6(a), as the case may be, in the case of a rule under section 6(a) , the statement required by section 6(c) (1), and in the case of a rule under section 6(e), the findings required by paragraph (2)(B) or (3)(B) of such section, as the case may be ;

Jurisdiction.

Petition copies,
transmittal to
Administrator
and Attorney
General.

"Rulemaking
record."

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Notice,

publication in
Federal Register.

Review.

(C) any transcript required to be made of oral presentations made in proceedings for the promulgation of such rule ;

(D) any written submission of interested parties respecting the promulgation of such rule ; and

(E) any other information which the Administrator considers to be relevant to such rule and which the Administrator identified, on or before the date of the promulgation of such rule, in a notice published in the Federal Register.

(b) Additional Submissions and Presentations ; Modifications. -
If in an action under this section to review a rule the petitioner or the Administrator applies to the court for leave to make additional oral submissions or written presentations respecting such rule and shows to the satisfaction of the court that such submissions and presentations would be material and that there were reasonable grounds for the submissions and failure to make such submissions and presentations in the proceeding before the Administrator, the court may order the Administrator to provide additional opportunity to make such submissions and presentations. The Administrator may modify or set aside the rule being reviewed or make a new rule by reason of the additional submissions and presentations and shall file such modified or new rule with the return of such submissions and presentations. The court shall thereafter review such new or modified rule.

(c) Standard of Review. - (1) (A) Upon the filing of a petition under subsection (a) (1) for judicial review of a rule, the court shall have jurisdiction (i) to grant appropriate relief, including interim relief, as provided in chapter 7 of title 5, United States Code, and

(ii) except as otherwise provided in subparagraph (B), to review such rule in accordance with chapter 7 of title 5, United States Code.

(B) Section 706 of title 5, United States Code, shall apply to review of a rule under this section, except that -

(i) in the case of review of a rule under section 4(a), 5(b) (4), 6(a), or 6(e), the standard for review prescribed by paragraph (2) (E) of such section 706 shall not apply and the court shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;

(ii) in the case of review of a rule under section 6(a), the court shall hold unlawful and set aside such rule if it finds that-

(I) a determination by the Administrator under section 6(c) (3) that the petitioner seeking review of such rule is not entitled to conduct (or have conducted) cross-examination or to present rebuttal submissions, or

(II) a rule of, or ruling by, the Administrator under section 6(c) (3) limiting such petitioner's cross-examination or oral presentations,

has precluded disclosure of disputed material facts which was necessary to a fair determination by the Administrator of the rulemaking proceeding taken as a whole; and section 706(2) (D) shall not apply with respect to a determination, rule, or ruling referred to in subclause (I) or (II) ; and

(iii) the court may not review the contents and adequacy of-

(I) any statement required to be made pursuant to section 6(c)(1), or

(II) any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule

except as part of a review of the rulemaking record taken as a whole.

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The term "evidence" as used in clause (i) means any matter in the "Evidence." rulemaking record.

(C) A determination, rule, or ruling of the Administrator described in subparagraph (B)(ii) may be reviewed only in an action under this section and only in accordance with such subparagraph.

(2) The judgment of the court affirming or setting aside, in whole or in part, any rule reviewed in accordance with this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

(d) Fees and costs. - The decision of the court in an action commenced under subsection (a), or of the Supreme Court of the United States on review of such a decision, may include an award of costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate.

(e) Other remedies. - The remedies as provided in this section shall be in addition to and not in lieu of any other remedies provided by law.
SEC. 20. CITIZENS' CIVIL ACTIONS.

(a) In General. - Except as provided in subsection (b) , any person 15 USC 2619. may commence a civil action -

(1) against any person (including (A) the United States, and (B) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution) who is alleged to be in violation of this Act or any. rule promulgated under section 4, 5, or 6 or order issued under section 5 to restrain such violation, or

(2) against the Administrator to compel the Administrator to perform any act or duty under this Act which is not discretionary.

Any civil action under paragraph (1) shall be brought in the United States district court for the district in which the alleged violation occurred or in which the defendant resides or in which the defendant's principal place of business is located. Any action brought under paragraph (2) shall be brought in the United States District Court for the District of Columbia, or the United States district court for the judicial district in which the plaintiff is domiciled. The district courts Jurisdiction, of the United States shall have jurisdiction over suits brought under

this section, without regard to the amount in controversy or the citizenship of the parties. In any civil action under this subsection process may be served on a defendant in any judicial district in which the defendant resides or may be found and subpoenas for witnesses may be served in any judicial district.

(b) LiMrrATioN. - No civil action may be commenced -

(1) under subsection (a) (1) to restrain a violation of this Act or rule or order under this Act -

(A) before the expiration of 60 days after the plaintiff Notice, has given notice of such violation (i) to the Administrator,

and (ii) to the person who is alleged to have committed such violation, or

(B) if the Administrator has commenced and is diligently prosecuting a proceeding for the issuance of an order under section 16(a) (2) to require compliance with this Act or with such rule or order or if the Attorney General has commenced and is diligently prosecuting a civil action in a court of the United States to require compliance with this Act or with such rule or order, but if such proceeding or civil action is commenced after the giving of notice, any person giving such notice may intervene as a matter of right in such proceeding or action ; or

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Notice. (2) under subsection (a) (2) before the expiration of 60 days

after the plaintiff has given notice to the Administrator of the alleged failure of the Administrator to perform an act or duty which is the basis for such action or, in the case of an action under such subsection for the failure of the Administrator to file an action under section 7, before the expiration of ten days after such notification.

Rule. Notice under this subsection shall be given in such manner as the Administrator shall prescribe by rule.

(c) General. – (1) In any action under this section, the Administrator, if not a party, may intervene as a matter of right.

(2) The court, in issuing any final order in any action brought pursuant to subsection (a), may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(3) Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of this Act or any rule or order under this Act or to seek any other relief.

(d) Consolidation. – When two or more civil actions brought under subsection (a) involving the same defendant and the same issues or violations are pending in two or more judicial districts, such pending actions, upon application of such defendants to such actions which is made to a court in which any such action is brought, may, if such court in its discretion so decides, be consolidated for trial by order (issued after giving all parties reasonable notice and opportunity to be heard) of such court and tried in –

(1) any district which is selected by such defendant and in which one of such actions is pending,

(2) a district which is agreed upon by stipulation between all the parties to such actions and in which one of such actions is pending, or

(3) a district which is selected by the court and in which one of such actions is pending.

The court issuing such an order shall give prompt notification of the order to the other courts in which the civil actions consolidated under the order are pending.

SEC. 21. CITIZENS' PETITIONS.

15 use 2620. (a) In General. – Any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 4, 6, or 8 or an order under section 5(e) or (6) (b) (2).

(b) Procedures. - (1) Such petition shall be filed in the principal office of the Administrator and shall set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule under section 4, 6, or 8 or an order under section 5(6), 6(b) (1) (A), or 6(b)(1)(B).

Public hearing. (2) The Administrator may hold a public hearing or may conduct such investigation or proceeding as the Administrator deems appropriate in order to determine whether or not such petition should be granted.

(3) "Within 90 days after filing of a petition described in paragraph (1), the Administrator shall either grant or deny the petition. If the Administrator grants such petition, the Administrator shall promptly

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commence an appropriate proceeding in accordance with section 4, 5, 6, or 8. If the Administrator denies such petition, the Administrator shall publish in the Federal Register the Administrator's reasons for such denial.

(4) (A) If the Administrator denies a petition filed under this section (or if the Administrator fails to grant or deny such petition

within the 90-day period) the petitioner may commence a civil action in a district court of the United States to compel the Administrator to initiate a rulemaking proceeding as requested in the petition. Any such action shall be filed within 60 days after the Administrator's denial of the petition or, if the Administrator fails to grant or deny the petition within 90 days after filing the petition, within 60 days after the expiration of the 90-day period.

(B) In an action under subparagraph (A) respecting a petition to initiate a proceeding to issue a rule under section 4, 6, or 8 or an order under section 5(e) or 6(b) (2), the petitioner shall be provided an opportunity to have such petition considered by the court in a de novo proceeding. If the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that -

(i) in the case of a petition to initiate a proceeding for the issuance of a rule under section 4 or an order under section 5(e) -

(I) information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance to be subject to such rule or order; and

(II) in the absence of such information, the substance may present an unreasonable risk to health or the environment, or the substance is or will be produced in substantial quantities and it enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to it; or

(ii) in the case of a petition to initiate a proceeding for the issuance of a rule under section 6 or 8 or an order under section 6(b) (2), there is a reasonable basis to conclude that the issuance of such a rule or order is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment.

the court shall order the Administrator to initiate the action requested by the petitioner. If the court finds that the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act and there are insufficient resources available to the Administrator to take the action requested by the petitioner, the court may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes.

(C) The court in issuing any final order in any action brought pursuant to subparagraph (A) may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(5) The remedies under this section shall be in addition to, and not in lieu of, other remedies provided by law.

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Publication in
Federal Register.
Notice to
congressional
committee.

15 use 2622.

Notification.

Investigation.
Notification.

Notice, hearing.

SEC. 22. NATIONAL DEFENSE WAIVER.

The Administrator shall waive compliance with any provision of this Act upon a request and determination by the President that the requested waiver is necessary in the interest of national defense. The Administrator shall maintain a written record of the basis upon which such waiver was granted and make such record available for in camera examination when relevant in a judicial proceeding under this Act. Upon the issuance of such a waiver, the Administrator shall publish in the Federal Register a notice that the waiver was granted for national defense purposes, unless, upon the request of the President, the Administrator determines to omit such publication because

the publication itself would be contrary to the interests of national defense, in which event the Administrator shall submit notice thereof to the Armed Services Committees of the Senate and the House of Representatives.

SEC. 23. EMPLOYEE PROTECTION.

(a) In General. – No employer may discharge any employee or otherwise discriminate against any employee with respect to the employee's compensation, terms, conditions, or privileges of employment because the employee (or any person acting pursuant to a request of the employee) has –

(1) commenced, caused to be commenced, or is about to commence or cause to be commenced a proceeding under this Act ;

(2) testified or is about to testify in any such proceeding; or

(3) assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes of this Act.

(b) Remedy. – (1) Any employee who believes that the employee has been discharged or otherwise discriminated against by any person in violation of subsection (a) of this section may, within 30 days after such alleged violation occurs, file (or have any person file on the employee's behalf) a complaint with the Secretary of Labor (hereinafter in this section referred to as the "Secretary") alleging such discharge or discrimination. Upon receipt of such a complaint, the Secretary shall notify the person named in the complaint of the filing of the complaint.

(2) (A) Upon receipt of a complaint filed under paragraph (1), the Secretary shall conduct an investigation of the violation alleged in the complaint. Within 30 days of the receipt of such complaint, the Secretary shall complete such investigation and shall notify in writing the complainant (and any person acting on behalf of the complainant) and the person alleged to have committed such violation of the results of the investigation conducted pursuant to this paragraph. Within ninety days of the receipt of such complaint the Secretary shall, unless the proceeding on the complaint is terminated by the Secretary on the basis of a settlement entered into by the Secretary and the person alleged to have committed such violation, issue an order either providing the relief prescribed by subparagraph (B) or denying the complaint. An order of the Secretary shall be made on the record after notice and opportunity for agency hearing. The Secretary may not enter into a settlement terminating a proceeding on a complaint without the participation and consent of the complainant.

(B) If in response to a complaint filed under paragraph (1) the Secretary determines that a violation of subsection (a) of this section has occurred, the Secretary shall order (i) the person who committed such violation to take affirmative action to abate the violation, (ii)

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PUBLIC LAW 94-469- OCT. 11, 1976 90 STAT.

such person to reinstate the complainant to the complainant's former position together with the compensation (including back pay), terms, conditions, and privileges of the complainant's employment, (lii) compensatory damages, and (iv) where appropriate, exemplary damages. If such an order issued, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorney's fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

(c) Review. - (1) Any employee or employer adversely affected or aggrieved by an order issued under subsection (b) may obtain review of the order in the United States Court of Appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred. The petition for review must be filed within sixty days from the issuance of the Secretary's order. Review shall conform to chapter 7 of title 5 of the United States Code.

(2) An order of the Secretary, with respect to which review could have been obtained under paragraph (1), shall not be subject to judicial review in any criminal or other civil proceeding.

(d) Enforcement. - Whenever a person has failed to comply with Gvil action, an order issued under subsection (b)(2), the Secretary shall file a civil

action in the United States district court for the district in which the violation was found to occur to enforce such order. In actions brought Jurisdiction, under this subsection, the district courts shall have jurisdiction to grant all appropriate relief, including injunctive relief and compensatory and exemplary damages. Civil actions brought under this subsection shall be heard and decided expeditiously.

(e) Exclusion. - Subsection (a) of this section shall not apply with

respect to any employee who, acting without direction from the employee's employer (or any agent of the employer), deliberately causes a violation of any requirement of this Act.

SEC. 24. EMPLOYMENT EFFECTS.

(a) In General. – ^The Administrator shall evaluate on a continuing Evaluation, basis the potential effects on employment (including reductions in 15 USC 2623 employment or loss of employment from threatened plant closures)

of –

(1) the issuance of a rule or order under section 4, 5, or 6, or

(2) a requirement of section 5 or 6.

(b) (1) Investigations. – Any employee (or any representative of an employee) may request the Administrator to make an investigation of –

(A) a discharge or layoff or threatened discharge or layoff of the employee, or

(B) adverse or threatened adverse effects on the employee's employment,

allegedly resulting from a rule or order under section 4, 5, or 6 or a requirement of section 5 or 6. Any such request shall be made in writing, shall set foith with reasonable particularity the grounds for the request, and shall be signed by the employee, or representative of such employee, making the request.

(2) (A) Upon receipt of a request made in accordance with para- Public hearings graph (1) the Administrator shall (i) conduct the investigation requested, and (ii) if requested by any interested person, hold public hearings on any matter involved in the investigation unless the Administrator, by order issued within 45 days of the date such hearings are

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90 STAT. 2046

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Notification.

Publication in
Federal Register.

Recommendations.

15 use 2624.

Submittal to
Congress.
GAO review.

Consultation.

Report to
Congress.

15 use 2625.

requested, denies the request for the hearings because the Administrator determines there are no reasonable grounds for holding such hearings. If the Administrator makes such a determination, the Administrator shall notify in writing the person requesting the hearing of the determination and the reasons therefor and shall publish the determination and the reasons therefor in the Federal Register.

(B) If public hearings are to be held on any matter involved in an investigation conducted under this subsection -

(i) at least five days' notice shall be provided the person making the request for the investigation and any person identified in such request,

(ii) such hearings shall be held in accordance with section 6(c) (3), and

(iii) each employee who made or for whom was made a request for such hearings and the employer of such employee shall be required to present information respecting the applicable matter referred to in paragraph (1)(A) or (1) (B) together with the basis for such information.

(3) Upon completion of an investigation under paragraph (2), the Administrator shall make findings of fact, shall make such recommendations as the Administrator deems appropriate, and shall make available to the public such findings and recommendations.

(4) This section shall not be construed to require the Administrator to amend or repeal any rule or order in effect under this Act.

SEC. 25. STUDIES.

(a) Indemnification Study.- The Administrator shall conduct a study of all Federal laws administered by the Administrator for the purpose of determining whether and under what conditions, if any, indemnification should be accorded any person as a result of any action taken by the Administrator under any such law. The study shall -

(1) include an estimate of the probable cost of any indemnification programs which may be recommended ;

(2) include an examination of all viable means of financing the cost of any recommended indemnification ; and

(3) be completed and submitted to Congress within two years from the effective date of enactment of this Act.

The General Accounting Office shall review the adequacy of the study submitted to Congress pursuant to paragraph (3) and shall report the results of its review to the Congress within six months of the date such study is submitted to Congress.

(b) Classification, Storage, and Retrieval Study. - The Council on Environmental Quality, in consultation with the Administrator,

the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate Federal departments or agencies, shall coordinate a study of the feasibility of establishing (1) a standard classification system for chemical substances and related substances, and (2) a standard means for storing and for obtaining rapid access to information respecting such substances. A report on such study shall be completed and submitted to Congress not later than 18 months after the effective date of enactment of this Act.

SEC. 26. ADMINISTRATION OF THE ACT.

(a) Cooperation of Federal Agencies. – Upon request by the Administrator, each Federal department and agency is authorized – (1) to make its services, personnel, and facilities available (with or without reimbursement) to the Administrator to assist the Administrator in the administration of this Act; and

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(2) to furnish to the Administrator such information, data, estimates, and statistics, and to allow the Administrator access to all information in its possession as the Administrator may reasonably determine to be necessary for the administration of this Act.

(b) Fees. – (1) The Administrator may, by rule, require the payment of a reasonable fee from any person required to submit data under section 4 or 5 to defray the cost of administering this Act. Such rules shall not provide for any fee in excess of \$2,500 or, in the case of a small business concern, any fee in excess of \$100. In setting a fee under this paragraph, the Administrator shall take into account the ability to pay of the person required to submit the data and the cost to the Administrator of reviewing such data. Such rules may provide for sharing such a fee in any case in which the expenses of testing are shared under section 4 or 5. –

(2) The Administrator, after consultation with the Administrator Consultation, of the Small Business Administration, shall by rule prescribe standards for determining the persons which qualify as small business concerns for purposes of paragraph (1).

(c) Action With Respect to Categories. – (1) Any action authorized or required to be taken by the Administrator under any provision

of this Act with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the Administrator takes action under a provision of this Act with respect to a category of chemical substances or mixtures, any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category.

(2) For purposes of paragraph (1) : Definitions.

(A) The term "category of chemical substances" means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

(B) The term "category of mixtures" means a group of mixtures the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in the mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act.

(d) Assistance Office. – The Administrator shall establish in the Establishment. Environmental Protection Agency an identifiable office to provide technical and other nonfinancial assistance to manufacturers and processors of chemical substances and mixtures respecting the requirements of this Act applicable to such manufacturei^ and processors, the

policy of the Agency respecting the application of such requirements to such manufacturers and processors, and the means and methods by which such manufacturers and processors may comply with such requirements.

(e) Financial Disclosures. – (1) Except as provided under para- , graph (3), each officer or employee of the Environmental Protection Agency and the Department of Health, Education, and Welfare who –

(A) performs any function or duty under this Act, and

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90 STAT^2048 PUBLIC LAW 94-469- OCT. 11, 1976

(B) has any known financial interest (i) in any person subject to this Act or any rule or order in effect under this Act, or (ii) in any person who applies for or receives any grant or contract under this Act,

shall, on February 1, 1978, and on February 1 of each year thereafter, file with the Administrator or the Secretary of Health, Education, and Welfare (hereinafter in this subsection referred to as the "Secretary") , as appropriate, a written statement concerning all such interests held by such officer or employee during the preceding calendar year. Such statement shall be made available to the public.

(2) The Administrator and the Secretary shall -

(A) act within 90 days of the effective date of this Act -

(i) to define the term "known financial interests" for purposes of paragraph (1) , and

(ii) to establish the methods by which the requirement to file written statements specified in paragraph (1) will be monitored and enforced, including appropriate provisions for review by the Administrator and the Secretary of such statements; and

Report to (B) report to the Congress on June 1, 1978, and on June 1 of Congress. each year thereafter with respect to such statements and the actions taken in regard thereto during the preceding calendar year.

(3) The Administrator may by rule identify specific positions with the Environmental Protection Agency, and the Secretary may by rule identify specific positions with the Department of Health, Education, and Welfare, which are of a nonregulatory or nonpolicymaking nature, and the Administrator and the Secretary may by rule provide that officers or employees occupying such positions shall be exempt

from the requirements of paragraph (1).

(4) This subsection does not supersede any requirement of chapter 11 of title 18, United States Code.

Penalty. (5) Any officer or employee who is subject to, and knowingly violates, this subsection or any rule issued thereunder, shall be fined not more than \$2,500 or imprisoned not more than one year, or both.

(f) Statement of Basis and Purpose. – Any final order issued under this Act shall be accompanied by a statement of its basis and purpose. The contents and adequacy of any such statement shall not be subject to judicial review in any respect.

Appointment. (g) ASSISTANT ADMINISTRATOR. – (1) The President, by and with

the advice and consent of the Senate, shall appoint an Assistant Administrator for Toxic Substances of the Environmental Protection Agency. Such Assistant Administrator shall be a qualified individual who is, by reason of background and experience, especially qualified to direct a program concerning the effects of chemicals on human health and the environment. Such Assistant Administrator shall be responsible for (A) the collection of data, (B) the preparation of studies, (C) the making of recommendations to the Administrator for regulatory and other actions to carry out the purposes and to facilitate the administration of this Act, and (D) such other functions as the Administrator may assign or delegate.

(2) The Assistant Administrator to be appointed under paragraph (1) shall (A) be in addition to the Assistant Administrators of the Environmental Protection Agency authorized by section 1(d) of Reor-

5 use app. II. ganization Plan No. 3 of 1970, and (B) be compensated at the rate of pay authorized for such Assistant Administrators.

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90 STAT. 2049

EC. 27. DEVELOPMENT AND EVALUATION OF TEST METHODS.

(a) In General. – The Secretary of Health, Education, and Welfare, in consultation with the Administrator and acting through the Assistant Secretary for Health, may conduct, and make grants to public and nonprofit private entities and enter into contracts with public and private entities for, projects for the development and evaluation of inexpensive and efficient methods (1) for determining and evaluating the health and environmental effects of chemical substances and mixtures, and their toxicity, persistence, and other characteristics which affect health and the environment, and (2) which may be used for the development of test data to meet the requirements of rules promulgated under section 4. The Administrator shall consider such methods in prescribing under section 4 standards for the development of test data.

(b) Approval by Secretary. – No grant may be made or contract entered into under subsection (a) unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be submitted in such form and manner and contain such information as the Secretary may require. The Secretary may apply such conditions to grants and contracts under subsection (a) as the Secretary determines are necessary to carry out the purposes of such subsection. Contracts may be entered into under such subsection without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. '39; 41 U.S.C. 5).

(c) Annual Reports. – (1) The Secretary shall prepare and submit to the President and the Congress on or before January 1 of each year a report of the number of grants made and contracts entered into under this section and the results of such grants and contracts.

(2) The Secretary shall periodically publish in the Federal Register reports describing the progress and results of any contract entered into or grant made under this section.

EC. 28. STATE PROGRAMS.

(a) In General. – For the purpose of complementing (but not reducing) the authority of, or actions taken by, the Administrator under his Act, the Administrator may make grants to States for the establishment and operation of programs to prevent or eliminate unreasonable risks within the States to health or the environment which are associated with a chemical substance or mixture and with respect to which the Administrator is unable or is not likely to take action under this Act for their prevention or elimination. The amount of a grant under this subsection shall be determined by the Administrator, except that no grant for any State program may exceed 75 per centum of the

establishment and operation costs (as determined by the Administrator) of such program during the period for which the grant is made.

(b) Approval by Administrator. - (1) No grant may be made under subsection (a) unless an application therefor is submitted to and approved by the Administrator. Such an application shall be submitted in such form and manner as the Administrator may require and shall-

(A) set forth the need of the applicant for a grant under subsection (a),

(B) identify the agency or agencies of the State which shall establish or operate, or both, the program for which the application is submitted,

(C) describe the actions proposed to be taken under such program,

Consultation.
15 use 2626.

Grants or
contracts,
application.

Report to
President and
Congress.

Publication in
Federal Register.

15 use 2627.

Grants,
application.

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(D) contain or be supported by assurances satisfactory to the Administrator that such program shall, to the extent feasible, be integrated with other programs of the applicant for environmental and public health protection,

(E) provide for the making of such reports and evaluations as the Administrator may require, and

(F) contain such other information as the Administrator may prescribe.

Application (2) The Administrator may approve an application submitted in approval. accordance with paragraph (1) only if the applicant has established to the satisfaction of the Administrator a priority need, as determined under rules of the Administrator, for the grant for which the application has been submitted. Such rules shall take into consideration the seriousness of the health effects in a State which are associated with chemical substances or mixtures, including cancer, birth defects, and gene mutations, the extent of the exposure in a State of human beings and the environment to chemical substances and mixtures, and the extent to which chemical substances and mixtures are manufactured, processed, used, and disposed of in a State.

Report to (c) Annual Reports. - Not later than six months after the end of

Congress. each of the fiscal years 1979, 1980, and 1981, the Administrator shall

submit to the Congress a report respecting the programs assisted by grants under subsection (a) in the preceding fiscal year and the extent to which the Administrator has disseminated information respecting such programs.

(d) Authorization. - For the purpose of making grants under subsection (a) there are authorized to be appropriated \$1,500,000 for the fiscal year ending September 30, 1977, \$1,500,000 for the fiscal year ending September 30, 1978, and \$1,500,000 for the fiscal year ending September 30, 1979. Sums appropriated under this subsection shall remain available until expended.

SEC. 29. AUTHORIZATION FOR APPROPRIATIONS.

15 use 2628. There are authorized to be appropriated to the Administrator for

purposes of carrying out this Act (other than sections 27 and 28 and subsections (a) and (c) through (g) of section 10 thereof) \$10,100,000 for the fiscal year ending September 30, 1977, \$12,625,000 for the fiscal year ending September 30, 1978, \$16,200,000 for the fiscal year ending September 30, 1979. No part of the funds appropriated under this section may be used to construct any research laboratories.

SEC. 30. ANNUAL REPORT.

Report to The Administrator shall prepare and submit to the President and

President and Congress on or before January 1, 1978, and on or before January 1 of each succeeding year a comprehensive report on the administration

under section 2629. during the preceding fiscal year. Such report shall include -

(1) a list of the testing required under section 4 during the year for which the report is made and an estimate of the costs incurred during such year by the persons required to perform such tests;

(2) the number of notices received during such year under section 5, the number of such notices received during such year under such section for chemical substances subject to a section 4 rule, and a summary of any action taken during such year under section 5(g);

(3) a list of rules issued during such year under section 6 ;

(4) a list, with a brief statement of the issues, of completed or pending judicial actions under this Act and administrative actions under section 16 during such year ;

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(5) a summary of major problems encountered in the administration of this Act ; and

(6) such recommendations for additional legislation as the Administrator deems necessary to carry out the purposes of this

Act.

SEC 31. EFFECTIVE DATE.

Except as provided in section 4(f), this Act shall take effect on 15 USC 2601 January 1, 1977. Note.

Approved October 11, 1976.

LEGISLATIVE HISTORY :

HOUSE REPORTS: No. 94-1341 accompanying H.R. 14032 (Comm. on Interstate and Foreign Commerce) and No. 94-1679 (Comm. of Conference).

SENATE REPORTS: No. 94-698 (Comm. on Commerce) and No. 94-1302 (Comm. of Conference).

CONGRESSIONAL RECORD, Vol. 122 (1976):
Mar. 26, considered and passed Senate.

Aug. 23, considered and passed House, amended, in lieu of H.R. 14032.

Sept. 28, Senate and House agreed to conference report.

WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 12, No. 42:

Oct. 12, Presidential statement.

Note. - A change has been made in the slip law format to provide for one-time preparation of copy to be used for publication of both slip laws and the United States Statutes at Large volumes. Comments from users are invited by the Office of the Federal Register, National Archives and Records Service, Washington, D.C. 20408.

(Excerpt from Weekly Compilation of Presidential Documents, vol. 12, No. 42. Oct. 18, 1976, p. 1489]

Statement of the President on Signing S. 3149 Into Law -

October 12, 1976

I have signed S. 3149, the Toxic Substances Control Act. I believe this legislation may be one of the most important pieces of environmental legislation that has been enacted by the Congress.

This toxic substances control legislation provides broad authority to regulate any of the tens of thousands of chemicals in commerce. Only a few of these chemicals have been tested for their long-term effects on human health or the environment. Through the testing and reporting requirements of the law, our understanding of these chemicals should be greatly enhanced. If a chemical is found to present a danger to health or the environment, appropriate regulatory action can be taken before it is too late to undo the damage.

The legislation provides that the Federal Government through the Environmental Protection Agency may require the testing of selected new chemicals prior to their production to determine if they will pose a risk to health or the environment. Manufacturers of all selected new chemicals will be required to notify the Agency at least 90 days before commencing commercial production. The Agency may promulgate regulations or go into court to restrict the production or use of a chemical or to even ban it if such drastic action is necessary.

The bill closes a gap in our current array of laws to protect the health of our people and the environment. The Clean Air Act and the Water Pollution Control Act protect the air and water from toxic contaminants. The Food and Drug Act and the Safe Drinking Water Act are used to protect the food we eat and the water we drink against hazardous contaminants. Other provisions of existing laws protect the health and the environment against other polluting contaminants such as pesticides and radiation. However, none of the existing statutes provide comprehensive protection.

This bill provides broad discretionary authority to protect the health and environment. It is critical, however, that the legislation be administered in a manner so as not to duplicate existing regulatory and enforcement authorities.

In addition, I am certain that the Environmental Protection Agency realizes that it must carefully exercise its discretionary authority so as to minimize the regulatory burden consistent with the effective protection of the health and environment.

The administration, the majority and minority members of the Congress, the chemical industry, labor, consumer, environmental, and other groups all have contributed to the bill as it has finally been enacted. It is a strong bill and will be administered in a way which focuses on the most critical environmental problems not covered by existing legislation while not overburdening either the regulatory agency, the regulated industry, or the American people.

(53)

CHAPTER II

S. 3149 TOGETHER WITH REPORT AND DEBATE

Note. - S. 3149 was introduced as a clean bill: the original bill on which hearings were held was S. 776.

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94Tn CONGRESS
2d Session

Calendar No. 668

S. 3149

[Report No. 94-698]

IN THE SENATE OF THE UNITED STATES

March 16, 1976

Mr. TuNNEY (for himself and Mr. IIartke) introduced the following bill;
which was read twice and referred to the Committee on Commerce

March 16, 1976

Reported by Mr. Tunxev, without amendment

A BILL

To regulate commerce and protect human health and the envh-on-
ment by requiring testing and necessary use restrictions on

certain chemical substances, and for other purposes.

1 Be it enacted by the Senate and House of Representa-

2 tives of the United States of America in Congress assembled,

3 SIIIOET TITLE AND TABLE OF CONTENTS

4 Section 1. This Act may be cited as the ''Toxic Sub-

5 stances Control Act".

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Sec. 3. Definitions and exclusions.

Sec. 4. Testing of chemical substances and mixtures.

Sec. 5. Premarket notification of chemical substances.

Sec. 6. Regulation of chemical substances and mixtures.

Sec. 7. Imminent hazards.

Sec. 8. Reporting and retention of information.

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26.

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Sec.

27.

Annual report.

1 FINDINGS, POLICY, AND INTENT

2 Sec. 2. (a) Findings— The Congress finds that—

3 (1) humans and the environment are being ex-

4 posed to a large number of chemical substances and

5 mixtures each year;

6 (2) among the many chemical substances and mix-

7 tures constantly being developed and produced are some

8 whose manufacture, processing, distribution in com-

9 merce, use, or disposal may cause or contribute to an

10 unreasonable risk of injury to health or the environ-

11 ment; and

12 (o) the effective regulation of such chemical sub-

13 - stances and mixtures in interstate commerce necessitates

■^^ the regulation of such chemical substances and mixtures
in intrastate commerce as well.

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3

1 (b) Policy.— It is the policy of the United States

2 that—

3 (1) adequate data should be developed with re-

4 spect to chemical substances and mixtures concerning

5 their effect on human health and the environment and

6 that such data development should be die responsibil-

7 ity of those who manufacture and those who process

8 such chemical substances and mixtures ;

9 (2) adequate authority should exist to regulate

10 chemical substances and mixtures which cause or con-

11 tribute to an unreasonable risk of injury to health or the

12 environment, and to take action with respect to chemical

13 substances and mixtures Avhich are imminent hazards;

14 and

15 (3) authority over chemical substances and mix-

16 tures should be exercised m such a manner as not to

17 impede unduly or create unnecessary economic barriers

18 to technological innovation while fulfilling the primary

19 purpose of this Act to assure that such innovation and
20 commerce in such chemical substances and mixtures do
21 not cause or contribute to an unreasonable risk of injury
22 to health or the environment.

23 (c) Intent of Congress.— It is the intent of Con-
24 gress that the Administrator shall carry out this Act in a
25 reasonable and prudent manner, and that the Administrator

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1 shall consider the environmental, economic, and social impact
2 of any action the Administrator takes or proposes to take
3 under this Act.

4 DEFINITIONS AND EXCLUSIONS

5 Sec. 3. (a) Definitions— As used in this Act:

6 (1) The term "Administrator" means the Administra-
7 tor of the Environmental Protection Agency.

8 (2) (A) Except as provided in subparagraph (B), the
9 term "chemical substance" means —

10 (i) any organic or inorganic substance of a par-
11 ticular molecular identity including a combination of
12 such substances occurring as a result of a chemical
13 reaction, or

14 (ii) any element or uncombined radical.

15 (B) Such term does not include –

16 (i) any mixture,

17 (ii) any pesticide (as defined in the Federal In-

18 secticide. Fungicide and Rodenticide Act) when manu-

19 factured or distributed in commerce for use as a pesti-

20 cide,

21 (iii) tobacco or any tobacco product,

22 (iv) any source material, special nuclear material,

23 or byproduct material (as such terms are defined in the

24 Atomic Energy Act of 1954 and regulations issued under

25 such Act) ,

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5

1 (v) any article which, if sold by the manufacturer,

2 would be subject to the tax imposed by section 4181 of

3 the Internal Revenue Code of 1[^]54 (determined without

4 regard to any exemptions from such tax provided by sec-

5 tion 4182 or 4221 or any other provision of such Code) ,

6 and

7 (vi) any substance found in or on any food, or

8 any drug, cosmetic, or device (as such terms are de-

9 fined in section 201 of the Federal Food, Drug, and
10 Cosmetic Act) when (A) manufactured or distributed
11 in commerce for use in or on any such food, or as any
12 such drug, cosmetic, or device, or (B) produced for
13 research and development purposes and intended only
14 for use in or on any such food, or as any such drug,
15 cosmetic, or device.

16 The term "food" as used in clause (vi) of this subparagraph
17 includes poultry and poultry products (as defined in sections
18 4 (e) and 4(f) of the Poultry Products Inspection Act),
19 meat and meat food products (as defined in section 1 (j) of
20 the Federal Meat Inspection Act) , and eggs and egg prod-
21 ucts (as defined in section 4 of the Egg Products Inspection
22 Act).

23 (3) The term "commerce" means trade, traffic, or trans-
24 portation (A) between a place in a State and any place

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6

1 outside of such State, or (B) which affects such trade,
2 traffic, or transportation.

3 (4) The term "distribute in commerce" or "distribu-
4 tion in commerce" when used to describe an action taken

5 with respect to a chemical substance or mixture means to
6 sell, or the sale of, the substance or mixture; to introduce or
7 deliver for introduction into commerce, or the introduction or
8 delivery for introduction into commerce of, the substance or
9 mixture; or to hold, or the holding of, the substance or
10 mixture after its introduction into commerce.

11 (5) The term "environment" includes humans and
12 their environment, water, atmosphere, and land and the
13 interrelationships which exist among and between these.

11 (6) The term "health and safety study" means any
study of any effects of a chemical substance or mixture on
1^ health or the environment, including epidemiological studies,
1' studies of occupational exposure to a chemical substance or
mixture, toxicological, clinical, and ecological studies of a
1^ chemical substance or mixture, and any test performed pur-
-0 suant to this Act.

^1 (7) The term "manufacture" means to import, produce,
or manufacture for commercial purposes.

(8) The term "mixture" means any combination of two
^4 or more chemical substances if such substances (A) do not

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1 react chemically with each other and if the combination is not
2 the result of a chemical reaction, or (B) occur in nature.

3 (9) The term "new chemical substance" means any
4 chemical substance not included in the chemical substance
5 list compiled and published under section 8 (b) .

6 (10) The term "process" means the preparation of a
7 chemical substance or mixture for distribution in commerce –
8 (A) in the same form or physical state, or in a
9 different form or physical state from that in which it
10 was received by the person making such preparation, or
11 (B) as part of an article containing the chemical
12 substance or mixture.

13 (11) The term "processor" means any person who
14 processes a chemical substance or mixture.

15 (12) The term "standards for the development of test
16 data" means a prescription of –
17 . (A) the–
18 (i) health and environmental effects, and
19 (ii) type of information relating to toxicity,
20 persistence, and other characteristics which relate to
21 effects on health and the environment
22 for which test data for a chemical substance or mixture
23 are to be developed and any analysis that is to be per-
24 formed on such data, and

8

1 (B) to the extent necessary to assure that such data
2 are reliable and adequate, the manner in which such
3 data are to be developed, the specification of any test
4 protocol or methodology to be employed in the develop-
5 ment of data respecting such effects and characteristics,
6 and such other requirements as are necessary to provide
7 such assurance.

8 (13) The term "State" means any of the several
9 States, the District of Columbia, the Commonwealth of
10 Puerto Rico, the Virgin Islands, Guam, the Canal Zone,
11 American Samoa, or the Trust Territory of the Pacific
12 Islands.

13 (14) The term "United States", when used in the
14 geographic sense, means all the States.

15 (b) Exclusions.— The Administrator may exclude
16 from coverage of this Act or any provision of this Act any
17 chemical substance or mixture if the Administrator deter-
18 mines, by rule, that such substance or mixture does not
19 present an unreasonable risk of injury to health or the
20 environment, except that any such exclusion shall not apply
21 to section 7 or 8(e). Any such rule shall (A) be pro-
22 mulgated pursuant to the procedures specified in section
23 6(c) (2), (3), (4), and (5) and (B) may be modified,

24 amended, or revoked in accordance with the requirements

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1 of this subsection and pursuant to the procedures specified

2 in such section 6(c) (2), (3), (4), and (5).

3 TESTING OF CHEMICAL SUBSTANCES AND MIXTURES

4 Sec. 4. (a) Testing Eequirements .- If the Ad-

5 ministrator finds that -

6 (1) (A) (i) the manufacture, processing, distribu-

7 tion in commerce, use, or disposal of a chemical sub-

8 stance or mixture may present an unreasonable risk of

9 injury to health or the environment, or (ii) (I) that the

10 manufacture, processing, distribution in commerce, use,

11 or disposal of a chemical substance or mixture may

12 present significant human or environmental exposure

13 because it is or will be produced in substantial quantities

14 or for other reasons, and (II) that such substance or

15 mixture may perhaps present an adverse effect on health

16 or the environment,

17 " (^) there are insufficient data or experience upon

18 which the effects of such manufacture, processing, dis-

19 tribution in commerce, use, or disposal on health or

20 the environment can reasonably be determined or pre-
21 dieted, and
22 (C) testing of such substance or mixture with
23 respect to such effects is necessary to develop such data ;
24 and

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1 (2) in the case of a mixture, the effects which the
2 mixture's manufacture, distribution in commerce, proc-
3 essing, use, or disposal may have on health or the en-
4 vironment may not be reasonably and more eflSciently
5 determined or predicted by testing the chemical sub-
6 stances which comprise the mixture ;
7 the Administrator shall by rule require that testing be con-
8 ducted on such substance or mixture to develop data with
9 respect to the health and environmental effects for which
10 there is an insufficiency of data or experience and which
11 are relevant to a determination that the manufacture, distri-
12 bution in commerce, processing, use, or disposal of such
13 substance or mixture does or does not cause or contribute to
14 an unreasonable risk of injuiy to health or the environment.
15 In requiring tests under this subsection, the Administrator

16 shall consider the reasonably ascertainable costs and other
17 burdens associated with conducting such tests in light of the
18 possible risks of injury to health or the environment and shall
19 publish the same in the Federal Register. The finding in
20 paragraph (1) (A) (ii) (II) shall be presumed if the Ad-
21 ministrator has no reliable data or experience available to
22 him concerning the chemical substance or mixture. The find-
23 ing in paragraph (1) (A) (ii) (11) shall not be subject to
24 judicial review on any ground other than the fact that such
25 finding was not made.

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1 (b) (1) Testing Requirement Eule- A rule under
2 subsection (a) requiring the testing of a chemical substance
3 or mixture shall include -
4 (A) identification of the substance or mixture for
5 which testing is required,
6 (B) standards for the development of test data for
7 such substance or mixture, and
8 (C) with respect to chemical substances which are
9 not new chemical substances a specification of the period
10 (which period may not be of unreasonable duration)

11 within which the persons required to conduct the testing
12 shall submit to the Administrator data developed in
13 accordance with the standards referred to in subpara-
14 graph (B) .
15 Such a rule may require the submission of preliminary data
16 during the period prescribed under subparagraph (C).
17 (2)" (A) The health and environmental effects for which
18 standards for the development of test data may be pre-
19 scribed include carcinogenesis, mutagenesis, teratogenesis,
20 behavioral disorders, cumulative or synergistic effects, and
21 any other effect which may cause or contribute to an unrea-
22 sonable risk of injury to health or the environment, and the
23 characteristics of chemical substances and mixtures for which
24 such standards may be prescribed include persistence, acute
25 toxicity, subacute toxicity, chronic toxicity, and any other

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1 characteristic which may cause or contribute to such a risk
2 of injury. The methodologies that may be prescribed in such
3 standards include epidemiology, serial, or hierarchical tests;
4 in vitro tests; and whole animal tests.

5 (B) From time to time, but not less than once each
ft'

6 12 months, the Administrator shall review the adequacy
7 of the standards for development of data prescribed in rules
8 under subsection (a) and shall, if necessary, institute pro-
9 ceedings to make appropriate revisions of such standards.

10 (3) (A) A rule under subsection (a) respecting a
11 chemical substance or mixture shall require the persons
12 described in subparagraph (B) to conduct tests and submit
13 data on such substance or mixture, except that the Admin-
14 istrator may permit two or more of such persons to designate
15 one such person or a qualified third party to conduct such
16 tests and submit such data on behalf of the persons making
17 the designation.

18 (B) The following persons shall be required to conduct
19 tests and submit data on a chemical substance or mixture
20 subject to a rule under subsection (a) :

21 (i) Each person who manufactures or intends to
22 manufacture such substance or mixture if the Adminis-
23 trator made a finding described in subsection (a) (1)
24 (B) with respect to the manufacture of the substance

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1 or mixture which such person is engaged in or intends

2 to engage in.

3 (ii) Each person who processes or intends to process
4 such substance or mixture if the Administrator made a
5 finding described in subsection (a) (1) (B) with respect
6 to the processing of the substance which such person
7 is engaged in or intends to engage in.

8 (iii) Each person who manufactures or processes or
9 intends to manufacture or process such substance or mix-
10 ture if, with respect to the distribution in commerce, dis-
11 posal or use of such substance or mixture manufactured
12 or processed or to be manufactured or processed by such
13 person, the Administrator made a finding described in
14 subsection (a) (1) (B).

15 (4) Rules issued under subsection (a) (and any amend-
16 ment thereto or repeal thereof) shall be promulgated pur-
17 suant to section 553 of title 5, United States Code, except
18 that in promulgating, amending, or repealing any such rule
19 (A) the Administrator shall give interested persons an op-
20 portunity for the oral presentation of data, views, or argu-
21 ments, in addition to an opportunity to make written sub-
22 missions; and (B) a transcript shall be made of any oral
23 presentation.

24 (c) Exemption. - (1) Any person required by a rule

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1 under subsection (a) to conduct tests and submit data on a
2 chemical substance or mixture may apply to the Adminis-
3 trator (in such form and manner as the Administrator shall
4 prescribe) for an exemption from such requirement.

5 (2) If, upon receipt of an application under paragraph
6 (1) , the Administrator determines that -

7 (A) the chemical substance or mixture with respect
8 to which such application was submitted is equivalent
9 to a chemical substance or mixture for which data has
10 been submitted to the Administrator in accordance with
11 a rule under subsection (a) or for which data is being
12 developed pursuant to such a rule, and

13 (B) submission of data by the applicant on such
14 substance or mixture would be duplicative of data which
15 has been submitted to the Administrator in accordance
16 with such rule or which is being developed pursuant to
17 such rule,

18 the Administrator shall exempt, in accordance with para-
19 graph (3) or (4), the applicant from conducting tests and
20 submitting data on such substance or mixture.

21 (3) (A) If the exemption of any person from the re-

22 requirement to conduct tests and submit test data on a chemical
23 substance or mixture is granted on the basis of the existence
24 of previously submitted test data and if such exemption is

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1 granted during the reimbursement period for such test data

2 (as prescribed by subparagraph (B)), then (unless such

3 person and the persons referred to in clauses (i) and (ii)

4 agree on the amount and method of reimbursement) the

5 Administrator shall order the person granted the exemption

6 to provide fair and equitable reimbursement (in an amount

7 determined under rules of the Administrator) -

8 (i) to the person who previously submitted such test

9 data, for a portion of the costs incurred by such person

10 in complying with the requirement to submit such data,

11 and

12 (ii) to any other person who has been required

13 under this subparagraph to contribute with respect to

14 such costs, for a portion of the amount such person was

15 required to contribute.

16 In promulgating rules for the determination of fair and

17 equitable reimbursement to the persons described in clauses

18 (i) and (ii) for costs incurred with respect to a chemical

19 substance or mixture, the Administrator shall, after consul-
20 tation with the Attorney General and the Federal Trade
21 Commission, consider all relevant factors, including the
22 effect on competition within the chemical industry and the
23 share of the market for such substance or mixture of the
24 person required to provide reimbursement in relation to the

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1 share of such market of the persons to be reimbursed. An
2 order under this subparagraph for purposes of judicial
3 review shall be considered final agency action.

4 (B) For purposes of subparagraph (A) , the reimburse-
5 ment period for any test data for a chemical substance or
6 mixture is a period -

7 (i) beginning on the date such data was submitted
8 in accordance with a rule promulgated under subsection
9 (a) , and

10 (ii) ending-

11 (I) two years after the date referred to in
12 clause (i) , or

13 (II) at the expiration of a period which begins
14 on the date referred to in clause (i) and is equal to

15 the period which the Administrator determines was
16 necessary to develop such data,
17 whichever is later.

13 (4) (A) If the exemption of any person from the re-

19 quirement to conduct tests and submit test data on a chemical
20 substance or mixture is granted on the basis of the fact that
21 test data is being developed by one or more persons pursuant
22 to a rule promulgated under subsection (a) , then (unless
23 such person and the persons referred to in clauses (i) and
24 (ii) agree on the amount and method of reimbursement) the
25 Administrator shall issue an order to the person granted the

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1 exemption to provide fair and equitable reimbursement (In
2 an amount determined under rules of the Administrator) -

3 (I) to each such person who is developing such test
4 data, for a portion of the costs incurred by each such
5 person in complying with such rule, and

(J (ii) to any other person who has been required

7 under this subparagraph to contribute with respect to

8 the costs of complying with such rule, for a portion of

9 the amount such person was required to contribute.

10 In promulgating rules for the determination of fair and
11 equitable reimbursement to the persons described in clauses
12 (i) and (ii) for costs incurred with respect to a chemical
13 substance or mixture^ the Administrator shall, after consul-
14 tation with the Attorney General and the Federal Trade
15 Commission, consider all relevant factors, including the
16 effect on competition within the chemical industry and the
17 share - of this market for such substance or mixture of the
18 person required to provide reimbursement in relation to the
19 share of such market of the persons to be reimbursed. An
20 order under ' this subparagraph for purposes of judicial
21 review shall be considered final agency action.

22" (Sy i^ exemption' is granted on the basis of the fact
23 that one or more persons are developing test data pursuant to
24 a rule promulgated under subsection (a) and if after such
25 ' exemption is granted the Administrator determines that no

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1 such person has complied with such rule, the Administrator
2 shall (i) after providing written notice, to the person who
3 holds such exemption and an opportunity for a hearing, by

4 order terminate such exemption, and (ii) notify in writing
5 such person of the requirements of the rule with respect to
6 which such exemption was granted.

7 (5) If a person provides reimbursement pursuant to an
8 order issued under paragraph (3) (A) or (4) (A) in con-
9 nection with an exemption from a rule promulgated under
10 subsection (a) , such person may, subject to section 14, have
11 access to test data the submission or development of which
12 was the basis for such exemption.

13 (d) Notice. – Upon the receipt of any test data pur-
14 suant to a rule under subsection (a) , the Administrator shall
15 (subject to section 14) publish a notice of the receipt of
16 such data in the Federal Register and make the data avail-
17 able to the public within 15 days of receipt. Each such
18 notice shall (1) identify the chemical substance or mixture
19 for which data have been received; (2) list the uses or in-
20 tended uses of such substance or mixture and the information
21 required by the applicable standards for the development of
22 test data; and (3) describe the nature of the test data
23 developed.

24 (e) Priority List.– (1) (A) There is established
25 a committee to make recommendations to the Administrator

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1 respecting the chemical substances and mixtures to which the
2 Administrator should give priority consideration for the
3 promulgation of a rule under subsection (a) . In makmg such
4 a determination with respect to any chemical substance or
5 mixture, the committee shall consider all relevant factors,
6 including -

7 (i) the quantities in which the substance or mix-
8 ture is or will be manufactured,

9 (ii) the quantities in which the substance or mixture
10 enters or will enter the environment,

11 (iii) the number of persons who are or will be
12 exposed to the substance or mixture in their places of
13 employment and the duration of such exposure,

14 (iv) the extent to which humans are or will be ex-
15 posed to the substance or mixture,

16 (v) the extent to which the substance or mixture is
17 -closely related to a chemical substance or mixture which
18 is known to cause or contribute to an unreasonable risk
19 to health or the environment,

20 (vi) the existence of data concerning the effects of
21 the substance or mixture on health or the environment,

22 and

23 (vii) the extent to which testing of the substance
24 or mixture may result in the development of data upon
25 which the effects of the substance or mixture on health

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1 or the environment can reasonably be determined or
2 predicted.

3 The recommendations of the committee shall be in the form
4 of a list of chemical substances and mixtures which shall
5 be listed, either by individual substance or mixture or by
6 groups of substances or mixtures, in the order in which the
7 committee determines the Administrator should take action
8 under subsection (a) with respect to the substances and
9 mixtures. The committee shall give priority attention in
10 establishing such list to those chemical substances and mix-
11 tures which are known or are suspected of causing or con-
12 tributing to (i) cancer, (ii) gene mutations, or (iii) birth
13 defects.

14 (B) As soon as practicable but not later than nine
15 months after the date of the enactment of this Act, the com-
16 mittee shall publish in the Federal Register the list required

17 by subparagraph (A) together with the reasons for the com-
18 mittee 's inclusion of each chemical substance or mixture on
19 the Hst. At least every 6 months after the pubhcation of
20 the list pursuant to the preceding sentence, the committee
21 shall make such revisions in the list as it determines to be
22 necessary and shall pubhsh the list in the Federal Register
23 with the committee's revisions (if any) and the reasons for
24 the revisions. Within the 12-month period be^nning on the
25 date of the inclusion of a chemical substance or mixture on

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1 such a list the Administrator shall with respect to such
2 chemical substance or mixture either (i) initiate a rule-
3 making proceeding under section 4 (a) or (ii) if such a
4 proceeding is not initiated within such period, publish in
5 the Federal Register the Administrator's reasons for not
Q initiating such a proceeding.

7 (C) The Administrator may promulgate a rule under
8 subsection (a) with respect to a chemical substance or mix-
9 ture (i) wliidi is not contained on a list published under
10 this subsection or (ii) whether or not the Administrator has
11 published in the Federal Register reasons for not initiating
12 a proceeding under subparagraph (B) .

12, (2) (A) The committee established by paragraph (1)

14 (A) shall consist of seven members as follows :

15 (i) One member (or designee of the member)

16 appointed from the Department of Commerce by the

17 ■ Secretary.

18 (ii) One member (or designee of the member)

19 appointed from the Environmental Protection Agency

20 by the Administrator.

21 (iii) One member (or designee of the member)

22 appointed by the Secretary of Labor from officers of

23 the Department of Labor engaged in the Secretary's

24 activities under the Occupational Safety and Health

25 Act of 1970.

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1 (iv) One member (or designee of the member)

2 'appointed from the Council on Environmental Quality

3 by the Chairman of the Council.

4 (v) One member (or designee of the member)

5 appointed from the National Institute for Occupational

6 Safety and Health by the Director of the Institute.

7 (vi) One member (or the designee of the member)

8 appointed from the National Institute of Environmental

9 Health Sciences by the Director of the Institute.

10 (vii) One member (or designee of the member)

11 appointed from the National Cancer Institute by the

12 Director of the Institute. ^

13 (^iii) One member (or designee of the member)

14 appointed from the National Science Foundation by

35 the Director of the Foundation.

K) A member may designate an individual to serve on the

17 member's behalf only with the approval of the applicable

18 appointing authority and only if the individual is from the

19 entity from which the member was appointed. A vacancy in

20 the committee shall be filled in the same manner in which

21 the original appointment was made.

22 (^) (i) The term of office of a member of the committee

23 is 4 years, except that of the members first appointed,

24 four members shall have initial terms of 2 years. Any

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1 member appointed to fill a vacancy occurring prior to the

2 expiration of the term for which the member's predecessor

3 was appointed shall be appointed only for the remainder of

4 such term. If any member of the committee leaves the office

5 or entity from which the member was appointed, such mem-
6 ber's term of office shall be terminated and the member's
7 position shall be considered as being vacant. A member may
8 serve after the expiration of the member's term of office until
9 a successor has taken office. Members may be reappointed.

10 (ii) Initial appointments to the committee shall be
11 made not later than the 60th day after the date of the
12 enactment of this Act. Not later than the 90th day after
13 such date of enactment the members of the committee shall
14 hold a meeting for the selection of a chairman from among
15 their number and to determine, by lot, the four members
16 who shall have initial terms of 2 years.

17 (C) (i) No member of the committee, or designee of
18 such member, shall accept employment or compensation
19 from any person subject to any requirement of this Act, or
20 rules issued thereunder, for a period of at least 24 months
21 after termination of employment with such agency.

22 (ii) No person, while serving as a member of such
23 committee, or designee of such member, may own any stocks
24 or bonds, or have any pecuniary interest in any firm, asso-

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1 elation, or corporation engaged in the manufacture, process-
2 ing, or distribution of any chemical substance or mixture
3 subject to the provisions of this Act.

4 (iii) The Administrator or the Attorney General may
5 bring an action in the appropriate district court of the United
6 States to restrain any violations of this subparagraph.

7 (D) The Administrator shall provide the committee
8 such administrative and staff support services as may be
9 necessary for the committee to carry out its functions under
10 this subsection.

11 (f) Required Actions. - (1) Upon the receipt of
12 (A) any test data required to be submitted under this section
13 or under section 5, or (B) any other information available to
14 the Administrator which indicates that a chemical substance
15 or mixture has the potential, at levels for which human ex-
16 posure exists or may exist and with appropriate safety mar-
17 gins, to induce in human beings (1) cancer, (2) gene
18 mutations, or (3) birth defects, the Administrator shall take
19 appropriate action under section 5 (e) , 6 (a) , or 7, within
20 180 days after the receipt of such data or information to limit
21 exposure of human beings with respect to such substance or
22 mixture, or he shall publish in the Federal Register his find-
23 ing that no unreasonable risk of injury is presented and rea-
24 sons therefor. Any such finding under this subsection that no

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1 unreasonable risk is presented shall be reviewable in accord-
2 ance with chapter 7 of title 5, United States Code^

3 (2) Nothing contained in this subsection shall require
4 the Administrator to take action under section 5 (e) , 6 (a) ,
5 or 7, or publish his reasons for failing to take such action,
6 until 2 years after the date of enactment of this Act.

7 PEEMARKET NOTIFICATION OF CHEMICAL SUBSTANCES

8 Sec. 5. (a) General.— (1) Commencing 1 year and

9 30 days after the date of enactment of this Act, a

10 manufacturer shall notify the Administrator, who shall

11 notify the public as required in subsection (c) , of any

12 planned manufacture of a new ^chemical substance, at least

13 90 days prior to the commencement of such manufacture.

14 Such notice to the Administrator shall be accompanied by

15 all pertinent information referred to in section 8(a) (2),

1^ whether or not the Administrator has required the siibmis-

1'^ sion thereof under section 8(a) (2) . except that with respect

18 to the information referred to under section 8(a) (2) (E),

19 such manufacturer may submit a description of such infor-

20 mation, as defined by the Administrator, by rule.

21 (2) The Administrator shall give priority attention to

22 a chemical substance with respect to which information is

23 received indicating that serious economic or other hardships

24 are likely to result if there is any delay in manufacture.

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1 If the Administrator finds that such a substance does not
2 present an unreasonable risk to human health and the
3 environment, he may reduce the number of days, after sub-
4 mission of such information, during which manufacture may
5 not occur. The Administrator shall promptly publish (sub-
6 ject to section 14) his findings and the basis therefor in the
7 Federal Register.

8 (b) Submission of Data. - Any manufacturer of a
9 new chemical substance that is covered by section 4 (a) shall
10 submit to the Administrator (in addition to the information
11 required in subsection (a)) the data developed in accord-
12 ance with such requirement .at least 90 days prior to such
13 manufacture, and the Administrator shall make it publicly
14 available in accordance with subsection (c) .

15 (c) Data Availability. - Within 15 days after re-
16 ceipt, the Administrator shall promptly publish in the Fed-
17 eral Register (subject to section 14) the identity of each
18 chemical substance for which a notice has been received un-
19 der subsection (a) or (b) , the intended use or distribution

20 of such substance, and a statement that the data and other
21 information is available. The 90 days referred to in subsec-
22 tions (a) and (b) shall begin upon publication under this
23 subsection in the Federal Register.

24 (d) Extension. – The Administrator may extend, for
25 an additional period beyond the 90-day period referred to

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1 in subsection (a) or (b) , the date after which a new chemi-
2 cal substance may be manufactured. Such additional period
3 may not exceed 90 days and shall not be imposed except
4 for good cause shown. Notice of any such extension, and
5 the reasons therefor, shall be published (subject to section
6 14) in the Federal Register. Such an extension shall consti-
7 tute a final action for purposes of judicial review.

8 (e) Order.— (1) (A) If the Administrator finds, dur-
9 ing the 90-day period referred to in subsection (a) or (b)
10 or during any extension thereof, with respect to any new
11 chemical substance for which notification is required under
12 this section –

13 (i) that such new chemical substance is covered by
14 a test requirement under section 4(a), but that such

15 requirement requires additions or revisions with respect
16 to such substance ; or

17 (ii) that such new chemical substance is not cov-

18 ered by such a requirement under section 4(a), but

19 that such requirement should be established;

20 he shall issue an order in accordance with this subsection.

21 Such an order shall appropriately prohibit or restrict the

22 manufacture, processing, distribution in commerce, use, or

23 disposal of such new chemical substance pending the comple-

24 tion of a rulemaking proceeding under section 4(a) and

25 the submission of any data required thereunder, as described

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^ tinder sul)paragraph (B) ; shall contain a proposed rule

2 under section 4(a) ; and shall be immediately effective.

2 (B) Upon the issuance of any order under subpara-

^ gi'aph (A) , the Administrator shall proceed with a rulemak-

g ing procedure as expeditious^ as practicable under section 4

Q (a) and in accordance with subparagraph (C) . During the

rj course of, or upon the completion of, such rulemaking, the

g Administrator shall, if necessary, appropriately modify or

g rescind any order issued under subparagraph (A). If any

-^Q testing requirements are established as a result of such rule-

17 (d).
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(C) If Administrator issues an order under sub-
-j^g paragraph (A), the Administrator shall provide interested
20 persons reasonable opportunity, in accordance with section
21 4(b) (4) to make presentations and submissions with re-
22 spect to such order. If such presentation or submission is
23 requested, the Administrator shall comply within 30 days
24 from the date such request is made unless the Administra-
25 tor and the person making the request agree upon a later

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1 date. Within 10 days after such presentations and submis-
2 sion are concluded, the Administrator shall consider such
3 presentations and submissions and affirm, modify, or revoke
4 such order.

5 (2) (A) If the Admmistrator finds, during the 90-day

6 period referred to in subsection (a) or (b) or during any
7 extension thereof, with respect to any new chemical substance
8 for which notification is required under this section, that a
9 rule is appropriate under section 6(a), he shall issue an
10 order in accordance with this subsection, Such an order.
11 shall appropriately prescribe such requirements as are au-
12 thorized under section 6(a) ; shall contain a proposed rule
13 under section 6 (a) ; and shall be immediately effective.

14 (B) Upon the issuance of any order under subpara-
15 graph (A), the Administrator shall proceed with a rule-
16 making procedure as expeditiously as practicable imder sec-
17 tion 6(a) and in accordance wdth subparagraph (C) .
18 During the course of, or upon the completion of such rule-
19 making, the Administrator shall> if necessary, appropriately
20 modify or rescmd any order issued under subparagraph (A) .

21 (C) If the Administrator issues an order under sub-
22 paragraph (A), the Administrator shall provide interested
23 persons reasonable opportunity^, in accordance with section
24 6(c) (2) and (3) for an mformal hearing wdth respect to
25 s,uch order. If such hearing is requested, the Administrator

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1 shall comply within 30 days from the date such request is
2 made unless the Administrator and the person making the
3 request agree upon a later date. Within 10 days after such
4 hearing is concluded, the Administrator shall consider the
5 information presented at such hearing and affirm, modify,
6 or revoke such order.

7 (f) Statement of Reasons for Not Taking Ac-
8 tion. – Prior to the expiration of 90 days after the date
9 of publication under subsection (c) , of data and informa-
10 tion with respect to a new chemical substance, or prior to
11 the expiration of such period as extended under subsection
12 (d), the Administrator shall publish a statement of his
13 reasons in the Federal Register, if he decides not to take
14 action under subsection (e) or section 7 with respect to
15 such chemical substance during such period. Manufacture
16 may commence following publication of the Administrator's
17 statement. The Administrator's failure to issue such an order
18 under subsection (e) or take action under section 7 is an
19 action subject to judicial review in accordance with section
20 19. Nothing in this subsection prohibits the Administrator
21 from –
22 (1) promulgating a rule pursuant to section 6 or 4,
23 with respect to such a substance, after such manufacture
24 has commenced;

25 (2) taking action against any chemical substance

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X which is found to be an imminent hazard pursuant to

2 section 7 ; or

3 (3) taking any other action authorized by this Act.

4 (g) Exemption. - (1) The Administrator may upon

5 application (made in such form and manner as the Adminis-

6 trator may prescribe) exempt any person from the require-

7 ment of subsection (b) or (h) to submit data for a chemical

8 substance or mixture. If, upon receipt of an application

9 under the preceding sentence, the Administrator determines

10 that^

11 (A) the chemical substance or mixture with respect

12 to which such application was submitted is equivalent

13 to a chemical substance or mixture for which data has

14 been submitted to the Administrator in accordance with

15 subsection (b) or (h), and

16 (B) submission of data by the applicant with re-

17 spect to such substance would be duplicative of data

18 which has been submitted to the Administrator in

19 accordance with such subsection,

20 the Administrator shall exempt the applicant from submit-
21 ting such data with respect to such substance. No exemption
22 granted under this subparagraph with respect to the submis-
23 sion of data for a chemical substance or mixt[^]e may take
24 effect before the beginning of the reimbursement period
25 applicable to such data.

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1 (2) If the Administrator, under paragraph (1), ex-
2 empts any person from submitting under subsection (b) or
3 (h) data for a chemical substance or mixi.ture because of
4 the existence of previously submitted data and if such exemp-
5 tion is granted during the reimbursement period for such
6 data, then (unless such person and the persons referred to
7 in subparagraphs (A) and (B) agree on the amount and
8 method of reimbursement) the Administrator shall order the
9 person granted the exemption to provide fair and equitable
10 reimbursement (in an amount determined under rules of the
11 Administrator) -
12, (A) to the person who previously submitted the
13, data on which the exemption was basedj for a portion of
14 the costs incurred by such person in complying' with the

15 requirement under subsection (b) or (h) to submit
16 such data, and
17 (B) to any other person who has been required
18 under this subparagraph to contribute with respect to
19 such costs, for a portion of the amount such person
20 was required to contribute.
21 In promulgating rules for the determination of fair and
22 equitable reimbursement to the persons described in sub-
23 paragraphs (A) and (B) for costs incurred with respect to
24 a chemical substance or mixture, the Administrator shall,
25 after consulting with the Attorney General and the Federal

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1 Trade Commission, consider all relevant factors, including
2 the effect on competition within the chemical industry and
3 the share of the market for such substance or mixture of the
4 person required to provide reimbursement in relation to the
5 share of such market of the persons to be reimbursed. An
6 order under this subparagraph shall be considered final
7 agency action, for purposes of judicial review.

8 (3) For purposes of this paragraph, the reimbursement

9 period for any previously submitted data for a chemical
10 substance or mixture is a period –
11 (A) beginning on the date of the termination of
12 the prohibition, imposed under this section, on the manu-
13 facture or processing of such s.ubstance by the person
14 who submitted such data to the Administrator, and
15 (B) ending–
16 (i) two years after the date referred to in
17 subparagraph (A), or
18 (ii) at the expiration of a period which begins
19 on the date referred to in subparagraph (A) and is
20 equal to the period which the Administrator deter-
21 mines was necessary to develop such data,
22 whichever is later.
23 (h) Significant New Use.– (1) Within 6 months
24 after the date of enactment of this Act, and from time to
25 tune thereafter, the Administrator shall, by rule, establish

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1 criteria defining a significant new distribution in commerce,
2 use, or disposal of a chemical substance. In establishing such
3 criteria, the Administrator shall take into account -

4 (A) projected volume of production;

5 (B) projected category or categories of uses;

6 (C) projected increase in magnitude and duration

7 of human and environmental exposure;

8 (D) route or routes of exposure of human beings

9 or of the environment that are attributable to such

10 significant new use; and

11 (E) the human health and environmental effects

12, thereof.

13 (2) A chemical substance may not be manufactured or

14 processed for a distribution in commerce, use, or disposal

15 that is identified by the Administrator, in a rule, as a sig-

16 nificant new distribution in commerce, use, or disposal, unless,

17 at least 90 days prior to such manufacture or processing,

18 the person intending to manufacture or process such substance

19 for such distribution in commerce, use, or disposal submits a

20 notice of his intention to do so and any data required to be

21 developed under section 4 (a) to the Administrator. Any such

22 use of such substance shall be subject to all of the provisions
23 of this section.

24 (i) Special Exemption.— The Administrator may,

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^ upon application and by rule, exempt any person from the

2 foregoing requirements of this section —

3 (1) for the purpose of permitting such person to

4 manufacture, process, distribute in commerce, use, or

5 dispose of a new chemical substance to which a rule
Q under section (a) is applicable for test marketing pur-

7 poses or specially limited purposes (A) upon a show-

8 ing by such person that such activity will not cause or

9 contribute to an unreasonable risk of injury to human

10 health or the environment, and (B) under such restric-

11 tions as the Administrator considers appropriate; or

12 (2) to the extent that such person manufactures

13 chemical substances which are intermediate reaction

14 products formed during the manufacture of other chem-

15 ical substances and for which there is no exposure to

16 human beings or the environment.

17 (j) MiXTUEES— The Administrator is authorized to

18 specify any mixture which shall be subject to the provisions

19 of this section.

20 (k) Experimentation. – The requirements of subsec-
21 tions (a), (b), and (h) do not apply to any chemical sub-
22 stance which is manufactured or intended to be manufactured
23 only in small quantities (as defined by the Administrator
24 by rule) solely for scientific experimentation or analysis or

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' i for chemical .research or analysis, including such research
2 or analysis for the development of a product, except that
3 the Administrator may, by rule, include such chemical sub-
4 stances upon a finding that the manufacture, processing, dis-
•5 tribution in coimnerce, use, or disposal of such chemical sub-
6 stances may cause or contribute to an unreasonable risk of
7 injury to human health or the environment.

8 REGULATION OF CHEMICAL SUBSTANCES " AND MIXTURES

-10 Sec. 6. (a) Scope of Regulation – (1) If the Ad-
11 minis tra tor finds that the manufacture, processing, distribu-
12 tion in commerce, use, or disposal of a chemical substance
13 or mixture presents or is likely to present an unreasonable
-14 'risk of iitjury to health or the environment, the Adminis-
15 tiator shall by rule apply to such substance or mixture one

16 or more of the following requirements as is necessary to
17 adequately protect against such risk:

18 * (A) A requirement prohibiting the manufacturing,
19 processing, or distribution in commerce of such substance
-20 ' or mixture or limiting the amount of such substance or
'21 ' mixture which may be manufactured, processed, or dis-
'22 tributed in conuerce.

23 (B) A requirement-

*24: (I) prohibiting the manufacture, processing

25 or distribution in commerce of such substance or

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1 mixture for (i) a particular use or particular u^s

2 or (ii) a particular use or particular uses ini:a

3 concentration in excess of a level specified by the

4 Administrator in the rule imposing the requirement,

5 or

6 (II) limiting the amount of such substance or

7 mixture which may be manufactured, processed,

8 or distributed in commerce for (i) a particular use

9 or particular uses or (ii) a particular use or par-

10 ticular uses in a concentration in excess of a level

11 specified by the Administrator in the rule imposing

12 the requirement. : r

13 (C) A requirement regulating the manner or method

14 of Use or disposal of such substance or mixture.

15 (I[^]) A requirement that such substance or mixture

16 or any article containing such substance or mixture be

17 marked with or accompanied by clear and adequate

18 warnings and instructions with respect to its distribution

19 in commerce, use, or disposal. The form and content of

20 such warnings and instructions shall be prescribed by

21 the Administrator.

22 (E) A requirement directing manufacturers or

23 processors of such substance or mixture (i) to give

24 notice of such unreasonable risk of injury to distrib-

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1 utors in commerce of such substance or mixture and,

2 to the extent reasonably ascertainable, to other persons

3 in possession of such substance or mixture or exposed

4 to such substance or mixture, (ii) to give public notice

5 of such risk of injury, and (iii) to either replace or re-

6 purchase such substance or mixture whichever the person

7 to which the requirement is directed elects.

8 t^") -A. requirement that manufacturers and proc-
9 essors of such substance or mixture make and retain
10 records of the processes used to manufacture or process
11 such substance or mixture and monitor or conduct tests
12 which are reasonable and necessary to assure compliance
13 with the requirements of this subsection.

14 A requirement imposed under this subsection may be limited
15 in application to specified geographic areas.

16 (2) Rules limiting the amount of a chemical substance
17 or mixture which may be manufactured, processed, or distrib-
18 uted in commerce, or hmiting the amount of such substance
19 which may be manufactured, processed, or distributed for a
20 particular use, shall, upon the petition of any manufacturer,
21 processor, or distributor in commerce thereof, provide for as-
22 signing production, processing, and distribution quotas, to the
23 extent necessary, with respect to the chemical substance in-
24 volved. The permissible quota for each person who applies to
25 manufacture, process, or import such substance or to engage

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1 in its distribution in commerce shall be determined in accord-
2 ance with fair and equitable criteria which the Secretary of

3 Commerce, in consultation with the Administrator and the
4 Attorney General, shall prescribe by rule. Such criteria shall
5 take into account all relevant factors, including (A) effects on
6 competition; (B) the market shares, productive capacity,
7 and product and raw material inventories of the precursors
8 of the chemical substance or mixture of persons applying for
9 quotas; (C) emergency conditions; and (D) effects on
10 technological innovation.

11 (3) (A) Prior to the issuance of a quota under para-
12 graph (2), the persons who apply under such paragraph
13 shall attempt to develop a voluntary agreement limiting the
14 quantities which each such person shall manufacture, process,
15 import, or distribute. The availability of immunity from the
16 antitrust laws with respect to the development of such volun-
17 tary agreement shall be limited to the provisions of this
18 subsection.

19 (B) The Secretary of Commerce, with the approval of
20 the Attorney General, after each of them has consulted with
21 the Federal Trade Commission, shall prescribe, by rule,
22 standards and procedures by which persons seeking to manu-
23 facture, process, import, or otherwise distribute a chemical
24 substance or mixture for which limitations on quantity have
25 been prescribed pursuant to paragraph (B) (II) of subsec-

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1 tion (a) of this section may develop and carry out such
2 voluntary agreements as are permissible pursuant to this
3 subsection.

4 (C) The standards and procedures prescribed under
5 subparagraph (A) shall include the following requirements:

6 (i) Meetings held to develop or carry out a volun-
7 tary agreement under this subsection shall permit at-
8 ■ tendance by representatives of Committees of Congress
9 and interested persons, including all persons interested
10 in the chemical substance or mixture involved, and the
11 public; shall be preceded by timely and adequate notice
12 with identification of the agenda of such meeting to the
13 Secretary of Commerce, the Attorney General, the Fed-
11 era! Trade Commission, the Administrator and the pub-
15 lie; and shall be chaired by a regular full-time Federal
16 employee.

,17 (ii) ^ full and complete record, and where prac-
18 ticable a verbatim transcript, shall be kept of any
19 meeting held, and a full and complete record shall be
20 kept of any communication (other than in a meeting)
21 made, between or among participants or potential par-
22 ticipants, to develop, or carry out a voluntary agree-

23 ment under this subsection. Such record or transcript
24 shall be deposited, together with any agreement result-
25 ing therefrom, with the Secretary of Commerce and
26 the Administrator and shall be available to the Attor-

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1 ney General and the Federal Trade Commission. Such
2 records or transcripts shall be available for public
3 inspection and copying in accordance with section 552
4 of title 5, United States Code.

5 (I^) (i) The Attorney General and the Federal Trade
6 Commission shall participate from the beginning in the
7 development, and when practicable, in the carrying out of
8 voluntary agreements and plans of action authorized under
9 this section. Each may propose any alternative which would
10 void or overcome, to the greatest extent practicable, possible
11 anticompetitive effects while achieving substantially the pur-
12 poses of this subsection. A voluntary agreement under this
13 subsection may not be carried out unless approved by the
14 Attorney General, after consultation with the Federal Trade
15 Commission. Prior to the expiration of the 20-day period
16 prescribed under clause (ii) , the Federal Trade Commission

17 shall transmit to the Attorney General its views as to
18 whether such an agreement or plan of action should be
19 approved, and shall publish such views in the Federal Reg-
20 ister. The Attorney General, in consultation with the Federal
21 Trade Commission, and the Secretary, shall have the right
22 to review, amend, modify, disapprove, or revoke, on his
23 own motion or upon the request of the Federal Trade Com-
24 mission or any interested person, any voluntary agreement
25 at any time, and, if revoked, thereby withdraw prospectively

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1 any immunity which may be conferred by subparagraphs

2 (F) or (I).

3 (ii) Any voluntary agreement entered into pursuant to

4 this section shall be submitted in writing to the Attorney

5 General and the Federal Trade Commission 20 days before

6 being implemented. Any such agreement shall be available

7 for public inspection and copying, to the extent to which

8 records or transcripts are so available as provided in the

9 last sentence of subparagraph (C) (ii) . Any action taken

10 pursuant to such voluntary agreement or plan of action

11 shall be reported to the Attorney General and the Federal

12 Trade Commission pursuant to such regulations as shall be
13 prescribed under clauses (iii) and (iv) of subparagraph
14 (E).

15 (E) (i) The Attorney General and the Federal Trade
16 Commission shall monitor the development and carrying
17 out of voluntary agreements authorized under this para-
18 graph in order to promote competition and to prevent
19 anticompetitive practices and effects.

20 (ii) In addition to any requirement specified under
21 subparagraph (B) and (C) of this paragraph and in order
22 to carry out the purposes of this section, the Attorney Gen-
23 eral, in consultation with the Federal Trade Commiission
24 and the Administrator, shall promulgate rules concerning
25 the maintenance of necessary and appropriate records re-

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1 lated to the development and carrying out of voluntaiy
2 agreements authorized pursuant to this section.

3 (iii) Persons developing or canying out voluntary
4 agreements authorized pursuant to this section shall main-
5 tain such records as are required by rules promulgated
6 under subparagraph (B) . The Attorney General and the

7 Federal Trade Commission shall have access to and the
8 right to copy such records at reasonable times and upon
9 reasonable notice.

10 (iv) The Attorney General and the Federal Trade Com-
11 mission may each prescribe such rules as may be necessar}^ or
12 appropriate to carry^ out their respective responsibihities under
13 this section. They may both utilize for such purposes and for
14 purposes of enforcement any powers conferred upon the
15 Federal Trade Conamission or the Department of Justice, or
16 both, by the antitrust laws or the Antitrust Civil Process Act;
17 and wherever any such law refers to ''the pui"poses of this
18 Act'' or like terms, the reference shall be understood to in-
19 elude this subsection.

20 (F) (i) There shall be available as a defense to any
21 civil or criminal action brought under the antitrust laws
22 (or any similar State law) in respect to actions taken to
23 develop or carry out a voluntary agreement by persons
24 engaged in the business of manufacturing, processing or dis-
25 tributing such chemical substance or mixture (provided that

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1 such actions were not taken for the purpose of injuring

2 competition) that -

3 (I) such actions were taken in the course of de-
4 veloping a voluntary agreement pursuant to this para-

5 graph to carry out a voluntary agreement authorized
6 and approved in accordance with this section, and

7 (II) such persons complied with the requirements
8 of this paragraph and the rules promulgated here-
9 under.

10 (ii) Persons interposing the defense provided by this
11 paragraph shall have the burden of proof, except that the
12 burden shall be on the person against whom the defense
13 is asserted with respect to whether the actions were taken
14 for the purpose of injuring competition.

15 (G) No provision of this section shall be construed
16 as granting immunity for, or as hmiting or in any way
17 affecting any remedy or penalty which may result from any
18 legal action or proceeding arising from, any act or practice
19 which occurred prior to the date of enactment of this Act
20 or subsequent to its expiration or repeal.

21 (H) The Attorney General and the Federal Trade
22 Commission shall each submit to the Congress and to the
23 President, at least once each year a report on the impact
24 on competition and on small business of actions authorized
25 by this section.

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1 (I) In any action in any Federal or State court for
2 breach of contract, there shall be available as a defense
3 that the alleged breach of contract was caused predomi-
4 nantly by action taken to carry out a voluntary agree-
5 ment authorized and approved in accordance with this
6 paragraph.

7 (J) As used in this paragraph, the term "'antitrust
8 laws" includes -

9 (i) the Act entitled "An Act to protect trade and
10 commerce against unlawful restraints and monopolies",
11 approved July 2, 1890;

12 (ii) the Act entitled *'An Act to supplement exist-
13 ing laws against unlawful restraints and monopolies,
14 and for other purposes", approved October 15, 1914;

15 (iii) the Federal Trade Commission Act;

16 (iv) sections 73 and 74 of the Act entitled "'An Act
17 to reduce taxation, to provide revenue for the Govern-
18 ment, and for other purposes", approved August 27,
19 1894; and

20 (v) tbe Act of June 19, 1936, chapter 592.

21 (b) Quality Control. - (1) If the Admuaistrator

22 has good cause to beheve that a particular manufacturer or

23 processor is manufacturing or processmg a chemical sub-

24 stance or mixture in a manner which causes the adultera-

25 tion of a chemical substance or mixture -

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1 (A) the Administi-ator may by order require such

2 manufactui'er or processor to submit a description of the

3 relevant quality control procedures followed in the man-

4 ufacturing or processing of such chemical substance or

5 mixture ; and

6 (B) if the Administrator thereafter determines on

7 the record, after opportunity for hearing in accordance

8 with section 554 of title 5, United States Code, that

9 such quality control procedures are inadequate to pre-

10 vent the chemical substance or mixtm*e from causing or

11 contributing to such risk, the Administrator may order

12 the manufacturer or processor to revise such quality

13 control procedures to the extent necessary to remedy

14 such inadequacy.

15 (2) As used in this section, a chemical substance or

16 mixture is adulterated if the manner in which it is manu-

17 factured or processed causes it to contain a particular mo-
18 lecular identity, an uncombined radical, an element, or any
19 combination thereof, which is found by the Administrator
20 to cause or contribute to an unreasonable risk of injury to
21 human health or the environment.

22 (c) Promulgation of Subsection (a) Rules.-

23 (1) In promulgating any rule under subsection (a) with
24 respect to a chemical substance or mixture, the Adminis-

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1 trator shall consider relevant factors and make findings

2 with respect thereto, including -

3 (A) the risks presented by such substance or mix-

4 ture to health and the magnitude of human exposure to

5 such substance or mixture.

6 (B) the risks presented by such substance or mix-

7 ture to the environment and the magnitude of environ-

8 mental exposure to such substance or mixture,

9 (C) the benefits of such substance or mixture for

10 such use or uses and the availability of other substances

11 or mixtures for such use or uses, and

12 (D) the reasonably ascertainable economic conse-

13 quences of the rule, including consideration of the
14 effect on the national economy, innovation, the environ-
15 ment, and public health.

16 Findings made under this paragraph shall be published in
17 the Federal Register.

18 (2) When prescribing a rule under subsection (a) the
19 Administrator shall proceed in accordance with section 553
20 of title 5, United States Code (without regard to any
21 reference in such section to sections 556 and 557 of such
22 title) , and shall also (A) publish a notice of proposed rule-
23 making with particularity the reason for the pro-
24 posed rule; (B) allow interested persons to submit written
25 data, views, and arguments, and make all such submissions

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1 publicly available; (C) provide an opportunity for an in-
2 formal hearing in accordance with paragraph (3) ; and (D)
3 promulgate, if appropriate, a final rule based on the matter
4 in the rulemaking record.

5 (3) The Administrator shall conduct informal hearings
6 required by paragraph (2) (C) of this subsection in ac-
7 cordance with the following procedure:

8 (A) Subject to subparagraph (B) of this para-
9 graph, an interested person is entitled –
10 (i) to present his position orally or by docu-
11 mentary submissions (or both) , and
12 (ii) if the Admmistrator determines that there
13 are disputed issues of material fact it is necessary
14 to resolve, to present such rebuttal submissions and
15 to conduct (or have conducted under subparagraph
16 (B) (ii)) such cross-examination of persons as
17 the Administrator determines (I) to be appropriate,
18 and (II) to be required for a full and true dis-
19 closure with respect to such issues.

20 (B) The Administrator may prescribe such rules
21 and make such rulings concerning proceedings in such
22 hearings to avoid unnecessary costs or delay. Such rules
23 or rulings may include (i) imposition of reasonable time
24 limits on each interested person's oral presentations, and
25 (ii) requirements that any cross-examination to which

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1 a person may be entitled under subparagraph (A) be
2 conducted by the Administrator on behalf of that person

3 in such manner as the Administrator determines (I) to
4 be appropriate, and (II) to be required for a full and
5 true disclosure with respect to disputed issues of material
6 fact.

7 (C) (i) Except as provided in clause (ii) , if a group
8 of persons each of whom under subparagraphs (A) and
9 (B) would be entitled to conduct (or have conducted)
10 cross-examination and who are determined by the Ad-
11 ministrator to have the same or similar interests in the
12 proceeding cannot agree upon a single representative of
13 such interests for purposes of cross-examination, the Ad-
14 ministrator may make rules and rulings (I) limiting the
15 representation of such interest for such purposes, and
16 (II) governing the manner in which such cross-exami-
17 nation shall be limited.

18 • (ii) When any person who is a member of a group
19 with respect to which the Administrator has made a
20 detennination under clause (i) is unable to agree upon
21 group representation with the other members of the
22 group, then such person shall not be denied under the
23 authority of clause (i) the opportunity to conduct (or
24 have conducted) cross-examination as to issues affecting
25 his particular interests if (I) he satisfies tlie Administra-
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1 tor that he has made a reasonable and good faith effort
2 to reach agreement upon group representation with the
3 other members of the group and (II) the Administrator
4 determines that there are substantial and relevant issues
5 which are not adequately presented by the group rep-
6 resentative.

7 (D) A verbatim transcript shall be taken of any
8 oral presentation, and cross-examination, in informal
9 hearings under this subsection. Such transcript shall be
10 available to the public.

11 (E) A substantive amendment to, or repeal of, a
12 rule promulgated under subsection (a) shall be pre-
13 scribed, and subject to judicial review, in the same man-
14 ner as a rule prescribed under such subsection.

15 (4) Any rule promulgated under this section shall be
16 judicially reviewable in accordance with section 19, except
17 that in addition to any basis for holding unlawful or setting
18 aside the rule under subparagraphs (A), (B), (C), or (D)

19 of section 706(2) of title 5, United States Code, the court
20 shall hold unlawful and shall set aside the rule if the court
21 finds that-

22 (A) the Administrator's determination under para-
23 graph (3) that the petitioner is not entitled to conduct
24 cross-examination or make rebuttal submissions, or

25 (B) the Administrator's rule or ruling under para-

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1 graph (3) limiting the petitioner's cross-examination or
2 rebuttal submissions,
3 has precluded disclosure of disputed material facts which
4 was necessary for fair determination by the Administrator
5 of the rulemaking proceeding taken as a whole.

6 (5) (A) The Administrator may, pursuant to rules
7 proscribed by him, provide compensation for reasonable attor-
8 neys fees, expert witness fees, and other costs of participating
9 in a rulemaking proceeding under this section to any person
10 (i) who has, or represents an interest (I) which would not
11 otherwise be adequately represented in such proceeding, and
12 (II) representation of which is necessary for a fair determi-
13 nation of the rulemaking proceeding taken as a whole, or

14 (ii) who is unable effectively to participate in such proceed-
15 ing because such person cannot afford to pay costs of making
16 oral presentations, conducting cross-examination, and making
17 rebuttal submission in such proceeding.

18 (B) The aggregate amount of compensation paid to
19 all persons in any fiscal year under this subsection may
20 not exceed \$1,000,000.

21 (d) Effective Date.— (1) The Administrator shall
22 specify in any rule under subsection (a) the date on which
23 it shall take effect, which date shall be as soon as feasible.

24 (2) Section 553 (b) (B) of title 5, United States Code,
25 shall be applicable to rules issued under subsection (a)

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1 notwithstanding any requirement of subsection (c) (2) or
2 (3).

3 IMMINENT HAZAEDS

4 Sec. 7. (a) Definition. – An imminent hazard shall
5 be considered to exist when the evidence is sufficient to show
6 that the manufacturing, processing, distribution in com-
7 merce, use, or disposal of a chemical substance or mixture
8 presents an unreasonable risk of death, serious illness or

9 serious personal injury, or serious environmental harm prior
10 to the completion of an administrative hearing or other
11 proceeding authorized under any other section of this Act.

12 (b) Actions Authorized. – The Administi*ator may
13 file an action in a United States district court –
M (1) against an imminently hazardous chemical sub-
15 stance or mixture for seizure of such substance or mixture,
16 (2) against any person who manufactures, processes,
17 distributes in commerce, uses, or disposes of such sub-
18 stance or mixture, or
19 (3) against both (A) such substance or mixture
20 and (B) such person.

21 An action under this subsection may be filed notwith-
22 standing the existence of a rule under section 4 (a) or 6 (a)
23 or an order under section 5(e) and notwithstanding the
24 pendency of any administrative or judicial proceeding under
25 any provision of this Act.

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1 (c) Jurisdiction of Court – (1) The United
2 States district court in which an action under subsection (b)
3 is brought shall have jurisdiction to grant such temporary

4 or permanent relief as may be necessary to protect against
5 such unreasonable risk of death, serious illness or serious
6 personal injury, or serious environmental harm presented
7 by the chemical substance or mixture involved in such action.

8 (2) In the case of an action under subsection (b)
9 brought against a person who manufactures, processes, dis-
10 tributes in commerce, uses, or disposes of a chemical substance
11 or mixture, the relief authorized by paragraph (1) may in-
12 elude the issuance of a mandatory order requiring (A) in the
13 case of purchasers of such substance or mixture known to
14 the defendant, notification to such purchasers of the risk as-
15 sociated with it ; (B) public notice of such risk ; (C) recall;
16 and (D) the replacement or repurchase of such substance
17 or mixture.

18 (3) In the case of an action under subsection (b)
19 against a chemical substance or mixture, such substance or
20 mixture may be proceeded against by process of libel for
21 its seizure and condemnation. Proceedings in such an action
22 shall conform as nearly as possible to proceedings in rem
23 in admiralty.

24 (d) Venue and Consolidation.- (1) (A) An ac-
25 tion under subsection (b) against a person who manufac-

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1 tures, processes, distributes in commerce, uses, or disposes of a
2 chemical substance or mixture may be brought in the United
3 States District Court for the District of Columbia or for any
4 judicial district in which any of the defendants is found,
5 resides, or transacts business; and process in such an action
6 may be served on a defendant in any other district in which
7 such defendant resides or may be found. An action under
8 subsection (b) against a chemical substance or mixture
9 may be brought in any United States district court
10 within the jurisdiction of which the substance or mixture
11 is found.

12 (B) In determining the judicial district in which an
13 action may be brought under subsection (b) in instances in
14 which such action may be brought in more than one judicial
15 district, the Administrator shall take into account the con-
16 venience of the parties.

17 (C) Subpoenas requiring attendance of witnesses in
18 an action brought under subsection (b) may run into any
19 judicial district.

20 (2) Whenever proceedings under subsection (b) in-
21 volving the same type of chemical substances or mixtures
22 are pending in courts in two or more judicial districts,

23 they shall be consolidated for trial by order of any
24 such court upon application reasonably made by any party
25 in interest, upon notice to all parties in interest.

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1 (e) Action Under Section 6 – Where appropriate,
2 concurrently with the filing of an action under subsection (b)
3 or as soon thereafter as may be practicable, the Administra-
4 tor shall -initiate a proceeding for the promulgation of a rule
5 under section 6 (a) .

6 (f) Representation– Notwithstanding any other
7 provision of law, in any action under subsection (b) , the
8 Administrator may direct attorneys of the Environmental
9 Protection Agency to appear and represent the Administra-
10 tor in such an action.

11 REPORTING AND RETENTION OF INFORMATION

12 Sec. 8. (a) Reports.– (1) The Administrator shall
13 promulgate rules under which –
14 (A) each person who manufactures or processes
15 or proposes to manufacture or process a chemical sub-
16 stance shall maintain such records, and shall submit to
17 the Administrator such reports, as the Administrator may

18 reasonably require, and
19 (B) each person who manufactures or processes or
20 proposes to manufacture or process –
21 (i) ^ mixture, or
22 (ii) a chemical substance in small quantities
23 (as defined by the Administrator by rule) solely for
24 scientific experimentation or analysis or for chemical

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1 research or analysis, including such research or
2 analysis for the development of a product,
3 shall maintain records and submit to the Administrator
4 reports but only to the extent the Administrator deter-
5 mines the maintenance of records or submission of re-
5 ports, or both, is necessary for the effective enforcement
7 of the Act.

8 For purposes of the compilation of the list of chemical
9 substances required under subsection (b) , the Administrator
10 shall promulgate rules pursuant to this subsection not later
11 than 180 days after the date of the enactment of this Act.

12 (2) The Administrator may require under paragraph

13 (1) reporting with respect to the following:

14 (A) The common name, trade name, the chemical
15 identity, and the molecular structure and identity of each
16 chemical substance or mixture for which such a report
17 is required, insofar as known to the person making the
18 report or insofar as reasonably ascertainable.

19 (B) The categories or proposed categories of use
20 of each such substance or mixture, insofar as known to
21 the person making the report or insofar as reasonably
22 ascertainable.

23 (C) Reasonable estimates of the amount of each
24 substance and mixture to be manufactured or processed
25 and, insofar as known to the person making the report

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1 or insofar as reasonably ascertainable, a reasonable esti-
2 mate of the amount of each such substance and mixture
3 to be manufactured or processed for each of its categories
4 or proposed categories of use.

5 (I)) ^ description of the byproducts resulting from
Q the manufacture, processing, use, or disposal of each such
7 substance or mixture, insofar as known to die person
3 making the report or insofar as reasonably ascertainable.

9 (E) All existuig data concerning the environmental
IQ and health effects of such substance or mixture, insofar
11 as known to the person making the report or are reasou-
12 ably ascertainable.

13 (F) Estimates of the number of persons who will
14 be exposed to such substance or mixture in their places
15 of employment and the duration of such exposure, insofar
16 as known to the person making the report or are reason-
17 ably ascertainable.

18 (b) Inventory.— The Administrator shall compile,
19 keep current, and publish a list of each chemical substance or
20 mixture which any person reports under subsection (a) or
21 under section 5 (a) is manufactured or processed in the United
22 States. The Administrator shall first publish such a list not
23 later than 270 days after the date of the enactment of this
24 Act. The Administrator shall not include in such list any

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1 chemical substance which is manufactured or processed only
2. in small quantities (as defined by the Administrator by rule)
3. solely for scientific experimentation or analysis or for chemi-
4 cal research or analysis, including such research or analysis
5 for the development of a product.

6 (c) Keceods.— Any person who manufactures, proc-
7 esses, or distributes in commerce or intends to manufacture,
8 process, or distribute in commerce any chemical substance

9 or mixture shall maintain records of adverse reactions to
10 health or the environment alleged to have been caused by
11 the substance or mixture. Records of such adverse reactions
12 to the health of employees shall be retained for 36^ years
13 from the date such reactions were first reported to or known
14 by the person maintaining such records; and any other
15 record of such adverse reactions shall be retained for 5 years
16 from the date the information contained in the records was
17 first reported to or known by the person maintaining the
18 records. Records under this subsection shall include records
19 of consumer allegations of personal injury or harm to health,
20 reports of occupational disease or injury, and reports or
21 complaints of injury to the environment submitted to the
22 manufacturer, processor, or distributor in commerce from
23 any source. Upon request of an officer or employee duly
24 designated by the Administrator, each person who is re-
25 quired to maintain records under this subsection shall permit

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1 the inspection of such records and shall submit copies of
2 such records.

3 (d) Health and Safety Studies- The Adminis-

4 trator shall promulgate rules under which the Administrator

5 requires any person who manufactures, processes, or dis-
6 tributes in commerce or who proposes to manufacture, proc-
7 ess, or distribute in commerce any chemical substance or
8 mixture to submit to the Administrator -

9 ' (1) lists of health and safety studies conducted or
10 initiated by or for such person with respect to such
11 substance or mixture at any time or known to such
12 person or are reasonably ascertainable, except that the
13 Administrator may exclude certain types or categories
14 of studies from the requirements of this subsection if he
15 finds that submission of lists of such studies are unneces-
16 sary to carry out the purposes of this Act ; and

17 (2) the Administrator may require the submission
18 of any study contained on a list submitted pursuant to
19 paragraph (1) or otherwise known by such person.

20 (e) Notice to Administrator of Unreasonable

21 Risks. - Any person who manufactures, processes, or dis-
22 tributes in commerce a chemical substance or mixture, and
23 any liability insurer of such person, who obtains information
24 which supports the conclusion that such substance or mixture
25 causes or contributes to an unreasonable risk of injury to

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1 health or the environment shall immediately inform the Ad-
2 ministrator of such risk unless such person has reason to
3 believe that the Administrator has been adequately informed
4 of such risk.

5 RELATIONSHIP TO OTHER FEDERAL LAWS

6 Sec. 9. (a) Laws Not Administered by the Ad-
7 MINISTRATOR. - (1) If the Administrator has reason to be-
8 lieve that the manufacture, processing, distribution in com-
9 merce, use, or disposal of a chemical substance or mixture
10 causes or contributes to, or is likely to cause or contribute to
11 an unreasonable risk of injury to health or the environment,
12 and determines, in his discretion, that such risk may be
13 prevented or reduced to a sufficient extent by action taken
14 under a Federal law not administered by the Administra-
15 tor, the Administrator shall request the agency which ad-
16 ministers such law (A) to issue an order declaring whether
17 or not the manufacture, processing, distribution in commerce,
18 use, or disposal of such substance or mixture causes or con-
19 tributes to or is likely to cause or contribute to such a risk,
20 and (B) if the agency issues an order declaring that such
21 manufacture, processing, distribution in commerce, use, or
22 disposal respecting such substance or mixture causes or con-
23 tributes to or is likely to cause or contribute to such a risk,

24 to determine if such risk may be prevented or reduced to a
25 sufficient extent by action taken under such law. Any such

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1 request shall be published in the Federal Register and shall
2 be accompanied by a detailed statement of the information
3 on which it is based. The agency receiving the request shall
4 consider carefully all data submitted by the Administrator
5 and other information available to it and shall issue an appro-
6 priate order upon request, and shall make any resulting de-
7 termination within such reasonable time as the Adminis-
8 trator specifies in the request, but such time specified may
9 not be less than 90 days from the date the request was
10 made. The report of an agency in response to a request made
11 under this paragraph shall be accompanied by a detailed
12 statement of the findings and conclusions of the agency re-
13 specting the order and determination requested to be made,
14 (2) If the Administrator makes a request under para-
15 graph (1) with respect to a chemical substance or mixture
16 and the agency to which such request was made either -
17 (A) issues an order declaring that there is no
18 unreasonable risk of injury to health or the environment
19 associated with such substance or mixture, or
20 (B) initiates, within 90 days of the publication

21 in the Federal Register of the report of the agency
22 under paragraph (1) in response to such request, action
23 under the law (or laws) administered by such agency
24 to protect against such a risk,
25 the Administrator may not take any action under section 6

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1 or 7 with respect to the risk associated with such substance
2 or mixture. Nothing contained herein shall prevent the
3 Administrator from (A) making any subsequent request
4 under paragraph (1) with respect to such risks or (B) to
5 take subsequent action under this Act with respect to such
6 risks if the requirements of this subsection are satisfied.
7 (3) If the Administrator has initiated action under sec-
8 tion 6 or 7 with respect to a risk of injury associated with a
9 chemical substance or mixture which was the subject of a
10 request made to an agency under paragraph (1) , such
11 agency shall before taking action under the law (or laws)
12 administered by it to protect against such risk consult with
13 the Administrator for the purpose of avoiding duplication of
14 Federal action against such risk.
15 (b) Laws Administeed BY THE Admixisteador. -
16 The Administrator shall coordinate actions taken under this
IT Act with actions taken under other Federal laws administered

18 in whole or in part by the Administrator. The Administrator
19 shall use the authorities contained in such other Federal laws
20 to protect against any risk to health or the environment asso-
21 ciated with a chemical substance or mixture unless the Ad-
22 ministrator, in his discretion, determines that such risk may
23 be more appropriately protected against under this Act. This
24 subsection shall not be construed to relieve the Administrator

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1 of any requirement imposed on the Administrator by such
2 other Federal laws. Nothing contained in this subsection shall
3 (1) affect any final action taken under such other Federal
4 law, or (2) in any way affect the extent to which human
5 health or the environment is to be protected under such other
6 Federal law.

7 (c) Occupational Safety and Health. – In exer-
8 cising any authority under this Act, the Administrator shall
9 not, for purposes of section 4(b) (1) of the Occupational
10 Safety and Health Act of 1970, be deemed to be exercising
11 statutory authority to prescribe or enforce standards or regu-
12 lations affecting occupational safety and health.

13 (d) Coordination. – In administering this Act, the

14 Administrator shall consult and coordinate with the Secre-
15 tary of Health, Education, and Welfare and the heads of
16 any other appropriate Federal executive . department or
17 agency, any relevant independent regulatory agency, and
18 any other appropriate instrumentality of the Federal Gov-
19 ernment for the purpose of achieving the maximum enforce-
20 ment of this Act while imposing the least burdens of dupli-
21 cative requirements on those subject to the Act and for other
22 purposes. The Administrator shall report annually to the
23 Congress on actions taken to coordinate with such other Fed-
24 eral departments, agencies, or instrumentalities, and on

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1 actions taken to coordinate the authority under this Act with
2 the authority granted under other Acts referred to in sub-
3 section (b) .

4 (e) Exception. - Nothing contained in this section shall
5 limit any requirement of section 4, 5 (other than section
6 5 (e) (2)) , or 8, or rules promulgated thereunder.

7 RESEARCH, COLLECTION, DISSEMINATION, AND

8 UTILIZATION OF DATA

9 Sec 10. (a) Authority.- The Administrator shall, in

10 consultation and cooperation with the Secretary of Health,
11 Education, and Welfare and with other heads of appropriate
12 agencies, conduct such research and monitoring as h neces-
13 sary to carry out the purposes of this Act.

14 (b) Data Systems.— (1) The Administrator shall
15 establish, administer, and be responsible for the continuing
16 activities of an interagency committee which will (A) de-
17 sign, establish, and coordinate an efficient and effective sys-
18 tern, within the Environmental Protection Agency, for the
19 collection, dissemination to other Federal agencies, and use
20 of data submitted to the Administrator under this Act and
21 (B) coordinate the regulation of chemical substances among
22 Federal agencies.

23 (2) (A) The Administrator shall, in consultation with
24 the Secretary of Health, Education, and Welfare and other
25 heads of appropriate agencies, design, establish, and coordi-

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1 nate an efficient and effective system for the retrieval of toxi-
2 cological and other scientific data which could be useful to the
3 Administrator in carrying out the purposes of this Act. Sys-
4 tematized retrieval shall be developed for use by all Federal

5 and other agencies with responsibilities in the area of regula-
6 tion or study of chemical substances and mixtures and their
7 effect on health or the environment.

8 (c) Grants and Contracts.— The Administrator, in

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9 consultation with the Secretary of Health, Education, and
10 Welfare, is authorized to make grants and enter into con-
11 tracts in order to carry out his responsibilities under this sec-
12 tion. Contracts may be entered into under this section without
13 regard to sections 3648 and 3709 of the Revised Statutes
14 (31 U.S.C. 529, 41 U.S.C. 5).

15 INSPECTIONS AND SUBPOENAS

16 Sec. 11. (a) Inspections.— (1) For purposes of ad-
17 ministring this Act (including any rule or order promul-
18 gated under this Act) the Administrator, or any representa-
19 tive of the Administrator duly designated by the Administra-
20 tor, may inspect any establishment, facility, or other premises
21 in which chemical substances or mixtures are manufactured,
22 processed, stored, or held before or after distribution in com-
23 merce and any conveyance being used to transport chemical
24 substances or mixtures in connection with distribution in com-
25 merce. Such an inspection may only be made upon presenting

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1 appropriate credentials and a written notice to the owner,
2 operator, or agent in charge of the premises or conveyance
3 to be inspected. A separate notice shall be given for each
4 such inspection, but a notice shall not be required for each
5 entry made during the period covered by the inspection.

6 Each such inspection shall be commenced and completed
7 with reasonable promptness and shall be conducted at rea-
8 sonable times, within reasonable limits, and in a reasonable
9 manner.

10 (2) An inspection under paragraph (1) shall extend to
11 all things within the premises or conveyance inspected (in-
12 cluding records, files, papers, processes, controls, and facili-
13 ties) bearing on whether the requirements of this Act appli-
14 cable to the chemical substances or mixtures within such
15 premises or conveyance have been complied with.

16 (b) Subpoenas. - ^In carrying out his or her duties under
17 the provisions of this Act, the Administrator may by subpoena
18 require the attendance and testimony of witnesses and the
19 production of reports, papers, documents, answers to ques-
20 tions, or other information that the Administrator deems

21 advisable. Witnesses shall be paid the same fees and mileage
22 that are paid witnesses in the courts of the United States. In
23 the event of contumacy, failure, or refusal of any person to
24 obey any such order, any district court of the United States
25 in which venue is proper shall have jurisdiction to order any

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1 such person to comply therewith. The failure to obey such
2 order of the Court is punishable by the Court as a contempt
3 thereof.

4 EXPORT

5 Sec. 12. (a) General.— (1) Except as provided in
6 paragraph (2) and subsection (b), this Act (other than
7 section 8) shall not apply to any chemical substance or
8 mixture, if —
9 (A) it is shown that such substance or mixture
10 is being manufactured, processed, sold, or held for sale,
11 for export from the United States, unless such substance
12 or mixture is, in fact, manufactured, processed, or dis-
13 tributed in commerce, for use in the United States, and
14 (B) such substance or mixture, when distributed
15 in commerce, or any container in which it is enclosed

16 when so distributed, bears a stamp or label stating
17 that such substance or mixture, is intended for export.
18 (2) Paragraph (1) shall not apply to any chemical
19 substance or mixture if the Administrator finds that the
20 substance or mixture will cause or contribute to an unreason-
21 able risk of injury to the health of persons within the United
22 States or to the environment of the United States or may
23 cause or contribute to such risk. The Administrator may
24 require, under section 4, testing of a chemical substance or
25 mixture exempted from this Act by paragraph (1) to

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1 determine whether or not such substance or mixture causes
2 or contributes to an unreasonable risk to health within the
3 United States or to the environment of the United States.
4 (b) Notice. - (1) If any person exports or intends
5 to export to a foreign country a chemical substance or mix-
6 ture for which the submission of data is required under sec-
7 tion 4 or 5, such person shall notify the Administrator of
8 such exportation or intent to export and the Administrator
9 shall furnish to the government of such country notice of the
10 availability of the data (subject to section 14) submitted to
11 the Administrator under section 4 or 5 for such substance or
12 mixture. ^

13 (2) If any person exports or intends to export to a for-
14 eign country a chemical substance or mixture for which a rule
15 has been proposed or promulgated under section 5 or 6, or
16 with respect to which an action is pending, or relief has been
17 granted, under section 7, such person shall notify the Ad-
18 ministrator of such exportation or intent to export and the
19 Administrator shall furnish to the government of such coun-
20 try notice of such rule, action, or relief.

21 ENTEY INTO CUSTOMS TERRITORY OF THE UNITED STATES

22 Sec. 13. (a) General.— (1) The Secretary of the
23 Treasury shall refuse entry into the customs territory of the
24 United States (as defined in general headnote 2 to the Tariff

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3 Schedules of the United States) of any chemical substance or
2 mixture offered for entry if -

3 (^) it fails to conform with any requirement of this
4 Act or any rule in effect thereunder, or

5 (B) it is otherwise prohibited pursuant to this Act
Q from being distributed in commerce.

7 (2) If a chemical substance or mixture is refused
8 entry under paragraph (1) , the Secretary of the
9 Treasury shall notify the consignee of such entry refusal,
10 shall not release it to the consignee, and shall cause its

11 disposal or storage (under such regulations as the Secre-
12 tary of the Treasury may prescribe) if it has not been ex-
13 ported by the consignee within 90 days from the date
14 of receipt of notice of such refusal, except that the Secre-
15 tary of the Treasury may, pending a review by the Admin-
16 istrator of the entry refusal, release to the consignee such
17 substance or mixture on execution of bond for the amount
18 of the full invoice of such substance or mixture (as such
19 value is set forth in the customs entry), together with
20 the duty thereon. On failure to return such substance or
21 mixture for any cause to the custody of the Secretary
22 of the Treasury when demanded, such consignee shall be
23 liable to the United States for liquidated damages equal
24 to the full amount of such bond. All charges for storage,

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1 cartage, and labor on such substances or mixtures which
2 are refused entry or release under this section shall be
3 paid by the owner or consignee, and in default of such
4 payment shall constitute a lien against any future entry
5 made by such owner or consignee. Nothing contained
6 herein shall limit any other remedy to which the United

7 States is entitled.

8 (b) KULES. – The Secretary of the Treasury, after
9 consultation with the Administrator, shall issue rules for
10 the enforcement of subsection (a) of this section.

11 DISCLOSURE OF DATA

12 Sec. 14. Any information reported to, or otherwise
13 obtained by, the Administrator or his representative, under
14 this Act, shall be subject to section 552 of title 5, United
15 States Code ; except that such information shall be disclosed –
16 (1) upon request, to officers or employees of the
17 United States, in connection with their official duties
18 (A) under laws protecting human health or the en-
19 vironment or (B) for specific law enforcement purposes ;
20 (2) to contractors with the United States and
21 employees of such contractors if in the opinion of the
22 Administrator such disclosure is necessary for the satis-
23 factory performance by the contractor of a contract
24 with the United States entered into on or after the date

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1 of enactment of this Act for the performance of work
2 in connection with this Act and under such conditions

3 as the Administrator may specify ;

4 (3) whenever the Administrator determines it nec-

5 essary to protect human health or the environment; or

6 (4) to any duly authorized committee of the Con-

7 gress upon written request of such committee or any

8 chairman thereof.

9 PROHIBITED ACTS

10 Sec. 15. It shall be unlawful for any person to-

11 (1) fail or refuse to comply with- (A) an}- rule or

12 order promulgated under section 4, (B) any requirement

13 prescribed by section 5, or (C) any rule or order pro-

14 mulgated under section 5 or 6;

15 (2) use or dispose of a chemical substance or mix-

16 ture which such person knew or had reason to know was

17 manufactured, processed, or distributed in commerce in

18 violation of section 5 or a rule or order under section 6;

19 (3) fail or refuse to (A) establish or maintain rec-

20 ords, (B) submit reports, notices, or other informa-

21 tion, or (C) permit access to or copying of records, as

22 required by this Act or a rule thereunder; or

23 (4) fail or refuse to permit entry or inspection as

24 required by section 11.

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2 PENALTIES

2 Sec. 16. (a) Civil. - (1) Any person who violates

3 a provision of section 15 of this Act shall be liable to the

4 United States for a civil penalty in an amount not to exceed

5 \$25,000 for each such violation. Each day such a violation
Q continues shall for purposes of this subsection constitute a
rj separate violation of section 15.

g (2) (A) A civil penalty for a violation of section 15

9 shall be assessed by the Administrator by an order made on

"I^Q the record after opportunity (provided in accordance with

II this subparagraph) for a hearing in accordance with sec-

-^2 tion 554 of title 5, United States Code. Before issuing such

;i^3 an order, the Administrator shall give written notice to the

24 person to be assessed a civil penalty under such order of the

25 Administrator's proposal to issue such order and providing

26 such person an opportunity to request, within 15 days

27 of the date the notice is received by such person, such a

28 hearing on the order.

29 (B) In determining the amount of a civil penalty, the
20 Administrator shall take into account the nature, circum-
22 stances, exten', and gravity of the violation or violations

22 and, with respect to the violator, ability to pay, effect on

23 ability to continue to do business, any history of prior such

24 violation.^, the degree of culpability, and such other matters

25 as justice may require.

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1 (C) The Administrator may compromise, modify, or
2 remit, with or without conditions, any civil penalty which
3 may be imposed under this subsection. The amount of such
4 penalty, when finally determined, or the amount agreed
5 upon in compromise, may be deducted from any sums owed
6 by the United States to the person charged.

7 (3) Any person who requested in accordance with
8 paragraph (2) (A) a hearing respecting the assessment of a
9 civil penalty and who is aggrieved by an order assessing a
10 civil penalty may file a petition for judicial review of such
11 order with the United States Court of Appeals for the Dis-
12 trict of Columbia Circuit or for any other circuit in which
13 such person resides or transacts business. Such a petition
14 may only be filed within the 30-day period beginning on
15 the date the order making such assessment was issued.

16 (4) If any person fails to pay an assessment of a civil
17 penalty after it has become a final and unappealable order,
18 or after a court in an action brought under paragraph (3)
19 has entered final judgment in favor of the Administrator,
20 the Attorney General shall recover the amount assessed

21 (plus interest at currently prevailing rates from such date)
22 in any appropriate United States district court. In such
23 action, the validity, amount, and appropriateness of such
24 penalty shall not be subject to review.

25 (b) Criminal. - (1) Any person who knowingly or

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1 willfully violates any provision of section 15 shall, in addi-
2 tion to or in lieu of a civil penalty which may be imposed
3 under subsection (a) of this section for such violation, be
4 subject upon conviction, to a fine of not more than \$25,000
5 for each day of violation, or to imprisonment for not more
6 than 1 year, or both.

7 (2) For purposes of paragraph (1), the term "know-
8 ingly"* means having actual knowledge.

9 SPECIFIC ENFORCEMENT AND SEIZURE

10 Sec. 17. (a) Specific Enforcement.- (1) Upon
11 application of the Administrator or the Attorney General
12 the United States district courts shall have jurisdiction over
13 civil actions to -
14 (A) restrain any violation of section 15,

15 (B) restrain any person from manufacturing or
16 processing a chemical substance before the expiration
17 of the period during which such manufacturing or proc-
18 essing is prohibited under section 5,
19 (C) restrain any person from taking any action
20 prohibited by a requirement prescribed under section
21 5 or 6 or rules or orders issued thereunder or,
22 (U) direct any manufacturer or processor of a
23 chemical substance or mixture not in compliance with
24 any order issued under section 5 (e) or any rule issued
25 under section 4 or 6, (i) to give notice of such fnct to

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1 distributors in commerce of such substance or mixture
2 and, to the extent reasonably ascertainable, to other
3 persons in possession of such substance or mixture or
4 exposed to such substance or mixture, (ii) to give public
5 notice of such risk of injury, and (iii) to either replace
6 or repurchase such substance or mixture whichever
7 the person to which the requirement is directed elects.
8 (E) compel the taking of any action required by
9 or under this Act.

10 (A) An action described in paragraph (1) may be
11 brought -

12 (A) in the case of a civil action described in sub-
13 paragraph (A) of such paragraph, in the United States
14 district court for the judicial district wherein any act,
15 omission, or transaction constituting a violation of sec-
16 tion 15 occurred or wherein the defendant is found or
17 transacts business, or

18 (B) in the case of any other civil action described
19 in such paragraph, in the United States district court
20 for the judicial district wherein the defendant is found
21 or transacts business.

22 In any such civil action process may be served on a defend-
23 ant in any judicial district in which a defendant resides or
24 may be found. Subpoenas requiring attendance of witnesses
25 in any such action may run into any judicial district.

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1 (b) Seizure. - Any chemical substance or mixture
2 which was manufactured, processed, or distributed in com-
3 merce in violation of this Act or any rule or order promul-
4 gated under this Act shall be liable to be proceeded against,
5 by process of libel for the seizure and condemnation of such

Q substance or mixture in any United States district court
7 within the jurisdiction of which such substance or mixture
8 is found. Such proceedings shall conform as nearly as pos-
9 sible to proceedings in rem in admiralty.

10 PEEEMPTION

11 Sec. 18. (a) Effect on State Law.— (1) Except
12 as provided in paragraph (2), nothmg in this hct shall
13 affect the authority of any State or political subdivision of a
14 State to establish or continue in effect regulation of any
15 chemical substance or mixture containing a chemical sub-
16 stance or mixture.

17 (2) Except as provided in subsection (b) —
18 (^) if the Administrator requires by rule promul-
19 gated under section 4 the testing of a chemical sub-
20 stance or mixture, no State or political subdivision may,
21 after the effective date of such mle, require the testing
22 of such substance or mixture for purposes similar to
23 those for which testing is required under such rule;
24 and

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2 (B) if the Administrator prescribes a requirement

2 under section 5 or 6 of this Act which is applicable to
2 a chemical substance or mixture and which is designed
4 to protect against a risk to health or the environment
5 associated with such substance or mixture no State or
Q political subdivision of a State may, after the effective
rj date of such requirement, establish or continue in effect
g a requirement applicable to such substance or mixture
9 and designed to protect against such risk unless such
requirement is identical to the requirement prescribed
H by the Administrator or unless such State or political
^2 subdivision requirement prohibits the use or distribution
of such substance or mixture within the territorial juris-
14 diction of the State or political subdivision.
15 (b) Exemption- Upon application of a State or
16 political subdivision of a State, the Administrator may by
17 rule exempt such State or subdivision from subsection (a)
18 (2), under such conditions as may be prescribed in such
19 rule, if-
20 (1) compliance with the requirement would not
21 cause the substance or mixture to be in violation of the
22 applicable requirement under this Act described in sub-
23 section (a) (2) , and
24 (2) the State or political subdivision requirement

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1 (A) provides a significantly higher degree of protection
2 from such risk than the requirement under this Act de-
3 scribed in subsection (a) (2), and (B) does not, through
4 difficulties in marketing, distribution, or other factors,
5 unduly burden interstate commerce.

Q JUDICIAL REVIEW

7 Sec. 19. (a) General.— Not later than 60 days
8 following the promulgation of any rule under this Act or an
9 order under section 5 (e), any interested person may file a
10 petition for judicial review of such rule or order with the
11 United States Court of Appeals for the District of Columbia
12 Circuit, or for the circuit in which such person resides or in
13 which such person's principal place of business is located.
14 Copies of the petition shall be forthwith transmitted by the
15 clerk of such court to the Administrator and to the Attorney
16 General. The Administrator shall transmit to the Attorney
17 General, who shall file in the court, the record of the pro-
18 ceedings on which the Administrator based such rule or
19 order as provided in section 2112 of title 28, United
20 States Code. For purposes of this section, the term "record"
21 means such rule or order, any transcript required of any
22 oral presentation; any written submission of interested par-
23 ties; and any other information which the Administrator
24 considers to be relevant to such rule or order and with respect
25 to which the Administrator, on or before the date of the

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1 promulgation of such rule or order, published a notice in
2 the Federal Register identifying such information.

3 (b) Additional Data. - ^If the petitioner applies to
4 the court for leave to adduce additional data, views, or
5 arguments, and shows to the satisfaction of the court that
6 such additional data, views, or arguments are material and
7 that there are reasonable grounds for the petitioner's failure
8 to adduce such data, views, or arguments in the proceeding
9 before the Administrator, the court may order the Adminis-
10 trator to provide additional opportunity for oral presentation
11 of data, views, or arguments and for written submissions.
12 The Administrator may modify findings or determinations
13 upon which the rule or order, subject to review by such court
14 was based, or make new findings or determinations by reason
15 of the additional data, views, or arguments so taken and shall
16 file such modified or new findings or determinations, and the
17 Administrator's recommendation, if any, for the modifica-
18 tion or setting aside of such rule or order, with the return of
19 such additional data, views, or arguments.

20 (c) AUTHORITY AND Review Standard.- (1) Upon

21 the filing of a petition under subsection (a) , the court shall

22 have jurisdiction (A) to review the rule or order involved,
23 in accordance with chapter 7 of title 5, United States Code,
24 and (B) to grant appropriate relief, including interim relief,

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2 as provided in such chapter, except that any rule promulgated
2 by the Administrator under section 3(b), 5, or 6 of this
3 Act and reviewed under this section shall be affirmed, unless
4 the rule is not supported by substantial evidence on the record
5 taken as a whole.

Q (2) The judgment of the court affirming or setting aside,
6 in whole or in part, any rule or order reviewed in accordance
7 with this section shall be final, subject to review by the
8 Supreme Court of the United States upon certiorari or certifi-
9 cation, as provided in section 1254 of title 28, the United
10 States Code.

22 (3) The judgment of the court in an action brought
23 pursuant to subsection (a) may include an award of costs
24 of suit and reasonable fees for attorneys and expert witnesses
25 if the court determines that such an award is appropriate.
IQ The Supreme Court of the United States in its decision on a
17 review of a judgment in such an action may provide for the
18 award of costs of suit and reasonable fees for attorneys if the

19 court determines that such an award is appropriate.

20 (d) Other Remedies. – The remedies provided in this

21 section shall be in addition to and not in lieu of any other

22 remedies provided by law.

23 citizen's civil action

24 Sec. 20. (a) In General.– Except as provided in

25 subsection (b) , any person may commence a civil action –

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1 (1) against any person (including (A) the United

2 States, and (B) any other governmental instrumentality

3 or agency to the extent permitted by the eleventh amend-

4 ment to the Constitution) who is alleged to be in viola-

5 tion of this Act or any rule or order prescribed under

6 section 4, 5, or 6 (a) to restrain such violation, or

7 (2) against the Administrator to compel the Admini-

8 strator to perform any act or duty under this Act

9 which is not discretionary.

10 Any civil action under paragraph (1) shall be brought in the

11 district court of the United States for the district in which

12 the alleged violation occurred or in which the defendant

13 resides or in which the defendant's principal place of busi-

14 ness is located. Any action brought under paragraph (2)
15 shall be brought in the district court for the District of Colum-
16 bia, or the United States district court for the judicial district
17 in which the plaintiff is domiciled. The district courts shall
18 have jurisdiction over suits brought under this section, with-
19 out regard to the amount in controversy or the citizenship of
20 the parties. In any civil action under this subsection, process
21 may be served on a defendant in any judicial district in which
22 the defendant resides or may be found and subpoenas for
23 witnesses may run into any judicial district.

24 (b) Limitation.— No civil action may be com-
25 menced —

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1 (1) under subsection (a) (1) to restrain a viola-
2 tion of this Act or rule or order under this Act —

3 (A) before the expiration of sixty days after

4 the plaintiff has given notice of such violation (i)
^ to the Administrator, and (ii) to the person who
g is alleged to have committed such violation, or

-tjf (B) if Administrator (or Attorney General
g. on his behalf) has commenced and is diligently
g prosecuting a civil action in a court of the United
20 States to require compliance with this Act or such
j2 rule, but if such action is commenced after the giv-
j2 ing of notice, any person giving such notice may
j3 intervene as a matter of right in such action ; or
14 (2) under subsection (a) (2) before the expira-
15 tion of 60 days after the plaintiff has given notice
16 to the Administrator of the alleged failure of the Ad-
17 ministrator to perform an act or duty which is the basis
18 for such action or, in the case of an action under such
19 subsection for the failure of the Administrator to file an
20 action under section 7, before the expiration of 10 days
21 after such notification.
22 Notice under this subsection shall be given in such manner
23 as the Administrator shall prescribe by rule.
24 (c) General.— (1) In any action under this section,

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1 the Administrator, if not a party, may intervene as a matter
2 of right.

3 (2) The court, in issuing any final order in any action
4 brought pursuant to subsection (a), may award costs of suit
5 and reasonable fees for attorneys and expert witnesses if the
6 court determines that such an award is appropriate. Any
7 court, in issuing its decision in an action brought to review
8 such an order, may award costs of suit and reasonable fees
9 for attorneys if the court determines that such an award is
10 appropriate.

11 (3) Nothing in this section shall restrict any right which
12 any person (or class of persons) may have under any statute
13 or common law to seek enforcement of this Act or any rule
14 under this Act or to seek any other relief.

15 (d) Consolidation. – When two or more civil actions
16 brought under subsection (a) involving the same defendant
17 or plaintiffs and the same issues or violations are pending
18 in two or more judicial districts, such pending actions, upon
19 application of such defendant or plaintiff to such actions
20 which is made to a court in which any such action is
21 brought, may, if such court in its discretion so decides, be
22 consolidated for trial by order (issued after giving all parties
23 reasonable notice and opportunity to be heard) of such court
24 and tried in –

1 (1) any district which is selected by such defendant
2 or plaintiff and in which one of such actions is pending.

3 (2) a district which is agreed upon by stipulation
4 between all the parties to such actions and in which one
5 of such actions is pending, or

6 (3) a district which is selected by the court and
7 in which one of such actions is pending.

8 The court issuing such an order shall give prompt notification
9 of the order to the other courts in which the civil actions con-
10 solidated under the order are pending.

11 citizens' petitions

12 Sec. 21. (a) In General. – Any person may petition
13 the Administrator to issue a rule or order, or to take other
14 action under this Act, the purpose of which is to protect
15 against an unreasonable risk of injury to health or the
16 environment.

17 (b) Peoceduees.– (1) Such petition shall be filed in
18 the principal office of the Administrator and shall set forth
19 the facts which it is claimed estabhsh that such rule, order, or
20 other action is necessary.

21 (2) The Administrator may hold a public hearing or
22 may conduct such investigation or proceeding as the Admin-
23 istrator deems appropriate in order to determine whether or
24 not such petition should be granted.

25 (3) Within 90 days after filing of a petition de-

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1 _ scribed in paragraph (1) , the Administrator shall either
2 grant or deny the petition. If the Administrator grants
3 such petition, the Administrator shall promptly commence
4 an appropriate proceeding to comply with such petition. If
5 the Administrator denies such petition, the Administrator
6 shall publish in the Federal Register the Administrator's rea-
7 sons for such denial.

8 (4) (A) If the Administrator denies a petition filed
9 under this section (or if the Administrator fails to grant or
10 deny such petition within the 90-day period), the peti-
11 tioner may commence a civil action in a United States dis-
12 trict court to compel the Administrator to initiate the action
13 requested. Any such action shall be filed within 60 days
14 after the Administrator's denial of the petition or, if the Ad-
15 ministrator fails to grant or deny the petition within 90
16 days after filing the petition, within 60 days after the ex-
17 piration of the 90-day period.

18 (B) If the petitioner can demonstrate to the satisfaction
19 of the court, by a preponderance of the evidence in a de novo

20 proceeding before such court, that the action requested in the
21 petition conforms to the applicable requirements of this Act,
22 the court shall order the Administrator to initiate the action
23 requested by the petitioner.

24 (C) The court in issuing any final order in any action
25 brought pursuant to subparagraph (A) , may award costs of

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-j^ suit and reasonable fees for attorneys and expert witnesses

2 if the court determines that such an award is appropriate,

o Any court, in issuing its decision in an action brought to

4 review such an order, may award costs of suit and reason-

5 able fees for attorneys if the court determines that such an
Q award is appropriate.

ij (5) The remedies under this section shall be in addi-

g tion to, and not in lieu of, other remedies provided by law.

9 NATIONAL DEFENSE WAIVER

Sec. 22. The Administrator shall waive compliance

-^1 with any provision of this Act upon request of the Secretary

22 of Defense and upon a determination by the President that

;j^3 the requested waiver is necessary in the interest of national

14 defense. The Administrator shall maintain a written record
35 of the basis upon which such waiver was granted and make
16 such record available for in camera examination when relc-
17 vant in a judicial proceeding under this Act. Upon the is-
18 suance of such a w^aiver, the Administrator shall publish in
19 the Federal Register a notice tliat the waiver was granted
20 for national defense purposes, unless, upon the request of
21 the Secretary of Defense, the Administartor determines to
22 omit such publication because the publication itself would
23 be contrary to the interests of national defense, in which
24 event the Administi-ator shall su]mit notice thereof to the

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2 Armed Services Committees of the Senate and the House of
2 Representatives.

3 EMPLOYEE PROTECTION

4 Sec. 23. (a) Geneeal. - No employer may discharge

5 any employee or otherwise discriminate against any em-
Q ployee with respect to the employee's compensation, terms,
tj conditions, or privileges of employment because the employee
g (or any person acting pursuant to a request of the employee)
Q has -

(1) commenced, caused to be commenced, or is
about to commence or cause to be commenced a pro-

j2 ceeding under this Act;

13 (2) testified or is about to testify in any such pro-

14 ceeding ; or

15 (3) assisted or participated or is about to assist or

16 participate in any manner in such a proceeding or in

17 any other action to carry out the purposes of this Act.

18 (b) Remedy. - (1) Any employee who believes that

19 he or she has been discharged or otherwise discriminated

20 against by any person in violation of subsection (a) of this

21 section may, within 30 days after such alleged violation

22 occurs, file (or have any person file on the employee's

23 behalf) a complaint with the Secretary of Labor (herein-

24 after in this section referred to as the "Secretary") alleging

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1 such discharge or discrimination. Upon receipt of such a

2 complaint, the Secretary shall notify the person named in

3 the complaint of the filing of the complaint.

4 (2) (A) Upon receipt of a complaint filed under para-

5 graph (1) , the Secretary shall conduct an investigation of the

6 violation alleged in the complaint. Within 30 days of the

7 receipt of such complaint, the Secretary shall complete such

8 investigation and shall notify in writing the complainant

9 (and any person acting on behalf of the complainant) and

10 the person alleged to have committed such violation of the
11 results of the investigation conducted pursuant to this para-
12 graph. Within 90 days of the receipt of such complaint the
13 Secretary shall, unless the proceeding on the complaint is
14 terminated by the Secretary on the basis of a settlement
15 entered into by the Secretary and the person alleged to have
16 committed such violation, issue an order either providing
17 the relief prescribed by subparagraph (B) or denying the
18 complaint. An order of the Secretary shall be made on the
19 record after notice and opportunity for agency hearing. The
20 Secretary may not enter into a settlement terminating a
21 proceeding on a complaint without the participation and
22 consent of the complainant.

23 (B) If in response to a complaint filed under paragraph
24 (1) the Secretary determines that a violation of subsection

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1 (a) of this section has occurred, the Secretary shall order (i)
2 the person who committed such violation to take affirmative
3 action to abate the violation, (ii) such person to reinstate
4 the complainant to the complainant's former position to-
5 gether with the compensation (including back pay) , terms,

6 conditions, and privileges of the complainant's employment,
7 (iii) compensatory damages, and (iv) where appropriate,
8 exemplary damages. If such an order is issued, the Secre-
9 tary, at the request of the complainant shall assess against
10 the person against whom the order is issued a sum equal
11 to the aggregate amount of all costs and expenses (including
12 attorney's fees) reasonably incurred, as determined by the
13 Secretary, by the complainant for, or in connection with,
14 the bringing of the complaint upon which the order was
15 issued.

16 (c) Review. - (1) Any person adversely affected or
17 aggrieved by an order issued under subsection (b) may
18 obtain review of the order in the United States Court of
19 Appeals for the circuit in which the violation, with respect
20 to which the order was issued, allegedly occurred. The peti-
21 tion for review must be filed within 60 days from the
22 issuance of the Secretary's order. Review shall conform to
23 chapter 7 of title 5 of the United States Code.

24 (2) An order of the Secretary, with respect U) which

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1 review could have been obtained under paragraph (1) , shall

2 not be subject to judicial review in any criminal or other
3 civil proceeding.

4 (d) Enforcement – (1) Whenever a person has
5 failed to comply with an order issued under subsection (b)
6 (2), the Secretary shall file a civil action in the United
7 States distiict court for the district in which the violation
8 was found to occur to enforce such order. In actions brought
9 under this subsection, the district courts shall have jurisdic-
10 tion to grant all appropriate relief, including injimctive relief
11 and compensatory and exemplary damages. Civil actions
12 brought under this subsection shall be heard and decided
13 expeditiously.

14 (2) Any nondiscretionary duty imposed by this section
15 is enforceable in a mandamus proceeding brought under sec-
16 tion 1361 of title 28, United States Code.

17 (e) Exclusion. – Subsection (a) of this section shall
18 not apply with respect to any employee who, acting with-
19 out direction from the employee's employer (or any agent of
20 the employer) , deliberately causes a violation of any require-
21 ment of this Act.

22 (f) Employment Effects.– (1) The Administrator
23 shall conduct continuing evaluations of the potential loss or
24 shifts of employment which may result from the issuance of

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1 any rule or order under this Act, including, where appro-
2 priate, investigating threatened plant closures or reductions
3 in employment allegedly resulting from such rule or order.

4 (2) Any employee who is discharged or whose employ-
5 ment is otherwise interrupted, or is threatened with discharge
6 or such interruption, or otherwise discriminated against by

7 any person because of the results of an}- rule or order issued
8 under this Act, or a representative of such employee, may

9 request the Administrator to conduct a full investigation of
10 the matter. The Administrator shall thereupon investigate

11 the matter and, at the request of any interested party, shall
12 hold a public hearing on not less than 5 days notice, and

13 shall at such hearings require the parties, including the em-
11 ployer involved, to present information relating to the actual
13 or potential effect of such rule or order on employment and

16 on any alleged discharge, interruption of employment, or
17 other discrimination and the detailed reasons or justification

18 therefor. Any such hearing shall be of record and shall be
19 conducted in accordance with section 554 of title 5, United

20 States Code.

21 (3) Upon receiving the report of any such investigation,
1:2 the Administrator shall make findings of fact as to the effect

23 of such rule or order on employment and the alleged dis-

24 charge, interruption of employment, or discrimination and

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1 shall make such recommendations as he deems appropriate.

2 Such report, findings, and recommendations shall be avail-

3 able to the public.

4 (4) Nothing in this subsection shall be construed to

5 require the Administrator to modify or withdraw any rule or

6 order issued under this Act.

7 STUDIES

8 Sec. 24. (a) Indemnification. - The General Ac-

9 counting Office shall conduct a study of all Federal laws

10 administered by the Administrator for the purpose of deter-

11 mining whether and under what conditions, if any, indem-

12 nification should be accorded any person as a result of any

13 action taken by the Administrator under any such law. The

34 study shall -

15 (1) include an estimate of the probable cost of any

16 indemnification programs which may be recommended;

17 (2) include an examination of all viable means of

18 financing the cost of any recommended indemnification ;

19 and

20 (3) be completed and submitted to Congress not

21 less than 2 years from the date of enactment of this Act.

22 (b) Classification, Storage, and Keteieval.-

23 The Council on Environmental Quality, in consultation
24 with the Administrator, the Secretary of Health, Edu-
25 cation, and Welfare, the Secretary of Commerce, and the

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1 heads of otlier appropriate Federal departmeiits or agen-
2 cies, shall coordinate a study of the feasibihty of estabUshing
3 (1) a standard classifioation system for chemical substances
4 and related substances, and (2) a standard means for
5 storing and for obtaining rapid access to information re-
6 specting such substances. A report on such study shall be
7 completed and submitted to Congress not later than 18
8 months after the date of the enactment of this Act.

9 ADMINISTRATION OF ACT

10 Sec. 25. (a) Cooperation of Federal Agencies.-

11 Upon request by the Administrator, each Federal depart-
12 ment and agency is authorized -

13 (1) to make its services, personnel, and facilities
14 available (with or without reimbursement) to the Ad-
15 ministrator to assist the Administrator in the admin-
16 isti*ation of this Act ; and

17 (2) to furnish to the Administrator such informa-
18 tion, data, estimates, and statistics, and to allow the
19 Administrator access to all information in its possession
20 as the Administrator may reasonably determine to be
21 necessary for the admnstration of this Act.

22 (b) Fees. - The Administrator may, by rule, require
23 the payment of a reasonable fee from any person required
24 to submit data under section 4 or 5 of this Act to de-

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1 fray the cost of administering this Act. Such rules shall not
2 provide for any fee in excess of \$2,500. In settiag such a fee,
3 the Administrator shall take into account the ability to pay
4 of the person required to submit the data and the cost to the
5 Administrator of reviewing such data. Such rules may pro-
6 vide for sharing such a fee in any case in which the expenses
7 of testing are shared under section 4 or 5 of this Act.

8 (c) Action With Respect to Categobies - (1)

9 Any action which may be taken by the Administrator under
10 any provision of this Act with respect to a chemical sub-
11 stance or mixture may be taken by the Administrator in
12 accordance with that provision with respect to a category

13 of chemical substances or mixtures. Whenever the Administrator
14 takes action under a provision of this Act with respect
15 to a category of chemical substances or mixtures, any refer-
16 ence in this Act to a chemical substance or mixture (insofar
17 as it relates to such action) shall be deemed to be a refer-
18 ence to all chemical substances or mixtures in such category.

19 (2) For purposes of paragraph (1) :

20 (A) The term "category of chemical substances"

21 means a group of chemical substances the members of
22 which are similar in molecular structure, in physical,
23 chemical, or biological properties, in use, or in mode of
24 entrance into the human body or into the environment,
25 or the members of which are in some other way ascertainable

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1 for classification as such for purposes of this Act, except
2 that such term does not mean a group of chemical sub-
3 stances which are grouped together solely on the basis
4 of their being new chemical substances.

5 (B) The term "category of mixtures" means a

6 group of mixtures the members of which are similar in
7 molecular structure, in physical, chemical, or biological

8 properties, in use, or in mode of entrance into the human
9 body or into the environment, or the members of which
10 are in some other way suitable for classification as such
11 for purposes of this Act.

12 (d) Statement of Purpose and Justification. –

13 Any proposed or final rule or order issued under this Act
14 shall be accompanied by a statement of purpose and justifi-
15 cation. Such a statement shall be considered part of the
16 "record of the proceedings" for purposes of judicial review
17 under section 19 (a) .

18 (e) Assistant Administrator.– The President, by
19 and with the advice and consent of the Senate, shall appoint
20 an Assistant Administrator for Toxic Substances of the Envi-
21 ronmental Protection Agency. Such Assistant Administrator
22 shall be a qualified individual who is, by reason of back-
23 ground and experience, especially qualified to direct a pro-
24 gram concerning the effects of chemicals on human health
25 and the environment. Such Assistant Administrator shall be

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1 responsible for the collection of data, the preparation of
2 studies, and the making of recommendations to the Adminis-

3 trator for regulatory and other actions to carry out the
4 purposes, and to facilitate the administration of this Act.

5 AUTHORIZATION FOR APPROPRIATIONS

6 Sec. 26. (a) In General.— There is authorized to be
7 appropriated to the Administrator, for purposes of carrying
8 out this Act, \$11,100,000 for the fiscal year ending June 30,
9 1976, \$2,600,000 for the period beginning July 1, 1976 and
10 ending September 30, 1976, and \$10,100,000 for the fiscal
11 year ending September 30, 1977. No part of the funds so
12 authorized to be appropriated shall be used to construct any
13 research laboratories.

14 (b) Budget Requests.— Whenever the Administra-
15 tor directly or indirectly submits, in connection with this
16 Act, any budget requests, supplemental budget estimates,
17 legislative recommendations, prepared testimony for con-
18 gressional hearings, or comments on legislation to the Presi-
19 dent or to the Office of Management and Budget, or per-
20 sons acting on their behalf, the Administrator shall con-
21 currently transmit a copy thereof to the Congress. No officer
22 or agency of the United States shall have any authority to
23 require the Administrator to submit budget requests or esti-
24 mates, legislative recommendations, prepared testimony for
25 congressional hearings, or comments on legislation relating

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1 to this Act to any officer or agency of the United States for
2 approval, comments, or review, prior to the submission of
3 such requests, estimates, recommendations, testimony, or
4 comments to the Congress.

5 ANNUAL REPORT

6 Sf-C. 27. The Administrator shall prepare and submit
7 to the President and the Congress on or before January 1 of
8 each year a comprehensive report on the administration of
9 this Act during the preceding fiscal year. Such report shall
10 include -

11 (1) a list of the testing required under section 4
12 during the year for which the report is made and an
13 estimate of the costs incurred during such year by the
14 persons required to perform such tests;

15 (2) the number of notices received during such year
16 under section 5, the number of such notices received dur-
17 ing such year under such section for chemical substances
18 and mixtures subject to a section 4 rule, and a summary
19 of any action taken during such year under section 5 (e) ;

20 (3) a list of rules issued during such year under
21 section 6;

22 (4) a list, with a brief statement of the issues, of

23 continued or pending' judicial or enforcement actions
2- under this Act during such year;

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1 (5) a summary of major problems encountered in

2 the administration of this Act; and

3 (6) such recommendations for additional legislation

4 as the Administrator deems necessary to carry out the

5 purposes of this Act.

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Calendar No. 668

94th Congress \ (Sii^-iTi- / Report

2d Session / si>.>Ait -j^ j^., 94-098

TOXIC SUBSTANCES CONTROL ACT

REPORT

OF THE

SENATE COMMITTEE ON COMMERCE

ON

S. 3149

together with
ADDITIONAL VIEWS

TO REGULATE COMMERCE AND PROTECT HUMAN HEALTH
AND THE ENVIRONMENT BY REQUIRING TESTING AND
NECESSARY USE RESTRICTIONS ON CERTAIN CHEMICAL
SUBSTANCES, AND FOR OTHER PURPOSES

March 16, 1976. - Ordered to be printed

57-010

U.S. GOVERNMENT PRINTING OFFICE
WASHINGTON : 1976

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Calendar No. 668

<)4th Congress) SENATE (Report

2d Session f (No. 94-698

TOXIC SUBSTANCES CONTROL ACT

March 16, 1976. - Ordered to be printed

Mr. Magnusox, from the Committee on Commerce,
submitted the following

REPORT

together with
ADDITIONAL VIEWS

[To accompany S. 3149]

The Committee on Commerce having considered the bill (S. 3149) to regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes, reports favorably thereon and recommends that the bill do pass.

Purpose and Brief Description

The purpose of S. 3149 is to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances. The bill is designed to fill a number of regulatory gaps which currently exist. They are :

1. PREMARKET REVIEW

While certain environmental health statutes may be used to protect health and the environment from chemical substances, only pesticides, drugs, and food additives undergo premarket scrutiny prior to first manufacture. The Clean Air Act (77 Stat. 392), the Federal Water Pollution Control Act (60 Stat. 755), the Occupational Safety and Health Act (84 Stat. 1590), and the Consumer Product Safety Act (81 Stat. 1207), do not provide for this type of premarket scrutiny.

2. DIRECT REGULATION OF CHEMICALS

While air and water laws authorize limitations on discharges and emissions, the Occupational Safety and Health Act authorizes the establishment of ambient air standards for the workplace, and the Consumer Product Safety Act authorizes standards with respect to

(1)

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consumer products, there are no existing statutes which authorize the direct control of industrial chemicals themselves for their health or

environmental effect (except section 211 of the Clean Air Act, which authorizes the re~~x~~ulation of fuel additives).

^^Hiile these otlier authorities will in many cases be sufficient to adequately protect health and the environment, the alternative of preventing or regulating the use of the chemical in the first instance may be a far more effective way of dealing with the hazards. If expensive sewage treatment facilities can be avoided, for example, through removing dangerous materials from household and industrial wastes, the authority to do so ought to be provided.

3. COXSIDERATION OF ALL THE RISKS

"^While individual agencies may be authorized to regulkte occupational, environmental or direct consumer hazards with respect to a chemical substance, there is no agency which has the authority to look comprehensively at the hazards associated with the chemical. Existing authority allows the agencies to only look at the hazards within their jurisdiction in isolation from other hazards associated with the same chemical. The bill would grant the Environmental Protection Agency the authority to look at the hazards in total.

4. COLLECTION OF TEST DATA

The committee bill also provides a mechanism whereby information with respect to health and environmental effects can be collected from manufacturers and processors of chemical substances. While other statutes provide regulatory authority, they do not place the responsibility for gathering information in support of the regulatory program squai^ly with persons who are responsible for the manufacture or processing of the chemical substance or mixtures.

Specificallv, the bill provides:

(1) That manufacturers of neio ch emical suhsfances give notification to EPA 90 days in advance of first manufacture and that test data accompany that notification if required by EPA. The provision is not applicable to research chemicals unless EPA specifically includes any such chemical.

(2) That the EPA Administrator require manufacturers to test or have tested those chemical substances which he determines may present an unreasonable risk of injury to health or the enviromnent or those for which significant human or environmental exposure takes place or will take place. The provision is applicable both to new and existing chemical substances.

(3) Manufacturers and processors of chemical substances are

required to maintain certain records and reports to better enable the Administrator to determine if unreasonable risks exist. Importantly, manufacturers must maintain with the Administrator lists of health and safety studies conducted, whether or not they have been conducted as a result of this legislation. The Administrator is authorized to require the submission of any study on the list.

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(4) Citizens are authorized to bring suits to enjoin certain violations and to require the Administrator of EPA to perform his mandatory duties. A citizens' petition provision is also provided whereby citizens may receive judicial review of petitions to EPA which were denied or not acted upon.

Background and Needs

The last century has witnessed the ever-accelerating growth of the chemical industry. Sales now exceed \$100 billion a year. This industry has developed a vast new array of chemicals. In fact, it is estimated that there are presently 2 million recognized chemical compounds in existence with nearly 20,000 new compounds produced each year. While most of these compounds will never be commercialized, the Environmental Protection Agency estimates that approximately 1,000 new chemicals each year will find their way into the marketplace and subsequently into the environment through use or disposal.

As the industry has grown, we have become literally surrounded by a man-made chemical environment. We utilize chemicals in a majority of our daily activities. We continually wear, wash with, inhale, and ingest a multitude of chemical substances. Many of these chemicals are essential to protect, prolong, and enhance our lives. Yet, too frequently, we have discovered that certain of these chemicals present lethal health and environmental dangers.

In 1971, the Council on Environmental Quality in a report entitled "Toxic Substances"- concluded that regulatory mechanisms to control toxic chemicals were "inadequate." This report was the impetus for the original Toxic Substances Control Act legislation.

After 15 days of hearings and extensive analysis over the last 5

years, the Toxic Substances Control Act has evolved into a comprehensive measure to protect the public and the environment from exposure to hazardous chemicals. The legislation would assure that chemicals receive careful premarket scrutiny before they are manufactured or distributed to the public. This provision would end the present situation where chemicals can be marketed without notification of any governmental body and without any requirement that they be tested for safety. Thus, this provision would no longer allow the public or the environment to be used as a testing ground for the safety of these products.

In a recent speech supporting toxic substances control legislation, Russell E. Train, the Administrator of the Environmental Protection Agency, pointed out that -

Most Americans had no idea, until relatively recently, that they were living so dangerously. They had no idea that when they went to work in the morning. Or when they ate their breakfast- that when they did the things they had to do to earn a living and keep themselves alive and well- that when they did things as ordinary, as innocent and as essential to life as eat, drink, breathe or touch, they would, in fact, be laying their lives on the line. They had no idea that, without their knowledge or consent, they were often engaging in a grim game of chemical roulette whose result they would not know until many years later.

Dr. Train's view is a reflection of the fact that in the last few years the list of commonly utilized and widely dispersed chemicals that

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have been found to be potentially significant health and environmental dangers has been constantly growing. A partial list includes:

- (1) Kepone, which has been implicated in causing brain damage and other nervous system disorders ;
- (2) vinyl chloride, arsenic, and asbestos, all found to be potentially extremely potent cancer-causing agents in man ;
- (3) mercury, lead, and other heavy metals ;
- (4) PCB's which have been found to cause liver cancer in rats and to have contaminated numerous fish stocks throughout the United

States; and

(5) fluorocarbons, propellants in aerosols and coolants in refrigerators and air-conditioners, suspected of depleting the Earth's ozone layer which protects humans from excessive ultraviolet radiation that can cause skin cancer.

Furthermore, the interaction of chemical substances in some cases, makes these dangers multiplicative rather than additive. Dr. Irving Selikoff, of the Mount Sinai Medical School, for example, pointed out that asbestos workers who are nonsmokers do not have an appreciably higher lung cancer rate than the population at large. However, Dr. Selikoff noted that if an asbestos worker smokes, his chances of getting lung cancer are eight times greater than the average cigarette smoker and are 92 times greater than an individual who is neither an asbestos worker or a smoker. Thus, the risks appear to be multiplied by these interactions.

Russell Peterson, Chairman of the Council on Environmental Quality, after analyzing these chemical dangers concluded at last year's hearings, "Toxic substances legislation is probably the most important environmental legislation now before the Congress." Many doctors and scientists concur with Dr. Peterson noting that controlling toxic chemicals in the environment is one of the crucial health requirements facing this Nation. Dr. David Rall, Director of the National Institute of Environmental Health Sciences of the National Institutes of Health, has stated, for example :

Recent experience with vinyl chloride, bischloromethyl ether, methoxyacetone, and sulphuric acid mist indicate that these compounds are not theoretical threats, but known causes of illness and death. Many of these compounds are toxic to man in relatively low concentrations. Man is assaulted by these compounds alone and in combination from multiple sources. This problem constitutes possibly the major health hazard of this decade. (*Italics added.*)

Cancer, which was projected to kill as many Americans in 1975 as all the battle deaths in Vietnam, Korea, and the Second World War combined, appeals particularly susceptible to a preventive approach through control of toxic substances in the environment. The National Cancer Institute, for example, estimates that 60 to 90 percent of the cancers occurring in this country are a result of environmental contaminants. Furthermore, the National Cancer Institute has plotted the incidence of cancer around the industrial centers of the United States. Almost without exception the industrial centers, where industrial chemicals are obviously found in largest concentrations, had the highest incidence of cancer.*[^] Thus, the Toxic Substances Control Act, which provides authority for increased testing of chemicals for their cancer-causing effects, can serve as an early warning system to signal

potential dangers before products are widely dispersed and irretrievable societal danger has been unleashed.

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Toxic chemicals have also been implicated in causing birth defects and genetic damage. The National Foundation-March of Dimes recently wrote to Senator Magnuson in support of toxic substances legislation stating :

More than 200,000 infants are born with physical or mental damage each year, a staggering 7 percent of all births * * * A total of 15 million Americans have birth defects serious enough to drastically affect their daily lives * ♦ * It is with alarm that our attention is drawn to some aspects of modern technology which work counter-productive to our aims. Each year billions of pounds of chemicals which are virtually untested and unregulated are produced in industrial processes and used in commercial products. Experience with vinylchloride has shown it to be a highly toxic substance which experimentally can cause cancer and birth defects ; but this experience came only with its burden of proof on the public. We look now to preventative testing of toxic substances in industrial

production prior to manufacture or distribution as one critical means to reduce exogenous causes of birth defects.

In order to protect against these dangers, the proposed Toxic Substances Control Act would close a number of major regulatory gaps, for while certain statutes, including the Clean Air Act, the Federal Water Pollution Control Act, the Occupational Safety and Health Act, and the Consumer Product Safety Act, may be used to protect health and the environment from chemical substances, none of these statutes provide the means for discovering adverse effects on health and environment before manufacture of new chemical substances. Under these other statutes, the Government regulator's only response to chemical dangers is to impose restrictions after manufacture begins.

The most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture. It is at this point that the costs of regulation in terms of human suffering, jobs lost, wasted capital expenditures, and other costs are lowest. Frequently, it is far more painful to take regulatory action after all of these costs have been incurred. For example, the hazards associated with

vinyl chloride have made headlines in recent months. Vinyl chloride has been implicated as causing liver cancer in industrial workers. At the same time the country has grown extremely reliant on the plastics which are produced from the chemical. In fact, 1 percent of our gross national product is associated with the vinyl chloride industry. Obviously, it is far more difficult to take regulatory action against this chemical now, than it would have been had the dangers been known earlier when alternatives could have been developed and polyvinyl chloride plastics not become such an intrinsic part of our way of life in this country.

The proposed Toxic Substances Control Act also provides a far more effective mechanism to protect against dangerous chemical materials contained in consumer and industrial products. While air and water pollution laws authorize limitations on discharges and emission and the Occupational Safety and Health Act authorizes workplace ambient standards, there are no statutes (except the fuel additives provisions of the Clean Air Act) which authorize the direct control of such chemicals for their health or environmental effects.

The regulation of the discharge of excessive levels of mercury into the environment is an example of the need for such controls. Recently, there has been growing concern about mercury pollution due to industrial discharges. Yet, testimony has indicated that an even greater

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threat of pollution may be posed by the presence of mercury in such consumer products as paint, home thermometers, sponges, and a variety of other products. Industrial pollution often can be pinpointed and corrective action rapidly taken ; however, it is nearly impossible to prevent an individual householder from disposing of products containing toxic substances either down the drain or out with the garbage. While many dangerous materials can be removed from municipal sewage, many others cannot, therefore, it seems far more prudent to provide authority to limit the amounts of dangerous materials in consumer products than to allow them to escape into a municipal sewage plant or to vainly ask the householder not to dispose of them. A prime purpose of the proposed Toxic Substances Control Act is to provide authority for such regulatory controls.

Another important provision would provide regulators timely access

to information regarding health and safety studies concerning chemicals covered by the Act. The importance of this provision was demonstrated in hearings of the Subcommittee on the Environment of the Senate Commerce Committee, where witnesses made detailed allegations that certain groups within the chemical industry had knowledge of the cancer-causing potential of vinyl chloride well in advance of the time that this information was released to the Government or the public. Similar charges were made that data was suppressed which suggested that industrial workers exposed to the chemical BCME were experiencing unusually high lung cancer rates. This legislation will provide the authority for EPA to gather this kind of information with respect to existing studies as well as studies which may be begun in the future.

The time has passed where human health and the environment is protected only after serious injury has occurred. As Russell Train has stated:

It is time we started putting chemicals to the test, not people. It is time we gave the people of this country some reason to believe that every time they take a breath or eat or drink or touch, they are not taking their life into their hands.

The Committee bill, which contains provisions to regulate chemical hazards, will help provide this needed assurance.

Description

1. testing of chemical substances

There are two multi-part bases under which the Administrator must require that testing be conducted on a chemical substance or mixture. First, if the manufacturer, processing, distribution in commerce, use, or disposal (a) may present an unreasonable risk, (b) there are insufficient data or experience upon which to judge the effects upon health and the environment, and (c) testing is necessary to develop data, the Administrator must require testing.

Second, if the Administrator finds that the chemical substance or mixture may present significant human or environmental exposure because it is or will be produced in substantial quantities or for other reasons, and that the substance or mixture may perhaps present an adverse effect on health and the requirements of (b) and (c) above are

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met, the Administrator must require testing. The finding with respect to an adverse effect is to be presumed if the Administrator has no reliable data or experience available to him.

In addition, the Administrator must consider the reasonably ascertainable costs and other burdens associated with conducting tests in light of the possible risks of injury to health or the environment. These findings are to be published in the Federal Register.

An eight member Federal advisory committee is established to develop a priority list of chemicals which it recommends to the Administrator for testing. The members of the committee are made up of Federal officials who either have regulatory responsibility in the area of chemical substances or have expertise with respect to testing needs.

Within 12 months after the date of inclusion of a chemical substance or mixture on the priority list, the Administrator is required to either (a) initiate a rulemaking proceeding to require testing or (b) publish in the Federal Register his reasons for not initiating such a proceeding.

2. PREMARKET NOTIFICATION

At least 90 days prior to the first manufacture (for commercial purpose) of a new chemical substance, manufacturers are to give notice to the Administrator. The notice is to contain information with respect to the identity of the substance, uses, estimates of amount to be produced, description of byproducts, a list of test data, and estimates of the number of employees who will be exposed to the substance.

If a testing requirement applicable to the new chemical has been established (see discussion of "Testing of Chemical Substances" above) the notification must be accompanied by the test data required.

The 90-day premarket notification period may be extended by the Administrator for an additional 90 days for good cause shown.

During the premarket notification period, the Administrator is authorized to issue an order which may restrict or prohibit the manufacturer of a new chemical substance on either of two bases :

(a) that a test requirement is necessary (or should be revised or added to) ; or

(b) that a restrictive rule is appropriate.

Orders issued during the premarket notification period are to be immediately effective and will trigger the appropriate rulemaking provisions under, section 6 (restrictions) or section 4 (testing requirements). A provision to expedite rulemaking under these provisions is provided.

If the Administrator determines that orders during the premarket notification period are inappropriate or that action should not be taken under the imminent hazards authority of section 7, he must publish a statement of his reasons in the Federal Register.

The premarket notification provisions would also apply to significant new uses of existing chemical substances.

Premarket notification would not take place with respect to mixtures or experimental or research chemicals unless the Administrator specifically includes any such chemical for purposes of the premarket notification.

The Administrator is also authorized to exempt persons from premarket notification for test marketing purposes or specially limited

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purposes or with respect to chemical substances which are intermediate reaction products formed during the manufacture of other chemical substances and for which there is no exposure to human beings or the environment.

3. RESTRICTIVE AUTHORITY

Restrictive requirements may be prescribed for any chemical substance or mixture which presents or is likely to present an unreasonable risk of injury to health or the environment. Remedies available to the Administrator range from outright prohibitions to simple labeling requirements.

In promulgating rules, the Administrator is to consider all relevant factors and make findings with respect to them. Included are the risks to human beings and to the environment, the benefits of the substance or mixture, and the reasonably ascertainable economic

consequences of the rule.

The Administrator is also authorized to seek orders in the district courts to protect against imminent hazards. Imminent hazards are defined as substances or mixtures which present an unreasonable risk of death, serious illness, or serious personal injury, or serious environmental harm prior to the completion of an administrative hearing or other proceeding authorized under the bill.

4. REPORTING AND RETENTION OF INFORMATION

The bill authorizes the Administrator to collect information which will prove extremely valuable in gathering information necessary to assess and take action against chemicals causing unreasonable risks. Manufacturers or processors may be required to submit pertinent information with respect to the identity, uses, amounts produced, byproducts, health effects, and exposure levels of chemical substances.

In addition, lists of health and safety studies conducted by, initiated by, or known to persons within the chemical industry must be submitted to the Administrator. The Administrator may then require the submission of any study appearing on the list. This will be valuable in avoiding the situations that have occurred in the past with chemicals like vinyl chloride and BCME where allegations have been made that the industry and trade associations withheld information which would have revealed hazards associated with these chemicals at a much earlier date.

In addition, persons within the chemical industry, and liability insurers of these persons, are required to submit any information to the Administrator which supports the conclusion that an unreasonable risk to health or the environment is presented.

5. RELATIONS TO OTHER FEDERAL LAWS

If an unreasonable risk may be prevented or reduced sufficiently by other Federal laws, the Administrator must request the agency administering the law to issue an order declaring whether or not

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such a risk is presented. If the agency agrees that such a risk is pre-

sented, it must determine if the risk can be prevented or reduced to a sufficient extent by action taken under the law administered by it.

If the other Federal agency issues the order declaring that there is no unreasonable risk or initiates action under the other law, the Administrator may not take action under this authority to prevent the unreasonable risk.

With respect to other laws administered by the Administrator, the Administrator is directed to coordinate his actions with actions taken under those Federal laws and to use the authority contained in those laws unless this authority would be more appropriate.

In order to insure that information is gathered and premarket notification takes place, the restriction on the Administrator's authority would not apply to section 4 (testing) , section 5 (premarket notification), or section 8 (reporting and information gathering).

6. CmZEXS PARTICIPATIOX

The bill contains a citizen's suit provision which authorizes suits against the Administrator where he has failed to perform a nondiscretionary duty and against others who are alleged to be in violation of sections 4 (testing), 5 (premarket notification), or 6(a) (restrictive rules). The provision is modeled after similar provisions in the Safe Drinking Water Act (88 Stat. 1660) Consumer Product Safety Act, Clean Air Act, Federal Water Pollution Control Act, and Noise Control Act.

In addition, citizens are authorized to petition the Administrator to take action the purpose of which is to protect against unreasonable risks of injury to health or the environment. If the Administrator fails to take action within 90 days on such a petition, or denies it, judicial review of the denial or failure is authorized. After gathering evidence in a de novo procedure, the courts would be authorized to require the initiation of the action requested if the petitioner has shown that the action requested is justified. The citizen's petition provision is similar to that contained in the Consumer Product Safety Act.

7. EMPLOYEE PROTECTION'

Discrimination against any employee who participates in proceedings, testifies in a proceeding, or participates in any other action necessary to carry out the purposes of the legislation is prohibited.

A procedure is provided whereby the Secretary of Labor would conduct a proceeding and may order the reinstatement of the employee

if violations are found.

In addition, the Administrator is required to continually evaluate the effects on employment which may result from the issuance of rules or orders under the bill. If requested by an employee whose employer has acted against him or her because of any rule or order issued under this bill, or when such actions are threatened, the Administrator is required to investigate the matter and to make findings of fact with respect to such allegations.

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Responses to Arguments

1. The bill does not contain excessive authority for EPA,

In the major regulatory provisions, section 4 (relating to test requirements) and section 6 (relating to restrictive authority), the Administrator is directed to consider costs and benefits when deriving appropriate rules.

Under section 6, the Administrator is required to make findings with respect to all relevant factors and to publish them in the Federal Register. This includes the risks to health and the environment, the benefits of the substance or mixture to be regulated, and the reasonably ascertainable economic consequences of the rule.

Under section 4, the Administrator is required to consider the reasonably ascertainable costs and other burdens associated with conducting the tests in light of the possible risks of injury to health or the environment and is required to publish these considerations in the Federal Register.

The rulemaking provisions of sections 4 and 6 provide an additional means to prevent improper action by EPA. Under section 4(b) (4) the Administrator is required to give interested persons an opportunity for the oral presentation of data, views, or arguments in addition to the opportunity to make written submissions.

Under the rulemaking provisions of section 6, an informal hearing must be provided with rights of cross-examination granted in appropriate instances.

Of course, judicial review of rules issued is available.

Finally, section 2(c) specifically states that it is the intent of Congress that the Administrator be reasonable and prudent in his administration of the bill, and that he is to consider the environmental, economic, and social impact of actions taken thereunder.

^ The premarket notification provisions are not too broad.

If hazards are to be discovered and prevented prior to the first manufacture of new chemical substances or prior to the imposition of significant new uses of existing substances, premarket notification is an essential provision.

Other alternatives to the committee bill now pending in the House of Representatives, would restrict premarket notification only to those chemical substances for which a finding of risk could be made. Thus, the EPA Administrator would be placed in the position of predicting not only what new chemical substances might be produced, but their level of hazard as well. The unpredictable new chemical substance would be completely missed by this procedure as would those substances for which hazards information does not exist. Thus, the premarket notification provisions' of the committee bill forms the backbone of the preventive aspects of health protection sought by this legislation.

While the EPA Administrator must be given the authority to act during the premarket notification period to gather more data or to take appropriate restrictive action, the notification burden itself should not be onerous. Unless testing has been otherwise required, notification only consists of reporting routine information which should be in the hands of the manufacturer in the first place. Included is information

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as to the identity of the product, categories of use, estimates of the amount to be produced and, insofar as reasonably ascertainable, to be produced for each of the categories of use, a description of byproducts, lists of existing test data, and estimates of the number of persons who will be exposed in their places of employment.

Estimates of the number of new chemicals to which this requirement will be applicable range from several thousand (Manufacturing Chemists' Association) to around 1,000 (EPA). This is contrasted with registration of pesticides by EPA, for example, which numbered nearly 8,000 in 1975.

3. The Committee bill does not extensively overlap with other Federal authorities and authority within EPA.

Section 9 of the Committee bill requires the Administrator of EPA to utilize other Federal laws which he administers unless he determines that the risk may be more appropriately protected against by utilizing this authority. The right to use this authority is an alternative that would be extremely important in certain instances. For example, EPA should be allowed to regulate a dangerous chemical substance contained within a consumer product, rather than being required to control it later through an effluent standard or emissions standard, which may be a far more inefficient and expensive method of regulation.

This relationship must exist if this legislation is to address the issue of controlling industrial chemicals as a means of preventing environmental degradation as an alternative to other forms of control.

With respect to statutes not administered by EPA, the Administrator is directed to give notice to other relevant Federal agencies if the risk associated with a chemical may be prevented or reduced to a sufficient extent by action taken under the other Federal laws not administered by EPA. The other agency is required to respond to the notice of the Administrator, but in not less than 90 days. If the other agency issues an order declaring that there is no unreasonable risk of injury to health or the environment, or initiates appropriate action under its own authority, the Administrator has no authority to take restrictive action under this Act.

In order to ensure that the vital premarket notification, testing, and reporting requirements are retained, nothing contained in the provision is to effect that authority or requirements.

Finally, the Administrator of EPA is required to consult and coordinate with the Secretary of Health, Education, and Welfare, and the heads of other appropriate Federal agencies for the purpose of achieving the maximum enforcement under this Act while imposing the least burdens of duplicative requirements.

The entire provision is designed to minimize duplication and overlap in the regulation of toxic chemicals, while providing EPA with sufficient authority to alert other agencies of chemical dangers where those other agencies have sufficient regulator}' authority to eliminate

these dangers.

4. The bill minimizes burdens on small business.

The bill contains a number of provisions which provide assurance that small business will not be overburdened by its requirements. First, it should be noted that small chemical manufacturers in general do

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not synthesize large numbers of new chemicals. Synthesis of new chemicals takes place primarily within the major companies which have the financial capability to engage in this kind of research. Therefore, most small chemical companies should not be subject to the premarket notification requirements of section 5.

There are also provisions which will serve to limit the small companies' financial obligations when testing is required. A cost-sharing procedure, for example, is provided where a chemical company that wishes to produce a chemical discovered by someone else shares the cost of developing the test data. One of the explicitly stated bases for determining how these costs are to be apportioned is the market shares of the company which is required to provide reimbursement. A small company will usually have a smaller market share and therefore the reimbursement requirements will be minimized.

Also, in each case where restrictive rules are authorized, the Administrator is required to protect against "unreasonable risks." In determining what is an "unreasonable" risk a balancing of risks and benefits is required. The effect of a rule on small business, of course, is one of the things that the Administrator must weigh in balancing risks and benefits.

The legislation also allows the Administrator to exclude substances from any or all provisions of the Act, if such substance does not present an unreasonable risk. The products developed by small businesses may be excluded by the Administrator utilizing this provision if such risks are not presented.

Under the rulemaking procedures of this legislation, compensation is available to pay attorneys' fees and other costs of representing persons before EPA who could not otherwise afford it. Small business-

men could well be eligible for such help. Also an amendment accepted by the committee provides authority to require replacement or re-purchase by manufacturer or processors of banned or restricted products. This provision will prevent small retailers and wholesalers from being saddled with large inventories of otherwise unusable products.

5. There is precedent for the de novo procedures contained in the citizens' petitions provisions and such procedures are necessary.

The citizens' petitions provision in the legislation is analogous to a provision contained in the Consumer Product Safety Act. This section will assure that the Environmental Protection Agency is forced to focus on the provisions of the bill directed at protecting health and the environment from the dangers of toxic chemicals. The citizens' petitions provision is limited to petitions "the purpose of which [are] to protect against an unreasonable risk of injury to health or the environment." If a citizen can show by a preponderance of the evidence that the action requested in a citizen's petition conforms to the applicable requirements, then EPA should be required to initiate an action. It should be noted that in reviewing a denial of the citizen's petition by the Environmental Protection Agency the court can only require EPA to initiate an action. The court would not be allowed in this situation to determine the content of a rule or outcome of such a proceeding.

The court, if petitioned, shall conduct a de novo review of any denial or failure to act on a citizen's petition by the Environmental Protection Agency. In a judicial review of the Administrator's denial of a

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citizen's petition or failure to act, there would be no record upon which the review could be based, and therefore a de novo procedure is essential to provide the opportunity to develop such a record.

The responsiveness of government is a critical concern and the citizens' petition provision will help to protect against lax administration of the bill.

6. The economic burdens that may be imposed as a result of this legislation are not substantial particularly when considered in the context of the economic and other benefits.

There have been widely varying estimates from the chemical industry of the total cost to the industry of the legislation. The Dow Chemical Co., for example, has estimated that the legislation would cost the chemical industry \$2 billion per year. The Manufacturing Chemists Association estimated that these costs would range from \$340 million to \$1.3 billion per year. The Environmental Protection Agency, however, estimates that the annual total cost to the chemical industry from the enactment of this legislation will be far lower and will range from \$80 to \$140 million per year.

In order to analyze the accuracy of these studies, the committee requested the General Accounting Office to examine these estimates. The General Accounting Office report to the committee seriously questioned the high estimates of the Dow and Manufacturing Chemists' Association studies, and stated that EPA's estimates were more reliable and realistic and that the legislation, if enacted, would cost the chemical industry between \$100 to \$200 million a year.

It is important to note that in the testing and key regulatory provisions of the legislation, it is specifically required that the Administrator evaluate the risks and the benefits of his actions before taking regulatory action. Thus, costs are not to be incurred unless they are offset by benefits of at least the same magnitude. In comparing risks, costs, and benefits, however, it is important to recognize that one is weighing noncommensurates, and it is not feasible to reach a decision just on the basis of quantitative comparisons. The burdens of human suffering and premature death are extraordinary and must be given full consideration in such decisions.

Legislative Background

S. 3149 had its genesis in the 92d Congress. On February 10, 1970, the Administrator of the Environmental Protection Agency transmitted by executive message a legislative proposal which was introduced by Senators Hart and Magnuson, by request, as S. 1478, the "Toxic Substances Control Act of 1971."

Eight days of hearings were held in the 92d Congress on S. 1478 and amendment No. 338 which proposed major changes in the legislation. The Senate passed the bill on May 30, 1972, following Committee action. The House of Representatives acted late in the session but there was insufficient time to reconcile the differences between the Senate and House bills.

In the 93d Congress, S. 426 was introduced on January 18, 1973 by Senators Magnuson, Tunney, and Hart. Three days of hearings were held on S. 426 and S. 888, the Administration's bill. •

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Following Committee action, the Senate passed S. 426 on July 18, 1973. The House of Representatives passed S. 426 with amendments in lieu of H.R. 5356 on July 23, 1973. However, as in the 92d Congress, the conference was unable to resolve the differences between the House and Senate bills.

In the 94th Congress, S. 776 was introduced on February 20, 1975, by Senators Tunney, Hart, and Magnuson. Hearings were held on March 3, 5, 10, April 5, and October 24, 1975.

The Subcommittee on Consumer Protection and Finance of the Interstate and Foreign Commerce Committee of the House of Representatives reported H.R. 10318 on December 3, 1975. The Senate Committee on Commerce met in executive session on February 3, 4, and 17, 1976, to consider a substitute text offered by Senators Hartke, Tunney, and Hart which conforms quite closely to H.R. 10318. The Committee unanimously ordered the substitute text reported favorably with amendments as an original bill, S. 3149.

Section-by- Section Analysis

section 1 short title and table of contents

The short title of the proposed Act is the "Toxic Substances Control Act." A table of contents is provided.

SECTION 2 - FINDINGS, POLICY, AND INTENT

Subsection (a) puts forth congressional findings that humans and the environment are exposed to a large number of chemical substances and mixtures and that some may cause an unreasonable risk of injury to health or the environment. The findings also state that the regulation of chemical substances and mixtures in intrastate commerce is necessary to the effective regulation of interstate commerce in such substances and mixtures.

Subsection (b) sets forth the policy of the United States that ade-

quate data should be developed with respect to chemicals and mixtures and that manufacturers should have the responsibility of developing the data. The subsection further states that adequate authority should exist to appropriately regulate substances and mixtures and that authority should not impede or unduly create unnecessary economic barriers to technological innovation.

Importantly, subsection (c) states that it is the intent of Congress that the Administrator "shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator proposes to take under this Act." While this section of the bill is not an operative section, the intent of Congress as stated in this subsection should guide each action the Administrator takes under other sections of the bill.

SECTION 3 – DEFINITIONS AND EXCLUSIONS

Subsection (a) sets forth the definitions which are used in the bill.

Of particular importance is the definition of a "chemical substance." The term means any substance of a particular molecular identity including a combination of substances occurring as a result of a chemical reaction, or any element or uncombined radical.

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The term does not include any mixture, which is a combination of chemical substances which do not react chemically with each other and the combination is not the result of a chemical reaction, or combination of chemicals occurring in nature. Mixtures may be addressed under the provisions of the Act. but is excluded from the definition of chemical substance so that automatic premarket notification does not take place under section 5. As the term 'mixture' includes "articles containing chemical substances", the use of the latter term has been deleted throughout the bill.

In addition, the term does not include pesticides, tobacco, or tobacco products, nuclear material (as defined in the Atomic Energy Act), firearms and ammunition (to the extent subject to taxes imposed under section 4181 of the Internal Revenue Code), or food, drugs, cosmetics, or medical devices (as defined in the Federal Food, Drug, and Cos-

metic Act). The term food also means food as defined in the Poultry Products Inspection Act, the Federal Meat Inspection Act, and the Egg Products Inspection Act. With respect to the explicit exclusion of nuclear materials, nothing in the bill should be construed as an implicit exclusion of such materials from related Acts which contain no explicit exclusion, such as the Federal Water Pollution Control Act.

Subsection (b) authorizes the Administrator to exclude from coverage under this Act or any provision of the Act, any substance or mixture if the Administrator determines, by rule, that an unreasonable risk of injury to health or the environment is not presented. The exclusion under this subsection would not apply to the imminent hazards authority of section 7 or the mandatory reporting of unreasonable risk information under section 8(e). Rules under this subsection are to be promulgated in accordance with the rulemaking provisions of section 6(c) which are similar to the rulemaking provisions of the Magnuson-OSS Warranty Federal Trade Commission Act (89 Stat. 2183).

Exclusions under this subsection must be carefully drawn so that unreasonable risks associated with the chemical substance or mixture which may occur subsequent to the time of the exclusion are avoided as well as risks known at the time of the exclusion. The situation must be avoided where it is unpredictable uses, for example, of a chemical substance, may not be properly controlled under the provisions of this Act because of the existence of an exclusion under this subsection.

SECTION 4 - TESTING OF CHEMICAL SUBSTANCES AND MIXTURES

Subsection (a) sets forth the conditions under which the Administrator must require testing of a chemical substance or mixture.

First, if a chemical substance or mixture (a) may present an unreasonable risk of injury to health or the environment, (b) there are insufficient data or experience to reasonably determine or predict the effects, and (c) testing is necessary to develop data, then the Administrator must require testing.

Second, if a chemical substance or mixture may present a significant human or environmental exposure because of production in substantial quantities or for other reasons, and the substance or mixture may perhaps present an adverse effect on health and the environment, the Administrator must require testing if the two other criteria (b) and (c) above) are also satisfied. If there is no reliable data or experience available to the Administrator, the finding required with respect

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to presentation of an adverse effect on health or the environment shall be presumed.

With respect to mixtures, an additional finding must be made that testing of components of the mixture is not a more reasonable and efficient means of determining the effects on health and the environment.

In requiring testing, the Administrator is to consider the reasonably ascertainable costs and other burdens associated with conducting tests in light of the possible risk of injury to health or the environment and shall publish this information in the Federal Register.

Of course, any judicial review of these considerations shall take place at the time the final rule is reviewed in accordance with section 19. There will be no separate review of these considerations as a procedural matter separate and apart from the review of the final rule.

Subsection (b) sets forth the requirements with respect to the content of the testing rule under subsection (a). An illustrative list of the kinds of health and environmental effects for which testing may be required is provided.

The Administrator is required, at intervals of not less than 12 months, to review the adequacy of the rules developed under subsection (a) and to make appropriate revisions, if necessary.

Rules developed under subsection (a) shall be promulgated in accordance with the informal rulemaking procedures of section 553 of title 5, United States Code. The Administrator is required to give interested persons an opportunity for the oral presentation of data, views, or argument and to make a transcript of the oral presentation. Any such oral presentation will be informal and not subject to many of the delays associated with more formal hearings.

Subsection (c) provides an exemption from the testing requirements so that the submission of duplicative data may be avoided. If an exemption takes place, a cost sharing procedure is provided so that the person granted the exemption provides fair and equitable reimbursement to the person who develops the data. So that small businessmen do not get assessed an undue proportion of the costs, the subsection requires that among the relevant factors to be considered by the Administrator in determining fair and equitable reimbursement, that he consider the effect on competition within the chemical industry and the

share of the market for such substance or mixture of the person required to provide reimbursement. Any exemptions provided under this subsection, or under section 5(g), are expected to be made available to the public in accordance with the confidentiality provisions of section 14 without delay. The most appropriate way would be to publish notice of the exemption in the Federal Register.

The reimbursement period lasts from 2 years after the date of submission or at the expiration of the period which the Administrator determined was necessary to develop the data, whichever is later.

Provision is also made for the sharing of data cost which is in the process of being developed.

Subsection (d) requires that the Administrator publish information received in response to a testing requirement and make the data available to the public (in accordance with the Freedom of Information Act provisions of section 14) , within 15 days of receipt.

Subsection (e) establishes a Federal agency advisory committee to advise the Administrator with respect to testing priorities. Eight

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members are provided including members from the Department of Commerce, EPA, the Department of Labor, Council on Environmental Quality, the National Institute for Occupational Safety and Health, the National Institute of Environmental Health Sciences, the National Cancer Institute, and the National Science Foundation. The members of the advisory committee are those Federal officials who either have regulatory responsibilities in the area of chemical substances or mixtures, or have expertise with respect to testing needs. In accordance with this principle, it is anticipated that the member from the Department of Commerce would represent the National Oceanic and Atmospheric Administration or the National Bureau of Standards, or some other agency within the Department of Commerce which has expertise with respect to testing needs.

Within 12 months after the inclusion of a chemical on the list, the Administrator shall either initiate a rulemaking under subsection (a) or publish reasons for not initiating the proceeding. It is expected that the Administrator's statement in the Federal Register will be specific

and will explain in some detail why the conditions for testing under subsection (a) are absent.

Subsection (f) specifies required actions of the Administrator in response to test data or other information which indicates that a substance or mixture has the potential to induce: (1) cancer; (2) gene mutations; or (3) birth defects. The Administrator must take appropriate action under the regulatory provisions of section 5(e), 6(a), or 7 within 180 days after the date of receipt of such data or information or publish in the Federal Register his finding that no unreasonable risk of injury is presented and his reasons for making such a finding. He is only required to take this action when the substance or mixture has a potential to induce these health effects at levels for which human exposure exists, or will exist, with appropriate safety margins.

So that the Administrator may gear up for making these kinds of determinations following the date of enactment, he is not required to take action, or publish his reasons for failing to take action, until 2 years after the date of enactment of the Act.

SECTION 5 PREMARKET NOTIFICATION OF CHEMICAL SUBSTANCES

Subsection (a) requires that manufacturers of new chemical substances give notice to the Administrator at least 90 days prior to the first manufacture of a new chemical substance. The notification is to be accompanied by all of the pertinent information referred to in section 8(a) (2) regardless of whether he has or has not otherwise required its submission under that section. Included would be the identity of the chemical substance, uses anticipated, amounts to be produced, amounts anticipated for each category of proposed use, by-products, lists of existing data concerning environmental or health effects, and estimates of the number of persons who will be exposed to the substance in their places of employment. If unreasonable risks are not presented, the Administrator is authorized to shorten the 90-day mandatory notification requirement.

In addition, if the chemical substance is covered by a testing requirement under section 4(a), the manufacturer is also required to submit the data developed in accordance with that requirement.

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Subsection (c) requires that the information submitted be published in the Federal Register within 15 days of receipt, subject to the provisions relating to confidentiality under section 14. The 90-day premarket notification period would begin upon publication in the Federal Register.

Subsection (d) authorizes the Administrator to extend the initial 90-day period for an additional 90 days for good cause shown. While the majority of chemicals may be adequately screened during the initial 90-day period, there are instances in which an additional 90 days may be necessary to adequately screen the substances. If a completely new substance is being examined, for example, more time to adequately review the information and take appropriate action would be necessary. Thus, if the Administrator has not had sufficient opportunity to review the premarket notification information, and to make a judgment as to whether further action is necessary, he would have the authority to postpone the manufacture of the substance for up to an additional 90 days.

Subsection (e) authorizes the Administrator to issue orders during the premarket notification period.

If the Administrator finds that a section 4(a) testing requirement should be established (or should be added to or revised) he is required to issue an order prohibiting or restricting the chemical substance pending the completion of a rulemaking proceeding under section 4(a) and the submission of any data required thereunder. The order is to be immediately effective and shall contain a proposed rule (or amendment or revision thereof) under section 4(a).

If the Administrator finds during the premarket notification period that a rule is appropriate under section 6(a), he shall issue an order which appropriately prescribes requirements authorized under section 6(a). The order is to be immediately effective and must contain a proposed rule under section 6(a).

The Administrator is directed to conclude the rulemaking procedures under section 4(a) or section 6(a) as expeditiously as practicable. If the oral presentation of data, views, or arguments, is requested under section 4(a) or the opportunity to make written submissions has been requested, the Administrator must begin this procedure within 30 days after such request. The same is true with respect to a rulemaking under section 6(a). If an informal hearing under that section is requested, the Administrator must comply within 30 days. In either case, the Administrator must affirm, modify, or revoke the order issued within 10 days after the conclusion of the submissions or oral presentation under section 4 or an informal hearing under section 6.

Subsection (f) requires the Administrator to publish in the Federal Register his reasons if he decides not to issue an order under subsection (e) or to take action under the imminent hazards authority of section 7 during the premarket notification period. The Administrator's failure to issue such an order or take action under section 7 is judicially reviewable in accordance with section 19. It is anticipated that the Administrator's statement in the Federal Register will be specific and contain sufficient information explaining why there are no unreasonable risks which should have been protected against or a need for more test data.

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Subsection (r) provides exemptions to avoid the submission of duplicative data which is similar to the procedure described under section 4(c) , described above.

Subsection (h) also provides for premarket notification procedures with respect to significant new uses of existing chemical substances. If a new use of an existing substance has been specified by the Administrator in accordance with this subsection, all of the premarket notification procedures and authority during the premarket notification period apply to such new use of an existing substance.

Subsection (i) creates special exemptions which authorize the Administrator to exempt from the premarket notification provisions persons who wish to engage in test marketing or specially limited purposes for chemical substances upon a showing that no unreasonable risks of injury to human health or the environment would result. Appropriate restrictions may be imposed by the Administrator.

In addition, premarket notification for those new chemical substances formed through intermediate reactions within reaction vessels or in other instances in which there is no exposure to human beings or the environment may be avoided through exemptions issued by the Administrator.

Subsection (j) authorizes the Administrator to specify any mixture which may be subject to any provision of the premarket notification procedures.

There are mixtures such as adhesives, paints and inks, which can produce chemical substances upon end use. Chemical substances produced upon end use of such mixtures should not be considered new chemical substances automatically subject to the premarket notification provisions of this section. Manufacture is defined under section 3(a)(7) to mean to "import, produce, or manufacture for commercial purposes." These types of substances would not be covered under the premarket notification provisions because they are not manufactured for commercial purpose, per se. Similarly, minor reactions occurring incidental to the mixing process or upon storage of a mixture, such as the cross-linking of polymers, would not constitute a basis for subjecting such mixtures to the premarket notification provisions intended for new chemical substances because the resulting substances are not manufactured for commercial purpose.

Such chemical substances arising during the formulation, storage or use of such mixture should be considered as byproducts of the precursor substance or substances. The responsibility for reporting and testing such byproducts under the provisions of this legislation would then fall upon the manufacturer of the precursor substance. Of course, the Administrator may specifically subject any mixture to the premarket notification provisions.

Subsection (k) specifically exempts from the premarket notification provisions chemical substances which are manufactured or intended to be manufactured in small quantities solely for scientific experimentation or analysis or for chemical research. The Administrator is authorized to include those kinds of chemical substances when they may result in an unreasonable risk of injury to human health or the environment.

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SECTION 6 – REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND

MIXTURES

Subsection (a) requires the Administrator to issue rules to protect against chemical substances or mixtures which present or are likely to present an unreasonable risk of injury to health or the environment. A number of remedies are available to the Administrator ranging from outright prohibitions to labeling requirements. A procedure is pro-

vided whereby production, processing, and distribution quotas may be developed in those instances where a rule of the Administrator specifies a total amount that may be produced, processed, or distributed and for Federal supervision of any voluntary agreements that might be entered into by persons who are the object of these rules and for adequate protection against anticompetitive practices.

The authority of section 6(a) is broad enough to authorize the control of those chemical substances or mixtures which may not be the sole cause of an unreasonable risk. For example, if a number of products are responsible for an unreasonable risk, the Administrator would be authorized to move against all of them even though no single one of them can be shown to be the sole cause. The authority is also broad enough to reach those chemical substances which may enhance the toxic properties of other substances or mixtures through the processes known as synergism or potentiation.

Subsection (b) authorizes the Administrator to define the manner in which a substance may be manufactured or processed if he has good cause to believe that such manufacturing or processing causes the adulteration of a chemical substance. A substance is considered adulterated if it contains another molecular identity, uncombined radical element, or any combination thereof which, through the manner in which it is manufactured or processed, causes or contributes to an unreasonable risk of injury to human health or the environment. Rules of this type would be developed in accordance with section 554 of title 5, United States Code.

Subsection (c) requires the Administrator to consider the relevant factors when issuing rules under subsection (a) and to make findings with respect to them. Included are the risks presented to humans and the environment, the benefits of the substance or mixture, and the reasonably ascertainable economic consequences of the rule, including the consideration of the effect on the national economy, innovation, and public health. As is the case in other instances under the legislation where the costs to the chemical industry of a rule are to be considered, it is expected that the chemical industry will come forward with data bearing on the actual costs of compliance.

Findings required to be made shall be published in the Federal Register. As is the case with respect to section 4(a) rules, and other rules issued under the bill, findings of this type are not to be judicially reviewed as a matter separate and apart from the final rule. Thus, the findings published in the Federal Register are informational and will not become the object of a separate judicial review.

This subsection also specifies the rulemaking procedures which are to be followed in promulgating subsection (a) rules. The rulemaking

procedures are to be informal and in accordance with section 553 of title 5, United States Code. Interested persons are entitled to orally present their position and to present documentary submissions. In

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addition, if the Administrator determines that there are disputed issues of material fact, he must provide interested persons with the opportunity to make rebuttal submissions and to conduct such cross-examination as he determines to be appropriate and required for a full and true disclosure with respect to the issues. Appropriate procedures for limiting the extent of cross-examination are provided.

The Administrator is authorized to provide compensation for reasonable attorneys fees, expert witness fees, and other costs of participating in rulemaking proceedings to those persons who would not otherwise be adequately represented in such proceedings if representation of these interests are necessary for a fair determination or such persons are unable to effectively participate in the proceeding because such persons cannot afford to pay the cost of participating. Thus, the provision will help insure that the interest of consumers, public interest organizations, and others are represented by the rulemaking procedures of this section. No more than \$1 million per year may be paid under the provisions of this section.

The rulemaking procedures of this subsection are virtually identical to those contained in the Magnuson-Moss Warranty Federal Trade Commission Act.

Subsection (b) requires the Administrator to specify in a rule issued under subsection (a) the date on which it shall take effect, which date shall be as soon as feasible. The relevant provisions of the Administrative Procedures Act are preserved which authorize the Administrator to waive certain notice and procedural requirements when these requirements are impracticable, unnecessary, or contrary to the public interest.

SECTION 7 - IMMINENT HAZARDS

Subsection (a) defines an imminent hazard to be a situation involving an unreasonable risk of death, serious illness or serious personal injury, or serious environmental harm which will occur prior to the

completion of an administrative hearing or other proceedings authorized under any other section of this bill.

Subsection (b) authorizes the district courts to take action against imminently hazardous chemical substances, mixtures, or articles containing the substance or mixture or against persons who manufacture, process, distribute in commerce, use, or dispose of these substances, mixtures, or articles, or to take action against both the substance, mixture, or article and any such person.

Subsection (c) authorizes the courts to grant such relief as may be necessary. The subsection includes a number of illustrative examples.

Subsection (d) contains venue and consolidation provisions with respect to suits brought under this section.

Subsection (e) requires the Administrator, where appropriate, to initiate a rulemaking under section 6(a).

Subsection (f) authorizes the representation of the Administrator by attorneys of the Environmental Protection Agency with respect to suits brought under this section.

SECTION 8 REPORTING AND RETENTION OF INFORMATION

Subsection (a) requires the Administrator to issue rules which require each person who manufactures or processes, or proposes to manufacture or process, a chemical substance to maintain those records

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and to make such reports as the Administrator may reasonably require. In addition, the Administrator is required to promulgate rules which require manufacturers or processors of mixtures or chemical substances produced in small quantities solely for scientific experimentation or analysis, or for chemical research or analysis, to maintain records and to submit to the Administrator reports only to the extent that it is necessary for the effective enforcement of the legislation.

This subsection also contains an illustrative list of the kind of information which the Administrator may require of manufacturers or

processors of chemical substances. Included are the identity of substances, categories or proposed categories of use, estimates of the amount to be produced, and estimates of the amount which will be produced for each of its categories or proposals of use, a description of by-products, all existing data concerning the environmental and health effects of the substance or mixture, and estimates of the number of workers who will be exposed to the chemical substance.

To determine which substances are new chemical substances for the purpose of the premarket notification provisions of section 5, subsection (b) requires the Administrator to publish an inventory of existing chemical substances not later than 270 days after the date of enactment of the Act. Substances not appearing on that inventory will be considered new chemical substances for the purposes of section 5. Of course, any information the Administrator receives under subsection (a) with respect to chemicals proposed to be manufactured shall not be included in the inventory until premarket notification occurs.

Subsection (c) requires persons who manufacture, process, or distribute in commerce chemical substances, or those intending to engage in these activities, to maintain records of adverse reactions to health or the environment alleged to have been caused by the substance or mixture. These kinds of records shall be maintained for 5 years from the date the information was reported to the person, except that reports dealing with occupational reactions shall be retained for 30 years.

Subsection (d) requires persons who manufacture, process, or distribute in commerce chemical substances or mixtures to maintain lists of health and safety studies conducted by them or for them with the Administrator. The Administrator is authorized to require the submission of any study appearing on the list. The Administrator is authorized to exclude certain types of categories of studies if they are unnecessary to carry out the purposes of the Act.

Subsection (e) requires persons who manufacture, process, or distribute chemical substances or mixtures in commerce, and liability insurers thereof, to inform the Administrator when they receive information which supports the conclusion that unreasonable risks or injuries to health or the environment are caused or contributed to by a substance or mixture.

The Committee is concerned that any allocation of risks or other information presented to the Administrator by employees of the chemical industry receive proper attention by EPA. The situation that existed with respect to the Kepone plant at Hopewell, Va., whereby an employee complaint to the Department of Labor allegedly was

insufficiently attended to, should not occur. EPA should respond prop-

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erly to complaints received in the context of this authority, and the Comptroller General may be asked by the committee to oversee EPA's procedures with respect to employee complaints.

SECTION 9 - RELATIONSHIP TO OTHER LAWS

This section is intended to minimize overlap and duplication between this act and other Federal laws while assuring protection from environmental and health dangers.

Subsection (a) deals with the action the Administrator is to take when he determines that a law administered by another agency could be used to prevent or sufficiently reduce an unreasonable risk to health or the environment presented by a chemical substance or mixture. In such a case the Administrator is to request that agency to (1) issue an order declaring whether or not such a risk is presented, and (2) if an order is issued declaring that an unreasonable risk is presented, to determine if the risk may be prevented or sufficiently reduced under the law administered by that agency. The agency is to respond to a request from the Administrator within 90 days and publish its findings and conclusions in the Federal Register.

The Administrator may not take action under sections 6 or 7 of this act if the agency to which the request was addressed either issues an order declaring there is no unreasonable risk or initiates action under the law which it administers within 90 days of the publication of its report.

Subsection (b) directs the Administrator to use the authorities under other laws he administers to prevent or reduce risks to health or the environment presented by chemical substances or mixtures unless he determines that such risks may more appropriately be protected against under this act.

Subsection (c) specifies that the exercise of authority by the Administrator under this act shall not constitute any limitation upon the authority of the Occupational Safety and Health Administration to prescribe or enforce standards or regulations affecting occupational

safety and health.

Subsection (d) directs the Administrator to consult and coordinate his activities under this act with the Secretary of Health, Education, and Welfare and the heads of other appropriate Federal agencies in order to achieve maximum enforcement of this act while imposing the least burden of duplicative requirements on those subject to the act. The Administrator is to report annually to the Congress on these efforts.

Subsection (e) specifies that nothing in this section shall limit any requirement of section 4, 5 (other than sec. 5(e)), or 8, or rules promulgated thereunder.

SECTION 10 RESEARCH, COLLECTION, DISSEMINATION, AND UTILIZATION

OF DATA

Subsection (a) directs the Administrator to conduct research and monitoring as is necessary to carry out the purposes of the act in consultation and cooperation with the Secretary of Health, Education, and Welfare and with other heads of appropriate Federal agencies.

Subsection (b) directs the Administrator to establish and administer

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an interagency committee to (1) construct within the Environmental Protection Agency an efficient system for the collection, dissemination to other Federal agencies, and use of data submitted to the Administrator under this act, and (2) coordinate the regulation of chemical substances among Federal agencies. In consultation with the Secretary of Health, Education, and Welfare and the heads of appropriate agencies, the Administrator is to design, establish and coordinate a system for the retrieval of toxicological and other scientific data useful to the Administrator in carrying out this Act.

Subsection (c) authorizes the Administrator, in consultation with the Secretary of Health, Education, and Welfare, to make grants and enter into contracts to carry out his responsibilities under this section.

SECTION 11 - INSPECTIONS AND SUBPOENAS

Subsection (a) authorizes the Administrator or his designee to inspect any establishment or facility in which chemical substances or mixtures are manufactured, processed, or stored, or any conveyance used to transport chemical substances or mixtures for their distribution in commerce. Such inspections shall require the presentation of appropriate credentials and a written notice to the owner or agent in charge of the premises or conveyance to be inspected, and shall be conducted in a reasonable manner. An inspection shall extend to all things within the premises or conveyance inspected (including records, files, papers, processes, controls, and facilities) bearing on whether the requirements of this act that are applicable to the chemical substances or mixtures within such premises or conveyance have been complied with.

Subsection (b) authorizes the Administrator to require, by subpoena, the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, or other information the Administrator deems advisable. In the event of controversy, failure, or refusal of any person to obey such order, any district court of the United States in which venue is proper shall have jurisdiction to order any such person to comply therewith. Failure to obey an order of the court is punishable by the court as a contempt.

SECTION 12 - EXPORTS

Subsection (a) exempts from the provisions of this Act (other than sec. 8) any chemical substance, mixture or article containing a chemical substance, mixture or article that (1) is manufactured, processed, sold, or held for sale solely for export from the United States, and (2) is labeled so as to show that it is intended for export. This exemption shall not apply to any substance, mixture or article that the Administrator finds would cause or contribute to an unreasonable risk to the health of persons within the United States or to the environment of the United States. This would provide control of substances exported to Canada, for example, which may impact the Great Lakes or substances to be disposed of by ocean dumping.

Subsection (b) requires that any person who exports or intends to export a chemical substance or mixture shall notify the Administrator of such exportation or intent to export if the chemical substance or mixture is one (1) for which data is required under section 4 or 5,

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(2) for which a rule has been proposed or promulgated under section 5 or 6, or (3) with respect to which an action is pending or relief has been granted under section 7. The Administrator shall furnish the appropriate information pertaining to the application of this act to the government of the foreign country for which the export is intended.

SECTION 13 - ENTRY INTO CUSTOMS TERRITORY OF THE UNITED STATES

Subsection (a) requires the Secretary of the Treasury to refuse entry into the customs territory of the United States of any chemical substance, mixture, or article containing a chemical substance or mixture offered for entry if (1) it fails to conform with any requirement of this act or any rule in effect thereunder, or (2) it is otherwise prohibited pursuant to this act from being distributed in commerce. The subsection details the procedures the Secretary of the Treasury is to follow in the event of an entry refusal.

Subsection (b) directs the Secretary of the Treasury, after consultation with the Administrator, to issue rules for the enforcement of subsection (a) of this section.

SECTION 14 - DISCLOSURE OF DATA

This section specifies that information obtained by the Administrator under this Act shall be subject to the Freedom of Information Act which establishes the availability of information received by Federal officials to the public. However, this section specifies that all information received shall be disclosed (1) upon request, to officers or employees of the United States in connection with their official duties under laws protecting human health or the environment or for specific law enforcement purposes; (2) to contractors of the United States when necessary in the performance of a contract; (3) whenever the Administrator determines it necessary to protect human health or the environment; or (4) to any duly authorized committee of the Congress upon written request. While information is not required to be disclosed in proceedings under this Act in order to prevent parties from joining such a proceeding just to get access to data, the Administrator is expected to release information, as he may do under the Freedom of Information Act, in proceedings when it will be used for legitimate purposes in the proceeding.

SECTION 15 - PROHIBITED ACTS

This section sets forth those acts that shall be unlawful under this

act. Such unlawful acts are (1) failure or refusal to comply with any rule or order promulgated under section 4, 5, or 6 or any requirement prescribed by section 5, (2) the use or disposal of a chemical substance or mixture by such person who knew or had reason to know it was manufactured, processed, or distributed in commerce in violation of section 5 or a rule or order under section 6, (3) failure or refusal to maintain records, submit reports, notices, or other information, or permit access to or copying of records as required by this act or a rule thereunder, or (4) failure or refusal to permit entry or inspection as required by section 11.

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SECTION 16 – PENALTIES

Subsection (a) provides civil penalties of up to \$25,000 per day for any person who violates this Act. Such civil penalty shall be assessed by the Administrator after the opportunity for an adjudicative hearing. In determining the amount of a civil penalty, the Administrator shall take into account the nature, circumstances, extent, and gravity of the violation as well as the violator's ability to pay, his ability to continue to do business, his history of prior violations, and his degree of culpability. The Administrator may compromise, modify, or remit any civil penalty imposed under this subsection.

Any person who requests an adjudicative hearing for the assessment of a civil penalty and is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the U.S. Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business.

If any person fails to pay an assessment of a civil penalty after it has become a final and unappealable order, the Attorney General is directed to recover the amount assessed, plus interest, in any appropriate district court.

Subsection (b) provides criminal penalties of up to \$25,000 per day, in addition to or in lieu of a civil penalty, for any person who knowingly (having actual knowledge) or willfully violates this Act.

SECTION 17 SPECIFIC ENFORCEMENT AND SEIZURE

Subsection (a) grants the U.S. district courts jurisdiction over civil actions sought by the Administrator or Attorney General, to restrain violations of this Act, to compel actions required by this Act, or to require manufacturers or processors of chemical substances or mixtures not in compliance with orders or rules issued under certain provisions of this Act to give notice of such fact and to either repurchase or replace such substances or mixtures. Such a civil action may be brought in the appropriate district court.

In the Committee's deliberations on the legislation, it was determined that the language of amendment No. 21 (sponsored by Senators Philip A. Hart, Xelson, and Percy) defining the burden a plaintiff must sustain in order to gain relief under laws administered by EPA, or relief sought by the Administrators, should not be incorporated in this committee bill. The amendment attempted to rectify a three-judge panel decision of the 8th circuit concerning relief sought against the Reserve Mining Co. As decisions reached by the courts in subsequent appeals are consistent with the requirements of amendment No. 21, the amendment is unnecessary.

Subsection (b) makes any chemical substance or mixture manufactured, processed, or distributed in commerce in violation of this Act or any article containing such substance or mixture liable to seizure and condemnation within the jurisdiction of any district court in which such substance, mixture, or article is found.

SECTION 18 - PREEMPTION

Subsection (a) asserts that, except for certain specified limitations, nothing in this Act shall affect any State's authority to regulate chem-

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ical substances, mixtures, or any article containing such substances or mixtures. The limitations are (1) if the Administrator has required by rule the testing of a chemical substance or mixture under section 4, no State or political subdivision may subsequently require testing for purposes similar to those required under the rule, and (2) if the Administrator prescribes a requirement under section 5 or 6 of this act to protect against an unreasonable risk presented by a chemical substance, mixture, or article containing a chemical substance or mixture, no State or political subdivision may subsequently regulate such sub-

stance, mixture, or article unless the regulation is identical to that prescribed by the Administrator or unless the State or political subdivision bans the use or distribution of such substance, mixture, or article within the territorial jurisdiction of the State or political subdivision.

Subsection (b) specifies conditions under which the Administrator may by rule exempt a State or subdivision from the limitations imposed in subsection (a). A State or subdivision may be exempted if their requirements would not cause a violation of this act, a significantly higher degree of protection is afforded, and undue burdens on interstate commerce would not result.

SECTION 19 - JUDICIAL REVIEW

Subsection (a) specifies that not later than 60 days after the promulgation of any rule under this Act or an order under section 5(e), any person may file a petition for judicial review of such rule. The Administrator shall transmit to the Attorney General, who shall file in the court, the record of the proceedings on which the Administrator based such rule or order as provided in section 2112 of title 28, United States Code. The term "record" means such rule or order, any transcript required of any oral presentation, any written submission of interested parties, and any other information the Administrator considers relevant and with respect to which the Administrator, on or before the date of promulgation of such rule or order, published a notice in the Federal Register identifying such information. Of course, the record need not contain written documentation of each and every widely accepted scientific principle or fact which may support the rule or order issued. In these cases, it should be presumed that agency expertise is definitive so that an extensive record need not be developed or judicial review result with respect to widely accepted scientific principle.

Subsection (b) authorizes petitioners to apply to the courts for leave to adduce additional data, views, or arguments. If the petitioner satisfies the court that such additional information would be material and that there are reasonable grounds for the petitioner's failure to adduce such information in the proceeding before the Administrator, the court may order the Administrator to provide additional opportunity for oral presentation and written submissions. Upon the basis of the additional information, the Administrator may modify the findings or determinations upon which the rule or order reviewed by the court was based. Modified or new findings together with the Administrator's recommendation, if any, for modifying or setting aside such rule or order shall be filed with the court.

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Subsection (c) grants the courts jurisdiction, upon the filing of a petition under subsection (a), (1) to review the rule or order involved in accordance with chapter 7 of title 5, United States Code, and (2) to grant appropriate relief, including interim relief, as provided in such chapter. This subsection explicitly states that any rule promulgated by the Administrator under section 5 or 6 and reviewed under this section shall be affirmed unless the rule is not supported by the substantial evidence on the record taken as a whole. Review of all other actions taken (or inaction) shall be on an "arbitrary or capricious" basis in accordance with chapter 7 of title 5, United States Code.

Any considerations or findings required of the Administrator in the process of developing a rule or order under this Act shall not be reviewable apart from the review of the final rule or order.

Subsection (d) specifies that remedies provided in this section shall be in addition to and not in lieu of any other remedies provided by law.

SECTION 2 citizen's CIVIL ACTION

The provisions of this section are intended to provide a remedy if the Administrator is lax in carrying out his duties under this Act. Subsection (a) authorizes any person to commence a civil action against persons alleged to be in violation of this act or any rule prescribed under section 4 (testing), section 5 (premarket notification), or section 6 (restrictive rules) to restrain such violation. In addition, actions are authorized against the Administrator to compel him to perform any duty which is not discretionary under this Act. Actions shall be brought in the appropriate district court.

Subsection (b) specifies certain limitations on the announcement of a civil action. No action may be commenced before the expiration of a specified time period after proper notice has been given of an alleged violation or failure of the Administrator to perform a duty under this act. Also, no action may be commenced if the Administrator, or Attorney General on his behalf, has commenced and is diligently prosecuting a civil action to require compliance with this Act.

Subsection (c) authorizes the Administrator to intervene in any civil action under this section to which the Administrator is not a

party. The court is authorized to award costs of suit and reasonable fees for attorneys and expert witnesses, if appropriate.

Nothing in this section shall restrict the right of any person under any statute or common law to seek enforcement of this Act, or any rule under this Act, or to seek any other relief.

Subsection (d) authorizes a court, upon application of the defendant, to consolidate two or more civil actions brought under subsection (a) involving the same defendant and the same issues or violations when such actions are pending in two or more judicial districts.

SECTION 21 CrnZEN'S PETITIONS

This provision provides a means to initiate procedures for issuance of a rule or order under this act to protect against unreasonable risk of injury to health or the environment. Included, for example, would be a testing requirement under section 4(a), a restrictive rule under

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section 6(a) . or a modification of a section 3(b) rule which would have the effect of further protecting against unreasonable risks by reducing the extent to which a chemical substance or mixture is excluded from coverage under the Act. Subsection (a) authorizes any person to petition the Administrator to issue such a rule or order.

Subsection (b) requires the Administrator to either grant or deny a petition within 90 days after filing. If a petition is granted, the Administrator shall promptly commence an appropriate proceeding to comply with such petition. If a petition is denied, the Administrator shall publish in the Federal Register the reasons for such denial.

If the Administrator denies a petition (or fails to act within the 90-day period), the petitioner may commence a civil action within 60 days, in a U.S. district court to compel the Administrator to initiate the action requested. Because of the absence of an adequate record for the court to review in such a case, the opportunity is granted to the petitioner for a judicial review based on a preponderance of the evidence in a de novo proceeding. If the petitioner can satisfy the court by a preponderance of the evidence in such a proceeding that the action requested in the petition conforms to the applicable requirements

of this act, the court shall order the Administrator to initiate the action requested by the petitioner.

SECnOX 2 2 NATIOXAL DEFENSE WAFV ER

The Administrator is directed to waive compliance with any provision of this Act upon request of the Secretary of Defense and upon a determination by the President that the requested waiver is necessary in the interest of national defense.

SECTION 2 3 EMPLOYEE PROTECTION

Subsection (a) prohibits an employer from discharging or otherwise discriminating against any employee because the employee, or any person acting pursuant to a request of the employee, participates or intends to participate in any way in any proceeding or action for the purposes of carrying out the intent of this Act.

Any employee who believes that he or she has been discharged or otherwise discriminated against is authorized by subsection (b) to file a complaint with the Secretary of Labor within 30 days of the alleged violation. The Secretary is to investigate such an alleged violation and shall, within 90 days, issue an order either providing relief or denying the complaint, unless the Secretary and the person alleged to have committed such violation agree to a settlement. The forms of relief which the Secretary can provide are prescribed in this subsection.

Subsection (c) authorizes judicial review of an order issued under subsection (b) upon petition by any person adversely affected or aggrieved by such order,

Whenever a person has failed to comply with an order issued under subsection (b), subsection (d) directs the Secretary of Labor to file a civil action in the appropriate district court to enforce such action. In such civil actions the district courts shall have jurisdiction to grant all appropriate relief, including injunctive relief and compensatory and exemplary damages.

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Subsection (e) excludes from the protection of subsection (a) any employee who, acting without direction from the employee's employer or any agent of the employer, deliberately causes a violation of any requirement of this Act.

Subsection (f) directs the Administrator to conduct continuing evaluations of the potential loss or shifts of employment which may result from the issuance of any rule or order under this act. Any employee who is discharged or threatened with discharge or otherwise discriminated against by any person because of the results of any rule or order issued under this act may request the Administrator to conduct a full investigation of the matter. The Administrator shall thereupon investigate the matter, and, at the request of any interested party, shall hold a public hearing. Upon receiving the report of any such investigation, the Administrator shall make findings of fact as to the effect of such rule or order on employment and shall make recommendations as he deems appropriate, which report, findings, and recommendations shall be available to the public. Nothing in this subsection shall be construed to require the Administrator to modify or withdraw any rule or order issued under this Act.

SECTION 24 - STUDIES

Subsection (a) directs the General Accounting Office to conduct a study of all Federal laws for the purpose of determining whether and under what conditions, if any, indemnification should be accorded any person as a result of action taken by the Administrator under any such law. The study shall include the probable cost and means of financing any recommended indemnification and be submitted to the Congress not less than 2 years from the date of enactment of this Act.

Subsection (b) directs the Council on Environmental Quality, in consultation with the Administrator, the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate Federal agencies to coordinate a study of the feasibility of establishing (1) a standard classification for chemical substances, and (2) a standard means for storing and retrieving information respecting such substances.

SECTION 25 ADMINISTRATION OF ACT

Federal agencies are authorized in subsection (a) to cooperate with the Administrator by making their services, personnel, and facilities available to assist in the administration of this act and by making available to the Administrator information necessary for the administration of this Act.

Subsection (b) authorizes the Administrator to require, by rule, the payment of a reasonable fee, not to exceed \$2,500, from any person required to submit data under section 4 or 5 to defray the cost of administering the Act.

Subsection (c) authorizes the Administrator to take action with respect to categories of chemical substances or mixtures as well as individual chemical substances or mixtures. For purposes of defining a category, chemical substances or mixtures may be grouped by virtue of similarities in their chemical structure, physical, chemical or biological properties, use, mode of entry into the human body or environ-

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ment, or in some other way suitable for purposes of this Act. This authority is given to the Administrator to facilitate the efficient and effective administration of this act and is not to be used in any way that would frustrate the intent of any provision of this Act. Thus, for example, categories might be appropriately used for purposes of compiling the inventory of section 8(b) so that every variation in the distribution of a polymer chain length would not be automatically subject to the premarket notification requirement. However, categories are not to be used in the section 8(b) inventory so as to effectively provide exemptions for new chemical substances intended to be covered under the premarket notification provision.

Subsection (d) specifies that any proposed or final rule or order issued under this Act shall be accompanied by a statement of purpose and justification. This statement shall identify the sources and precise nature of the most important information used in deciding upon the rule or order and shall indicate the weight or importance the Administrator gave to the various elements of information in arriving at his decision. Such a statement shall be considered part of the "record of the proceedings" for purposes of judicial review under section 19(a).

Subsection (e) directs the President, by and with the advice and consent of the Senate, to appoint as Assistant Administrator of the Environmental Protection Agency an individual who by reason of background and experience is especially qualified to direct a program concerning the effects of chemicals on human health and the environ-

ment. Such Assistant Administrator shall be responsible for the efficient collection and analysis of data necessary for making well-informed regulatory decisions and the development of a spectrum of regulatory options available to the Administrator.

SECTION 2 6 – AUTHORIZATION FOR APPROPRIATIONS

Subsection (a) authorizes to be appropriated to the Administrator for carrying out this act \$11 million for the fiscal year ending June 30, 1976; \$2,600,000 for the transition quarter, July 1 to September 30, 1976 ; and \$10 million for the fiscal year ending September 30, 1977. No part of these funds are to be used for the construction of research laboratories.

Subsection (b) requires that whenever any budget request, supplemental budget request, supplemental budget estimate, legislative recommendation, prepared testimony for congressional hearings or comments on legislation relating to this act is sent to the President or to the Office of Management and Budget, the Administrator shall concurrently transmit a copy to the Congress. This subsection further prohibits any officer or agency of the United States from requiring the Administrator to submit this information to him prior to its submission to Congress. The provision is virtually identical to that contained in the Consumer Product Safety Act.

SECTION 2 7 – ANNUAL REPORT

The Administrator is required to submit to the President and the Congress a comprehensive annual report on the administration of this Act. A list of items to be included in the report is presented.

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Changes in Existing Law

No changes in existing law are made by the bill as reported by the Committee.

Estimated Costs

Pursuant to the requirements of section 252 of the Legislative Re-organization Act of 1970, the Committee estimates the cost of the bill for each of the first 5 fiscal years as follows :

Fiscal years : Amount

1976 \$11,100,000

Transition quarter 2, 600, 000

1977 10,100,000

1978 11,000,000

1979 12,000,000

1980 13,000,000

The Committee knows of no cost estimates made by any Federal agency which differs from those tabulated above. The estimates were derived from information submitted by EPA.

Record Votes in Committee

1. On the motion by Senator Hartke to require that "reasonably ascertainable economic consequences" of section 6(a) rates be considered, that findings be made with respect to all relevant factors considered, and that such findings be published in the Federal Register.

TEAS (17)

Magnuson Tunney
Pastore Stevenson
Hartke Ford
Hart Pearson
Cannon Baker
Long Beall
Moss Weicker
Hollings Buckley
Inouye

NATS (1)

i Durkin

.2. On the motion of Senator Hartke to report the bill favorably:

jNIagnuson

Pastore

Hartke ■

Hart.

Cannon

Long

]ross

Hollings

Tnouye

Tunney

TEAS (20)

Stevenson

Ford

Durkin

Pearson

Griffin

Baker

Stevens

Beall

Weicker

Buckley

NAYS (0)

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Text of S. 3149, As Reported

Agency Comments

Ex\TROYMENTAL PROTECTION Agency,

Office of the Administrator,
Washington, D.C., June 23, 1975.

Hon. "Warren G. Magnuson,
Chairman^ Committee o^i Commerce,
U.S. Senate,
Washington, D.C.

Dear Mr. Chairman : This is in response to your request of March 6,
1975, for the views of the Environmental Protection Agency on S. 776,
the Toxic Substances Control Act.

We are in accord with the objectives of S. 776 and the general
approach taken in the bill to control toxic substances. As we testified
before your Subcommittee on the Environment on March 10, 1975, the
bill contains the authorities which we believe are essential for effective
toxic substances control legislation. We urged the enactment of toxic
substances control legislation and indic^ated that we would have sug-
gestions on some of the specific provisions of S. 776 when we submitted
our report.

We note that S. 776 contains significant improvements over some of
the toxic substances control bills that have been before the committee
the past 4 years. Many of thcvse improvements are consistent with past
EPA recommendations. It is not our intention in our report by con-
centrating on suggested revisions to the bill to detract from or fail
to recognize the effort and improvements already eWdent in S. 776.

We liave already stated in our testimony our objection to the pro-
vision that would preclude tlie Administrator from forwarding any
budget estimates, legislative proposals, comments on legislation, or
testimony to the Office of ^lanagement and Budget prior to the trans-
mission of these same materials to the Congress. We also stated in our

testimony that to designate by statute the specific responsibility of an Assistant Administrator may tend to create a problem of internal management.

We will discuss below a number of additional areas in S. 776 where we have particular problems and where we believe amendments are in order. These proposed amendments are set out in an attachment to

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this letter along with a number of important additional amendments and brief explanations of each. We urge that all of these amendments be favorably considered by the committee.

This report on S. 776, including the attached proposed amendments were jointly developed with the other concerned Federal departments and agencies and represents the views of the administration on S. 776.

Policy of Administration

We are proposing that the Declaration of Policy section of the bill include recognition of the role of this legislation in complementing and supplementing a number of present Federal programs that deal with various aspects of toxic substance control. We are also proposing that the general requirement of the bill for consultation and coordination make specific reference to this policy statement. Such amendments would be of great assistance in the day to day administration of this legislation, both by assuring due regard for the responsibilities of other agencies, and by helping to establish the atmosphere of cooperation and interchange which is vital to the successful operation of comprehensive toxic substances legislation.

In line with this policy, and because of the special role of the Occupational Safety and Health Act of 1970 in providing workers with protection from unsafe or unhealthful working conditions which may be created through the manufacture, distribution or use of toxic substances, we are also proposing some language for the bill and some language for the committee report to assure that there will be no question about the respective regulatory jurisdictions of EPA and the Department of Labor.

Definitions

We are proposing that the definition of "chemical substance" be amended to provide the Administrator with some flexibility to exclude, in appropriate situations, certain substances from the definitions and thus from the requirements of the act or from particular provisions of the act. It would be almost impossible to draft the bills to exempt certain substances from the act or, as more likely the case, from certain provisions of the act in each situation where such is necessary. Scientific laboratory reagents are an example. Here it may very well be appropriate to exclude such products from the testing and regulatory provisions, but not necessarily the reporting and adverse effects provisions when they are used by certain research or scientific laboratories: on the other hand, we would not likely wish to exclude high school laboratories from any labeling requirements. An exclusion may also be in order for a substance not manufactured in commercial quantities. An excessive burden and inconvenience to the industry or the user would be averted with this flexibility in the act.

We anticipate that the Administrator would exercise his discretion to exclude from the definition of chemical substances most substances manufactured in less than commercial quantities for the purpose of testing. Thus, most substances manufactured in less than commercial quantities would be exempt from the testing provisions of the bill. The proposed amendment would however enable EPA to require testing in those cases where the potential threat to health and the environment showed such testing to be necessary.

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We are also proposing to add to the act a definition for a "new chemical substance." This is necessary in order that chemical substances which were used in previous years for some purpose, and such use discontinued, do not become classified as existing chemicals, and thus exempt from certain requirements relating to new substances.

Testing

The testing provisions provide that standards for test protocols would be promulgated, rather than the test protocol itself. Testing would be required only for substances which the Administrator determines may present an unreasonable risk to health or the environment, where there are insufficient data to conclude that such a risk

does or does not exist, and where testing would assist in making such a determination.

There is a provision in the testing requirement of the bill that we foresee as an undue burden upon the Administrator. While we agree that provision should be made for the sharing of testing costs in the event that there is more than one manufacturer of a substance for which testing is required, we are very reluctant to become involved in designating which manufacturer – or possibly a third party – should conduct the tests if the parties cannot reach an agreement. We are therefore recommending deletion of the provisions authorizing the Administrator to designate which party should do the testing.

A further amendment we are proposing with regard to the testing provisions is a specific requirement that the Administrator must consider alternative methods for meeting the standards for test protocols proposed by a manufacturer, such as one that might be less costly or more effective. This would insure that industry is allowed to use the best test protocols in meeting the testing standards.

Premarket screening

We are proposing an amendment which will delete the authority in the bill to treat a rule proposed under section 6 during the premarket review period of a product as a final rule. Thus a chemical substance of product may be manufactured and distributed after the premarket review period unless a restriction is obtained under the imminent hazard provision of the act. The substance or product, however, remains subject to all other provisions of the act and a rule proposing restrictions on the substance or product may be proposed immediately during the premarket review period under section 6 and the rule-making proceedings initiated at that time.

If it appears that the manufacture, processing, or distribution of a chemical substance or product will result in any unreasonable threat to human health or the environment prior to the completion of the rule-making proceedings, action may be taken to restrict or ban it under the imminent hazard provisions of the bill, thus preventing it from becoming a threat to health or the environment.

Quotas

Another difficulty we have with S. 776 concerns the requirement that the Administrator provide for the assignment of quotas in any regulation limiting the amount of a substance which may be manufactured, imported, or distributed. The mandatory requirement of a quota system would make the regulatory process vastly more cumbersome and difficult to administer. Thus, we recommend that the quota provi-

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sion be deleted. The act already provides that when it is necessary to adopt a rule with respect to a chemical substance to protect against an unreasonable risk, the Administrator shall select the least stringent requirement practicable, consistent with protection of health and the environment. In our view, restrictions limiting the amount of a substance that may be manufactured would be the most stringent requirement, other than a total ban, and the establishment of quotas would seldom be necessary. Nevertheless, we strongly recommend against becoming involved in the establishment of quotas for various manufacturers, even in such limited situations.

Economic impact

S. 776 would require that the Administrator consider a number of relevant factors in promulgating iilcs with respect to a chemical substance. We are proposing that a specific provision be added that he also must consider the economic impact of such action, including, but not limited to, consideration of the effects on business, employment, and the national economy. Consideration of these factors are already inherent in the requirement that he consider all relevant factors. This amendment is submitted in lieu of other proposals that have already been made for the mandatory preparation of detailed economic impact statements at the time a regulation is promulgated.

Health and safety studies

We are proposing a revision of the requirement for the submission of health and safety studies, or lists of such studies, in order to provide some flexibility in this requirement. This should lessen the burden to industry in compiling the lists or submitting the studies, and to EPA in not being overburdened with information it does not need or cannot effectively use. The amendment would require submission of lists of ongoing and new studies, rather than the study, with a right to require the submission of a given study. It would authorize the Administrator to provide by regulation the types of studies

to be included on the lists and the number of years for which prior studies must be listed. The amendment would also provide that a person would list studies which he knows are being made or have been made.

Confidential information

We are recommending that the confidentiality provision, section 15 of S. 776, be amended in several respects. First, the substantive criterion for withholding data as confidential should be the test established by the Freedom of Information Act, 5 U.S.C. 552(b) (4). Our proposed amendment would have the effect of requiring nondisclosure of information obtained under the Toxic Substances Control Act which may be withheld under 5 U.S.C. 552(b)(4)., that is, "trade secrets and commercial or financial information obtained from a person and privileged or confidential." This will make the confidentiality standard more definite (because there exists a body of case law interpreting 5 U.S.C. 552(b) (4)), and will promote uniformity.

In addition to the exemption for disclosure to Federal officers and employees, a separate provision should allow disclosure to EPA contractors and their employees, under appropriate safeguards and after appropriate EPA findings that disclosure is necessary. EPA accom-

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plishes a great deal of its investigatory and analytical tasks by contract. If contractors are not allowed access to information under this bill, EPA could not perform its duties satisfactorily without substantial manpower increases. The recently enacted Privacy Act, 5 U.S.C. 552a, provides that, for purposes of the section of the Privacy Act which imposes penalties on Government employees for wrongful use or disclosure of information entitled to confidentiality, Government contractors and their employees are to be considered Government employees (5 U.S.C. 552a (m)). We recommend inclusion of such a provision in the toxic substances bill. Our proposed amendments allow disclosure to contractors, and include a penalty for wrongful disclosure of information by Government employees (including contractors and their employees) .

We also believe that the provisions relating to qualified scientists and individual names are not necessary. The term "qualified scien-

tists" would be difficult to interpret, and in any event a scientist would have no greater rights under the subsection than would any person under our (proposed) basic confidentiality criterion. We believe that the Federal Privacy Act and the Freedom of Information Act provide ample protection of the rights of individuals whose names appear in health and safety records.

Finally, with regard to access of information by Congress, we believe that such confidential information should be made available upon written request.

Exemption from Federal preemption

We do not recommend the provisions of S. 776 which would allow State and local agencies to petition the Administrator for exemption from the Federal preemption requirements. State and local agencies would be allowed to regulate any toxic substance until such time as the Administrator puts into effect regulations for testing or restricting a substance. Thereafter, they could impose only a total ban on a substance. In view of the fact that the bill authorizes the Administrator to regulate with respect to geographic areas there would appear to be no need for a State or local agency to duplicate any regulations with respect to a substance after Federal regulations are in effect.

Interagency cooperation and coordination

Several amendments are being proposed to the act to provide for the maximum cooperation and coordination among the several agencies of the Federal Government which have programs and responsibilities concerned with toxic substances. These amendments also would clarify that the act is intended to complement and supplement existing laws and regulations such as the occupational health and safety requirements.

A number of Federal agencies, particularly the Department of Health, Education, and Welfare and the Occupational Health and Safety Administration of the Department of Labor have extensive responsibilities relating to toxic substances and human health and would stand to benefit from various provisions of the act. For example, test results and other data generated in this area would, of course, be valuable to them and should be made available to all agencies concerned.

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We are also recommending that the provision contained in previous bills before the Congress directing the Council on Environmental Quality to coordinate a study on the feasibility of establishing a standard classification system for chemical compounds and means of obtaining rapid access to information on such substances be restored to the act. This section provides CEQ the lead in establishing information systems in a manner currently being initiated. This is being done in conjunction with the agencies that would have been represented on the interagency committee as set out in the provision proposed to be deleted.

Appropriations

We wish to make clear that our budget requests over the past several years have included funds to handle work anticipated to be required under toxic substances legislation, in the expectation that it would by now have been a reality. Consequently, considerable groundwork has been laid and we anticipate that activities during fiscal year 1976 can be met within the \$8 million requested in the President's budget. Furthermore, we would point out that EPA wishes to remain in accord with the President's stated policy of holding new spending to an absolute minimum. Consequently we would point out that the authorization levels in S. 776 are in excess of amounts required to implement its provisions.

We have outlined above in our letter a number of the proposed amendments to the act which we consider important : the attachment contains both these and additional amendments which we believe are of equal importance. We strongly believe that the adoption of these amendments would improve and strengthen the legislation and enable EPA to protect the health and the environment to the greatest practical extent while at the same time relieving the industry as well as the Government of some burdensome requirements.

With the favorable consideration of these proposed amendments, we would urge the enactment of S. 776.

My staff and I stand ready to assist your committee in any way possible.

We are advised by the Office of Management and Budget that there is no objection to the submission of this report from the standpoint of the program of the President.

Sincerely yours,

John R. Quarles, Jr.,

Acting Administrator.

Toxic Substances Control Act

PROPOSED AMENDMENTS BY EPA AND OTHER FEDERAL AGENCIES TO S. 77«

1. Definitions

a. Page 4, lines 1 and 2, delete the language "or in some other way suitable for formation of a group for the purposes of this Act".

Explanation. - This amendment would delete the open-ended authority to designate almost any grouping as a "category of chemical substances".

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b. Page 4, line 5, delete paragraph (3) and insert new paragraph

(3) "Chemical substance" means any chemical substance which (A) has an organic or inorganic particular molecular identity; (B) is any combined or uncombined radical or element; or (C) is any mixture; Provided[^] however, the Administrator may by regulation exclude from this definition as it applies to this Act, or to any provision of this Act, certain categories of chemical substances such as scientific laboratory reagents and samples, or chemical substances not manufactured in commercial quantities.

Explanation. - This amended definition of a "chemical substance" would provide the Administrator with flexibility to exclude, in appropriate cases, substances from the requirements of the Act, or a particular provision, where it does not need to be regulated, cannot be effectively regulated, or where meeting the requirements might be an undue burden. Scientific laboratory reagents, samples, and other chemical substances manufactured in less than commercial quantities are examples.

We urge the following language be included in the committee report with respect to this definition :

Chemical substance would be defined to permit the Administrator the flexibility to provide by regulation for exempting chemical substances in certain categories or in less than commercial quantities from certain provisions of the bill. With respect to those chemical substances, it is anticipated that the Administrator will exercise his discretion to exclude, and thereby exempt, most of them from the testing provisions of the bill. The Administrator retains the authority to require testing in those cases where he finds a potential threat to health and the environment which indicates that such testing is necessary.

c. Page 5, line- 2, delete the period and insert a semicolon after '^studies'' and delete remainder of paragraph ; and on line 12, delete "study-" and insert "study, including health and safety data developed pursuant to such study,".

ExplanatloTi. - Correspondence relating to alleged adverse effects on health and similar reports are already required to be maintained in the section 8(d) regarding records, and an amendment is proposed to authorize the Administrator to require submission of such records. There is no need to include unconfirmed complaints and notices in the definition of health and safety data and confusion results when this is attempted. It is also proposed to specifically provide that a health and safety "study" includes health and safety data developed pursuant to such study,".

d. Page 6, insert after line 14 the following and renumber other paragraphs accordingly.

(15) "new chemical substance" means any chemical substance which has not been manufactured or imported in commercial quantities into the United States during the 18-month

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period immediately prior to the effective date of this Act, regardless of its commercial production or importation in the United States prior to such time.

Explanation. - -A definition of "new chemical substance" is neces-

sary in order that chemical substances that were used in prior years and were discontinued do not become classified as existing chemicals for purposes of this Act.

2. Testing

a. Page 9, after line 8, insert new paragraph (4) as follows:

(4) The Administrator will consider alternative methods for meeting the standards for test protocols proposed by any person or governmental entity which is a manufacturer, processor, or importer of such chemical substance.

Explanation- This amendment would specifically direct the Administrator to consider alternative methods for meeting the standards for test protocols proposed by a manufacturer, such as less costly or more effective test protocols.

b. Page 9, line 14, delete the last two sentences in paragraph (1) beginning with "If", and insert in lieu thereof : "If such an arrangement is made the Administrator shall be notified and the remaining such persons shall be exempted from requirements to perform tests."

Explanation. - ^We do not believe that the Administrator should become involved in designating which part}^ (or a third party) should perform tests if the parties cannot agree among themselves. If a cost-sharing arrangement is made for one of the parties to do the testing, however, provision should be made to exempt the other parties from the testing requirements.

c. Page 11, line 15, insert after "arguments," the following: "and permit cross-examination to such extent and in such manner as in his discretion he determines is necessary and appropriate in view of the nature of the issue involved, the number of the participants and the nature of the interests of such participants,".

Explanation. - This amendment would permit limited cross-examination as is provided in the section 6 rulemaking procedures to restrict toxic chemicals.

3. Premarket screening; imminent hazard

a. Page 12, line 3, after "substance" add the following sentence:

Subsequent submission or request for submission of additional information shall not be regarded as changing the date \ of such notice.

Page 13, line 4, delete entire subsection (c) ; on line 25, delete beginning with "Unless" through "90 days" on line 2, page 14, and insert in lieu thereof "Ninety days" ; renumber following subsections accordingly.

Page 14, line 10, after "substance" insert "before or".

Page 22, line 13, after "environment," insert "that should be corrected immediately, and".

Explanation. - ^These amendments will delete the authority in the bill to treat a rule proposed under section 6 during the premarket review period of a product as a final rule.

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Thus a chemical substance or procluct may be manufactured and distributed after the premarket review period unless a restriction is obtained under the imminent hazard provision of the Act The substance or product, however, remains subject to all other provisions of the Act and a rule proposing restrictions on the substance or product may be proposed immediately durin^: the premarket review period under section 6 and the rule-making proceedings initiated at that time.

If it appeal's that the manufacture, processing, or distribution of a chemical substance or product will result in any unreasonable threat to human health or the environment prior to tJie completion of the rule-making proceedings, action may be taken to restrict or ban it under the imminent hazard provisions of the bill, thus preventing it from becoming a threat to health or the environment.

The other amendments would clarify the date premarket notice commences, that restrictive rules under section 6 may be- promulgated before or after manufacture or distribution of a substance, and that an imminent hazard is a risk that should be corrected immediately.

4. Restnctions on hazardous chemical substances

a. Page 17, line 23, delete "condition" and insert in lieu thereof "circumstances"*, and insert the following language in the committee report with respect to section 6 of the bill :

The provisions of section 6 of S. 776 provide EPA with regulatory authority which will complement and supplement existing authority to control hazardous substances but not to preempt authority already vested by statute in other Federal departments or agencies. Proposed new section 9(b) would preclude EPA from taking action under sections 6 and 7 which the Secretary of Labor could take under the Occupational Safety and Health Act. Thus, for example, the Administrator of EPA could not, under section 6(a) (3) require that a substance be labeled so as to prescribe requirements for its safe and healthful use which apply solely, to workers in their place of employment. The Department of Labor, pursuant to the Occupational Safety and Health Act of 1970, already has authority to prescribe safe and healthful working conditions. Similarly, section 6(b)(2) shall not be construed to allow the Administrator of EPA to establish occupational safety and health standards.

Explanation. - The clarification to paragraph 6(a)(2), together with the addition of legislative history with respect to paragraphs 6(a) (3) and 6(b) (2), will assist in implementation of the bill's policy to "complement and supplement" existing authority. These changes will assist in avoiding overlap between EPA and the Department of Labor's workplace safety and health authority.

b. Page 18, line 17, page 20, line 23, page 21, lines 6 and 12, delete "adulterated" (or "adulteration") and insert in lieu thereof "contaminated" (or "contamination").

Explanation. - We believe that the term "contaminated" (or "contamination") would more clearly express the intent of these provisions instead of "adulterated" which is often understood or defined as an intentional act.

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c. Page 19, line 11, delete entire paragraph (3).

Explanation. - We believe that the Administrator should not become involved in assigning quotas to industry. The mandatory requirement of a quota system would make the regulatory process vastly

more cumbersome and difficult to administer. The Act already provides that when it is necessary to adopt a rule with respect to a chemical substance to protect against an unreasonable risk, the Administrator shall select the least stringent requirement practicable consistent with protection of the health and the environment. It is expected that the establishment of quotas would seldom, if ever, be necessary as such would be a most stringent requirement. Nevertheless, we strongly recommend against becoming involved in the establishment of quotas..

d. Page 20, after line 15, insert the following :

(4) the economic impact of such action, including, but not limited to, consideration of the effects on business, employment, and the national economy.

Explanation. This amendment would specifically require the Administrator to consider economic impact in promulgating regulations, inherent in the requirement that he consider all relevant factors. This would be in lieu of proposals that have been made for the mandatory preparation of detailed economic impact statements for issuance at the time any regulation is promulgated.

5. Suits by U.S. attorneys instead of by Administrator'

Page 22, line 17, delete all after "may" through "so,", line 19 and insert in lieu thereof : "request a United States Attorney to petition an appropriate district court of the United States''

Page 39, line 3, delete "Administrator or the".

Page 46, line 7, delete "Administrator (or Attorney General on his behalf) " and insert in lieu thereof "Attorney General".

Page 46, line 8, after "commenced" delete "and is diligently prosecuting" on lines 8 and 9.

Explanation. - These amendments would carry out the long-time policy of having the Justice Department responsible for litigation instead of each Agency. In the citizen suit provisions, we believe that it is sufficient if the Attorney General has commenced an action and that it is not necessary to impose a further requirement that he be diligently prosecuting it, a concept which is at best difficult to litigate and at worst could lead to counter-productive court action.

(S. 8) Mission of records; health and safety studies

a. Page 25, line 3, add at end of sentence :

The* Administrator may require copies of such records pur-

suant to his responsibilities under sections 4, 5, 6, and 7 of this Act.

Explanation. - While the bill provides that records of adverse health effects caused by chemical substances are required to be maintained, no provision is made to require submission of such records. This amendment would correct that omission.

b. Page 25, line 4, delete subsection (e) and insert in lieu thereof:

;(e) Health and Safety Studies. The Administrator shall promulgate regulations under which he may require any per-

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son who manufactures, processes, or distributes in commerce any chemical substance (or with respect to paragraph (3), any person who has possession of a study) to submit to him-

(1) lists of health and safety studies in progress on or initiated after the date of enactment of this Act, conducted by or for such person, or known to such person;

(2) lists of health and safety studies conducted by or for such person, or known to have been made by any person, prior to the date of enactment of this Act ;

(3) copies of any such studies appearing on a list submitted pursuant to paragraphs (1) or (2), or otherwise known by him.

Explanation, - This amendment would revise the provision requiring industry to report on or submit all health and safety studies. It would require the submission of lists of ongoing and new studies rather than the study, with a right to require submission of studies. It would authorize the Administrator to provide by regulation for the types of studies to be included on the lists, and the number of years of prior studies for particular types of studies; and would require a person to also list studies which he knows are being made or have been made.

7. Additional exemption : additional limitation on authority

. a. Page 26, line 8, delete "or"; line 10, after "*Act)" insert a comma and add "cosmetics (as such term is defined in section 201 (i) of the Federal Food, Drug, and Cosmetic Act),"; line 18, replace the period with a semicolon, and add the following :

(3) any source material, special nuclear material or by-product material as defined in the Atomic Energy Act of 1954 (42 U.S.C. 2011), as amended, and regulations issued pursuant thereto ; or

(4) tobacco and tobacco products.

Explanation, - We believe that cosmetics should also be exempted and materials regulated under the AEC Act, and do not believe that tobacco products should be regulated under the Toxic Substances Control Act.

b. Page 26, after line 18, add new subsection (b) as follows, and renumber other subsections accordingly :

(b) Notwithstanding any provision of this Act, the Administrator shall have no authority under sections 6 and 7 of this Act to take any action which the Secretary of Labor is authorized to take pursuant to the Occupational Safety and

Health Act. In exercising authority pursuant to this Act, the Administrator shall not, for the purposes of applying section 4(b) (1) of the Occupational Safety and Health Act, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

Explanation. - The purpose of these changes is to eliminate the possibility of jurisdictional conflicts between EPA and the Department of Labor where actions taken by one authority might otherwise preclude or duplicate action of the other.

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8. Interagency cooperation and coordination

Page 3, after line 17^ add the following new paragraphli :

(5) such authority over chemicals be exercised in such a manner as to complement and supplement existing Federal policies, regulations, and public laws regarding the protection of health and the environment, including occupational health, consumer safety, food, drug, and cosmetic authorities.

Page 28, line 3, delete the sentence after "coordination. - " and insert in lieu thereof :

In administering the provisions of this Act, the Administrator shall consult and coordinate with the relevant agencies and instrumentalities of the Federal Government in accordance with the policies set forth in section 2(b) of this Act.

Page 30, line 2, delete the last sentence of subsection (a) and insert in lieu thereof :

The Administrator is authorized to make contracts and grants for research and monitoring as necessary to carry out the purposes of this Act in consultation with the Secretary of Health, Education, and Welfare on such contract and grant programs.

Page 30, line 7, delete entire subsection (b) and insert new subsection (b) as follows:

(b) The Council on Environmental Quality in consultation with the Administrator, the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate departments or agencies, shall coordinate a study of the feasibility of establishing (1) a standard classification system for chemical compounds and related substances, and (2) a standard means for storing and for obtaining rapid access to information respecting such materials. A report on such study shall be published within 18 months after enactment of this Act.

Expl/jfn/ition. - ^These proposed amendments are intended to clearly set forth that it is the policy of the Act that there be the maximimi cooperation and coordination among the several agencies of the Federal Government which have programs and responsibilities concerned with toxic substances ; that the Act is intended to complement and supplement existing laws and regulations such as the Federal occupational health and safety requirements; and that appropriate provisions are made to establish and to have access to information relating to chemical compounds.

A number of Federal agencies, particularly the Occupational Health and Safety Administration of the Department of Labor have extensive responsibilities relating to toxic substances and human health and would stand to benefit from various provisions of this Act. The testing of chemicals as they relate to the programs of these agencies and the test results and other information and data generated by the legislation would, of course, be valuable to them and must be made available.

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One of these amendments specifically provides that the EPA Administrator will consult with the Secretary of Health, Education, and Welfare on any contract and grant programs for carrying out the research and monitoring activities under the Act, but not necessarily on each individual contract or grant.

We are also recommending that the provision contained in the previous bills before the Congress directing the Council on Environmental Quality to coordinate a study on the feasibility of establishing a standard classification system for chemical compounds and means of obtaining rapid access to the information on such substances be restored to the Act. This section provides CEQ to have the lead in establishing information systems in a manner currently being initiated. This is being done in conjunction with the agencies that would have been represented on the interagency committee as set out in the provision proposed to be deleted.

0. Add to Title 29, section 105, subsection (a), the following:

Page 28, line 15, delete subsection (a), renumber subsections (b) and (c) accordingly.

Explanation. – This amendment would delete the provision for a special category Assistant Administrator for Toxic Substances.

10. Administrative inspections

Page 31, line 6, insert "(a)" after "Sec. 12", and after line 21 insert new subsection (b) :

(b) Notwithstanding the provisions of subsection (a), the

Administrator shall have authority to inspect financial data records pertaining to testing costs when he orders contribution or reimbursement for the costs of performing tests in connection with the provisions of sections 4(c) and 5(f).

Explanation. - Section 4(c) and 5(f) authorize the Administrator to determine the equitable contribution or reimbursement of testing costs where more than one person benefits from the testing. This amendment would authorize access to financial data on testing costs in order for the Administrator to carry out the requirement to apportion the costs among those benefits from the testing.

11. Disclosure of confidential information

Page 34[^]. line 18, delete entire section 15 and insert in lieu thereof the following revised section :

CONFIDENTIAL

Sec. 15. (a) Confidential - Any information reported to, or otherwise obtained by, the Administrator or his representative under this Act/ which is exempt from mandatory disclosure by reason of section 552(b) (4) of title 5, United States Code, shall be entitled to confidential treatment and shall not be disclosed by the Administrator or by any officer or employee of the United States, except that such information may be disclosed.

(1) to officers and employees of the United States in connection with their official duties :

(2) to contractors with the United States and employees of such contractors, if in the opinion of the Ad-

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Administrator such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States entered into on or after the effective date of this Act for the performance of work in connection with this Act ;

(3) when relevant in any proceeding under this Act,

except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding; or

(4) to the extent that the Administrator determines it is necessary to protect health or the environment.

(b) Access by ConcxRess. – Notwithstanding any limitation contained in subsection (a) or any other provision of law, all information reported to or otherwise obtained by the Administrator or his representative under this Act shall be made available upon written request of any duly authorized committee of the Congress.

(c) Criminal Penaett for Wrongful Disceosure. – (1) Any officer or employee of the United States, or former officer or employee of the United States, who by virtue of his employment or official position has obtained possession of, or has access to, material which is entitled to confidential treatment under subsection (a), and who laiwing that disclosure of the specific material is prohibited by this section, willfully discloses the material in any manner to any person not entitled to receive it, shall be guilty of a misdemeanor and fined not more than \$5,000.

(2) For the purposes of this subsection fc), any contractor with the United States who is furnished information pursuant to subsection (a) (2), and any employee of any such contractor, shall be considered to be an employee of the United States.

Exflmwitim. – This section should be amended in several respects First, the substance criterion for withholding data as confidential should be the test established by the Freedom of Information Act, 5 U.S.C. 552(b)(4). Our proposed amendment would have the effect of requiring nondisclosure of information obtained under the Toxic Substance Control Act which may be withheld under 5 U.S.C. 552 (b)(4), i.e., "trade secrets and commercial or financial information obtained from a person and priveleged or confidential." This will make the confidentiality standard more definite (because there exists a body of case law interpreting 5 U.S.C. 552(b)(4)), and will promote uniformity.

In addition to the exemption for disclosure to Federal officers and employees, a separate provision should allow disclosure to EPA contractors and their employees, under appropriate safeguards and after appropriate EPA findings that disclosure is necessary. EPA accomplishes a great deal of its investigatory atid analytical tasks by con-

tract. If contractors are not allowed access to information under this bill, EPA could not perform its duties satisfactorily without substantial manpower increases. The recently-enacted Privacy Act, 5 U.S.C. 552a, provides that, for purposes of the section of the Privacy Act

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which imposes penalties on Government employees for wrongful use or disclosure of information entitled to confidentiality, Government contractors and their employees are to be considered Government employees (5 U.S.C. 552a(m)). We recommend inclusion of such a provision in the toxic substances proposed bill. Our amendments allow disclosure to contractors, and include a penalty for wrongful disclosure of information by Government employees (including contractors and their employees).

We also believe that the provisions relating to qualified scientists and individual names are not necessary. The term "qualified scientists" would be difficult to interpret, and in any event a scientist would have no greater rights under the subsection than would any person under our (proposed) basic confidentiality criterion. We believe that the Federal Privacy Act and the Freedom of Information Act provide ample protection of the rights of individuals whose names appear in health and safety records.

Finally, with regard to access of information by Congress, we believe that release of such confidential information should be upon written request.

12. State exemption from Federal preemption
Page 42, line 14, delete subsection (b).

Explanation. - This amendment would delete the provision that would allow State and local governments to petition to be exempted from Federal preemption requirements.

13. Citizen suits for discretionary action

Page 45, line 13, delete language after "Act" through line 16, and insert in lieu thereof: "which is not discretionary with the Administrator."

Explanation. – This amendment would make the provision conform with the usual citizen suit provision and not authorize suits against the Administrator for discretionary acts. It would thus prevent the possibility of every decision of the Administrator from being re-decided in the district courts.

14. Indemnification study

Page 52, line 17, delete all of section 25 and renumber section 26 accordingly.

Explanation. – This amendment would delete the requirement for a study on Federal indemnification under laws administered by EPA. We believe sufficient information already exists to recommend against indemnification under programs administered by EPA.

15. Submission of budgets and testimony to Congress

Page 54, line 15, delete all of subsection (c) .

Explanation. – This amendment would delete the requirement that Agency budget requests, testimony and comments on legislation must not be submitted to OMB prior to submission to Congress. We continue to object to this provision.

16. Add various miscellaneous amendments

Page 2, line 16, add after "substances": "which may present an unreasonable risk to health or the environment."

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Page 3, line 8, insert after "to" the following : "ensure that adequate testing is conducted by those persons who manufacture, import or process, to " .

Page 5, line 17, after "ecological studies" insert "monitoring studies," .

Page 8, line 4, delete "proscribed" and insert "prescribed" .

Page 8, line 20, insert after "that" "one or more of the following" .

Page 8, line 24, insert after "synergistic properties," "persistence," .

Page 10, line 6, delete "section 5 (g) " and insert "section 5(f) " .

Page 22, line 12, delete "any".

Page 22, line 13, delete "threat" and insert in lieu thereof "risk".

Page 29, line 15, delete the period and add "if appropriate."

Page 33, line 20, delete "delivery" and insert in lieu thereof "release"; line 22, delete "three months" and insert in lieu thereof "90 days"; and on line 25, delete "deliver" and insert in lieu thereof "release".

Page 34, line 1, after "decision" insert "by the Administrator"; line 4, delete "article, together with the" and insert in lieu thereof "article as set forth in the Customs entry plus the estimated"; line 5, delete "forfeiture of" and insert in lieu thereof "liability for assessment of liquidated damages equal to"; line 6 delete "refusal" and insert in lieu thereof "failure"; line 10, delete "delivery" and insert in lieu thereof "release"; line 11, insert a comma after "payment" and delete "of and the comma after "charges"; and on line 16, delete "of subsection (a)".

Page 39, line 5, "section 17," should read "section 16,".

Explanation. - These amendments are technical corrections or are otherwise self-explanatory.

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ADDITIONAL VIEWS OF MR. BAKER

In my view, the Toxic Substances Control Act which is the subject of this Committee Report represents a considerable improvement over past efforts to develop legislation in this field, and I support the bill. There is clearly a need for regulatory authority which can, where possible, identify and control the introduction of harmful substances into the environment before damage to health or the environment occurs. This bill permits regulation of toxic chemicals at points in the chain of manufacture and use that are impossible to reach under existing laws. In addition, the concept of premarket screening will, in some cases, prove a boon to industry by providing a mechanism whereby a harmful substance can be halted before a manufacturer has invested a great deal of time and money in marketing and distributing it.

While I opposed some of the amendments which were added to the measure during the Committee's mark-up. I will confine these views

to a discussion of one section of the bill which was the subject of an amendment I offered. Unfortunately, that amendment was rejected by the Committee.

Section 4(e)(1) of the bill as reported creates an interagency advisors committee to advise the Administrator as to those chemicals which should be priorities for testing. The priority list is required to be published in the Federal Register, and the Administrator is required to institute a rulemaking procedure to develop testing requirements on these chemicals within 1 year or publish his reasons for not doing so.

These requirements pose several problems for both the industry and the Administrator which I believe the Committee has neglected to address adequately. First, publication of a priority list in the Federal Register is likely to generate a good deal of publicity in the media which will inevitably result in a perception by the public that chemicals on the list are harmful, even though they will not, at this point, have undergone testing for toxicity. This "blacklisting" effect will, in my opinion, work a substantial unfairness on manufacturers of products which contain a chemical appearing on the list.

While I feel strongly that the public should be advised of harmful chemicals in the marketplace, I see little or no benefit in mandatory disclosure of the advisory committee's list prior to any decision by the Administrator that those chemicals do, in fact, meet the criteria for testing established by the bill. Other sections of the bill provide for disclosure to the public of test data received by the Administrator, as well as information received when a chemical undergoes premarket screening. Moreover, section 14 of the bill requires the Administrator to disclose any information he has if he determines it is necessary to protect human health or the environment. These provisions insure continuing dissemination to the public through the Federal Register of information pertaining to the administration of the Act.

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Secondly, I do not believe that requiring the Administrator to take action on the advisory committee's list within 12 months or publish his reasons for not taking action is consistent with the proper role of an advisory committee. This requirement effectively removes the deci-

sion on whether to require testing from the Administrator and places it in the hands of the advisory committee - an entity not responsible for administration of the Act. The priority list developed by the committee should be received and evaluated by the Administrator as a recommendation. By requiring that he act on the advisory committee's recommendation, the bill removes from the Administrator the flexibility which he will need to make responsible decisions on the testing of chemicals.

Howard H. Bakeh, Jr.

SENATE CONSIDERATION OF S. 3149

[Excerpt from the Congressional Record, Mar. 26, 1976, Senate, pp. S4397-S4432]

Toxic Substances Control Act

The Senate continued with the consideration of the bill (S. 3149) to regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes.

Mr. TUNNEY. Mr. President, today the Senate will be considering S. 3149, the Toxic Substances Control Act. In my view this legislation is the most important environmental and health protection legislation that will come before the Congress this session. S. 3149 will close major gaps in the law that leave the public inadequately protected against the unregulated introduction of hazardous chemicals into the environment. S. 3149 will assure that chemicals will receive careful premarket scrutiny before they are manufactured or distributed to the public. This provision will end the present situation where chemicals can be marketed without notification of any governmental body and without any requirement that they be tested for safety. Thus, this legislation will no longer allow the public or the environment to be used as guinea pigs in order to determine the safety of these chemicals and products.

Mr. President, S. 3149 was reported unanimously from the Senate Commerce Committee. Furthermore, support for a strong toxic substances bill is extremely widespread. Dr. Russell Peterson, Chairman of the Council on Environmental Quality for example, concluded at last year's hearings:

Toxic substances legislation is probably the most important environmental legislation now before the Congress,

This view was echoed in a February 28, 1976, Washington Post editorial which stated in part :

In light of all that has been learned about environmental threats to health, it hardly seems unreasonable for Congress to require that substances should not be marketed until their health effects have been assessed as well as possible, and no serious hazards have been found. That course will not produce a world entirely free of risk. But it will inject far more care into the realms of chemistry and slow down the rate at which strange substances are spread about. Given the persistent and insidious nature of many toxic materials, precaution is not just important but imperative.

The need for this legislation has become increasingly clear. In the last 3 years, for example, I have chaired hearings before the Senate Committee on Commerce which have documented time and again the lethal dangers associated with chemicals like vinyl chloride, bischloromethyl ether- BCME- mercury and other heavy metals, arsenic, asbestos, and a multitude of others. In fact, over the 15 days of hearings

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conducted by the Committee on Commerce on this legislation over the last 5 years, in excess of 100 chemicals have been mentioned as candidates for regulation under this legislation.

Also, the National Cancer Institute has estimated that 60 to 90 percent of the cancers occurring in this country are a result of environmental contaminants. Many doctors and scientists now believe that cancer, which has been projected to kill as many Americans in 1975 as all the battle deaths in Vietnam, Korea, and the Second World War combined, appears particularly susceptible to a preventative approach through control of toxic substances.

It is indeed unfortunate that while the record of chemical dangers continues to grow, segments of the chemical industry have presented roadblocks at every juncture of this bill's development. There is no question in my mind that a statute would now be on the books providing effective protection against chemical hazards had it not been for the concerted effort of certain segments of the chemical industry to gut the essential provisions of this legislation.

Russell Train, Administrator of the Environmental Protection Agency, for example, discussing this lobbying effort has noted :

It is unfortunate that some segments of the chemical industry, which originally took an extremely constructive approach toward the legislation, has taken to actively lobbying against it, I do not believe that either the public interest, or the interests of the industry, are well served by charges that the legislation could - in words of one industry spokesman - "cripple" the chemical industry and give the Administrator of EPA "near-dictatorial authority over the introduction of new chemical products." The only real "crippling" that is going on is the kind which this legislation would try to prevent - the crippling of who knows how many Americans every year who contract cancer or some other affliction after exposure to some hazardous chemical agent. Nor has it been on the "near-dictatorial authority" of the EPA Administrator that so many such agents are introduced into the environment without any effort to find out what their health effects are, much less the public have any say about whether or not, or in what circumstances, it is willing to be exposed to them. Let there be no mistake; the only kind of authority that the legislation before the Congress would give us, the only kind of authority we would intend to exercise, is the authority to act reasonably and responsibly in the public interest - and that includes the very real interest the public has in a healthy and productive chemical industry.

In order to provide EPA adequate regulatory authority, the Toxic Substances Control Act will provide a mechanism to insure that that information with respect to health and environmental effects of chemicals can be collected from manufacturers and processors of chemical substances prior to manufacture. The bill contains the following important provisions :

First, manufacturers of new chemical substances must give notification to EPA 90 days in advance of first manufacture and, if required by EPA, include test data along with such notification [Sec. 5].

Second, the EPA Administrator may require manufacturers to test or have tested those chemical substances which he determines may present an unreasonable risk of injury to health or the environment or those for which significant human or environmental exposure takes place or will take place. This provision is applicable both to new and existing chemical substances [Sec, 4],

Third, manufacturers or processors of chemical substances are required to retain certain records and reports that will better enable the Administrator to determine if unreasonable risks exist. Also manufac-

turers must provide the Administrator with a list of health and safety studies on various chemical substances. The Administrator is authorized to require the submission of any study on the list. This provision is included due to the fact that, in hearings of the Committee on Commerce that I chaired, it was strongly alleged that health information that suggested certain chemicals were dangerous had been suppressed by industry from both the Government and chemical workers [Sec. 8].

Fourth, citizens are authorized to bring suit to enjoin violation of this act and to require the Administrator of EPA to perform his mandatory duties [Sec. 20].

Fifth, citizens are authorized to petition the Administrator to take action the purpose of which is to protect against unreasonable risks of injury to health or the environment. If the Administrator fails to take action within 90 days on such petition or denies it, judicial review of the denial or failure is authorized [Sec. 21].

Sixth, discrimination against any employee who participates in proceedings, testifies in a proceeding, or participates in any other action necessary to carry out the purposes of the legislation is prohibited. The legislation also sets up procedures to protect such employees [Sec. 23].

Certain industry representatives have claimed that this legislation will be detrimental to the economic health of the chemical industry. I believe this view is totally unjustified. The chemical industry in the last year had estimated sales of over \$100 billion. The Environmental Protection Agency and General Accounting Office both have estimated that the costs of this legislation will be somewhere between \$100 and \$200 million a year. This cost is completely justified in light of the need for protection of the public from potentially vast damage to health and the environment.

The chemical industry will reap very real benefits from this legislation as well. A prudent approach of premarket investigation and scrutiny will reduce the likelihood that we will have to take action against a chemical after industry has invested vast resources in its production and marketing, furthermore, as Russell Train has pointed out -

Far from stifling innovation toxic substances legislation should serve to encourage the industry to turn its remarkable skills and resources towards the discovery and use of less hazardous chemicals.

^Ir. President, I do not think there is a way to assure a risk free

society. However, the Toxic Substances Control Act will end the situation where we play Russian roulette by introducing vast numbers of untested chemicals into the environment. This legislation will assure that we will no longer have to wait for a body count or serious health damage to generate controls over hazardous chemicals. Mr. President, in closing these remarks I would like to provide a partial list of the groups that have called for strong toxic substances legislation :

AFL-CIO.

Blue Cross Association.

American Lung Association.

Center for Science in the Public Interest.

Consumer Action Now.

Consumer Federation of America.

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Environmental Action.

Environmental Defense Fund.

Environmental Lobby.

Environmental Policy Center.

Friends of the Earth.

Industrial Union Department, AFL-CIO.

League of Women Voters.

National Audubon Society.

National Foundation- March of Dimes.

Natural Resources Defense Council.

National Wildlife Federation.

Oil, Chemical and Atomic Workers.

Pulp and Paperworkers.

Sierra Club.

Textile Workers.

United Auto Workers.

United Mine Workers.

United Steel Workers.

Urban Environment Conference.

When I became a member of the Committee on Commerce 3½ years ago. Senator Magnuson asked me if I would be interested in chairing some hearings on the toxic substances bill, inasmuch as the bill had been before the committee for the preceding 2 years and there had not been any final action taken, as a result of the very strong lobbying influence of the chemical industry. So, approximately 3½ years ago, I started holding hearings on the legislation, with the idea of being able to move it quickly through Congress. We were able to get it through the Senate without any difficulty 3 years ago. Then we got to conference, and it was very clear in conference that the chemical industry had marshaled its forces and was going to do everything it could to sabotage the legislation in a way that was considered unacceptable not only to the Environmental Protection Agency, but to the Senate conferees as well.

I must say that I have never seen such an effective lobbying effort as was done against this legislation. I was the chairman of the Senate conferees and, for a period of 18 months we sat in conference with no appreciable headway being made because some of the vital provisions of this legislation, such as permarket notification, were provisions that were unacceptable to the House conferees. We could not get the spokesmen against the legislation who were on the conference committee to agree to ameliorating the strong opposition that they had to those provisions in the legislation.

But a lot has happened in the last 2 years. Particularly, a lot has happened in the way of educating the public in the last several months. We had a 60-minute CBS television special which outlined the impact of environmental cancer on society. We have had the National Institutes of Cancer come out with studies demonstrating that between 60 and 90 percent of cancer is environmentally induced. We have, had a cover story in Newsweek demonstrating the impact of environmental cancers on our society. We have had, in the last year, a large increase in the rate of cancer afflicting society, some 3 percent last year over the year before.

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I introduced into the Record yesterday an article which showed that cancer has now become the number one killer of youngsters 15 and under. There does not seem to be any question that it is the environmental carcinogens that are producing this cancer in youngsters.

In other words, Mr. President, what I am saying is that I think that this legislation is vitally needed and, despite the fact that there may be significant costs to the industry, it is going to save the public billions and billions of dollars in medical treatment to get rid of cancer. And, of course, it is going to save, in my view, thousands of lives.

The thing that we have learned in recent years about cancer which is so devastating for those of us who are concerned about our friends and our families is that you can be exposed to a carcinogen and never know that you have been exposed to it. It is a silent death. It takes maybe 20 to 25 years to kill you, but that death is just as sure in some instances as having put a revolver to your temple and pulled the trigger and have a bullet go into your brain.

I was horrified to learn that we have asbestos in many of our body powders, and that when youngsters' mothers put powder on them, this can be inhaled into their lungs and that asbestos sits in the follicles of the lung and can produce cancer 20 years later.

In the late forties or early fifties, we used to spray the ceilings of our schools with asbestos and now this asbestos is flaking off and can get into the atmosphere of the school, the classroom, and children can inhale it and, in 20 or 25 years, die of cancer.

The same is true of vinyl chloride. Back in the late forties and early fifties, workers were exposed to vinyl chloride in a way that could produce cancer today. People working in the factories would go down and work in the reaction vats with the vinyl chloride all around them, inhaling it at a level of parts per million that, if they were all susceptible to cancer, was sure to produce the cancer. Lord knows how many people are going to die of vinyl chloride-induced cancer.

The point simply is we have learned a tremendous amount about the causes of cancer in the last 25 years, not so much as we would like to learn about how to cure it, but an awful lot about the causes of cancer. It seems to me that this legislation, which is designed to give the Environmental Protection Agency a degree of regulatory control over

the introduction of new chemicals into the environment, is absolutely basic. I have many friends who are in the chemical industry. But I cannot imagine persons arguing against this degree of regulatory control over the industry.

As I say, if you are going to cost it out on an economic basis, on the basis of cost/benefit, you are going to find it is going to save billions of dollars to consumers in medical treatment that they will not need as a result of not being exposed to carcinogens in future years.

I would like to say that I deeply appreciate the leadership that has been shown by the chairman of the full committee. Senator Magnuson, in pushing this legislation for the past 5 years. If it had not been for his interest and his keeping the pressure on I do not know, but I am sure we would not have the bill before us today.

Mr. President, I rise to strongly urge the passage of the Toxic Substances Control Act. The Senate Commerce Committee has worked diligently on this legislation, and I believe the committee has brought forth an excellent legislative package. The Senate

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Commerce Committee has been concerned with developing methods to control toxic substances for more than 5 years. During this period, the committee has held 15 days of hearings and received testimony and submissions from numerous experts representing the views of all the affected groups.

Despite the complex nature of this legislation, the Senate Commerce Committee was able to report the toxic substances bill unanimously on February 17 of this year. In my view, we have reported a tough, fair, and comprehensive legislative solution to the ever-growing toxic chemical problem in this Nation.

This legislation requires the Administrator of EPA to carefully consider the costs and benefits involved in promulgating rules under the testing and restrictive authorities sections of this legislation. These provisions will help to insure that regulation under this legislation will be constructed so as to impose the least burden on industry and the general public [Sec. 6].

A prime example of the type of threat to human health and the environment which this bill is intended to prevent is that posed by

PCB's. This class of chemical is not only toxic but is also exceedingly persistent. Once released into the environment PCB's present an extremely long-term threat. Furthermore, PCB's are highly concentrated by aquatic life so that fish at the top of the food chain have been found with alarming concentrations of PCB residues. There was, for example, a serious incident concerning PCB's in my own State of Washington in September 1974. An inadequately crated electrical transformer containing almost 300 gallons of PCB's was dropped on a dock while being loaded for shipping to Alaska. The casing cracked and let PCB's leak directly into the Duwamish Waterway. The transformer was allowed to simply sit on the dock for a number of days, all the while leaking PCB's into the waterway.

Toxic substances legislation could greatly reduce or even eliminate the chance of this type of incident occurring again. Under this legislation, the Environmental Protection Agency would have the authority to require that proper precautions are taken in the handling and transportation of devices containing toxic substances. Furthermore, proper labeling could be required with instructions on what to do should any accident occur.

Of course, PCB's are only one example of the type of danger this legislation would combat. Our hearings have revealed or examined the potential dangers of a multitude of other chemicals, including mercury, asbestos, vinyl chloride, and fluorocarbons.

Mr. President, the public has a right to expect that the vast array of chemicals that have become an intrinsic part of our daily life have been carefully scrutinized to determine whether they are safe. The Toxic Substances Control Act will provide this assurance. In closing I would like to particularly cite the work of Senators Tunney and Hartke concerning the Toxic Substances Control Act. Their efforts were extremely valuable in facilitating the progress and development of this legislation. I believe they both deserve a great deal of credit.

The Senator from California mentioned something to the effect that we have been very active in the Commerce Committee over the years in many of these areas, and I personally am very active as the chairman of the Subcommittee on HEW Appropriations in the cancer

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field. As a matter of fact, the first bill I introduced in the Congress of the United States in 1938 as a young Member of the House of Repre-

sentatives established the National Cancer Institute.

But, getting back to this, the Senator from California mentioned youngsters. All of us, every member of the Commerce Committee, worked hard on the bill that dealt with flammable fabrics. A great many kids were being burned up by pajamas and sleep wear catching fire. But finally the Commerce Department required of the textile people, the manufacturers, that clothing be put on the market w^hich is nonflammable.

Well, it turned out that the clothing is nonflammable but it also turns out that here is some evidence to the effect that the chemicals they put in the cloth to make it nonflammable might cause cancer. We are now having an investigation of it, and there is pretty clear evidence.

If this bill had been enacted – and I know what the delay was about, the Senator from California mentioned it, it is well known to the Senator from Indiana, about all the problems we had on this, but had this bill been enacted, and if the conference the Senator mentioned had reported a bill back to us – there w^ould not be the kind of chemicals in the nonflammable fabrics for the kids that there is there now.

I suppose the industry said – "Well, we will put this chemical in and it will stop a pair of pajamas or something else from burning up and killing the kid or burning him so that he is disfigured and crippled for life." But nobody examined what they were going to put into these things.

I understand for the purposes of the Record that they all do not use the same chemical, but there are some of them – and the major use is what we are talking about.

So the importance of getting this bill passed and getting it moving is that it can apply to all these kinds of problems. It just so happened this was called to my attention this week after we had worked a long time to get industry finally to develop nonflammable children's wear, so that these thousands of kids would not be burned.

This bill will- provide that when the textile people decide to make something nonflammable it is going to have to be tested to see what kind of chemical it is going to be and w^hat its other after-effects or side effects are going to be. That is just one example of how[^] very important this bill is.

I wanted to also say, Mr. President, that I do not know of any bill in which I have had the complete cooperation of everybody on the

Commerce Committee to try to work out this matter. I pay my respects to the Senator from California (Mr. Tunney) who worked so hard and so long in the hearings; the Senator from Indiana, who did a yeoman's job in trying to solve some of these problems so that the industries would accept what we are trying to do; and many others too.

This is a very important bill. We have always said, and I have always said, down in the Appropriations Committee on HEW, with the millions of dollars that were expended for health and for research, we have not paid enough attention to what we would call preventive medicine, and that runs the gauntlet of everything.

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This is preventive ; that is what it amounts to. I applaud the action of the President in taking the leadership yesterday in preventive medicine and urging the availability of shots to try to stop a new flu epidemic.

The Senator from Indiana at one time stopped in - and I remember this well - when we did not have enough money in HEW and all of the doctors said, "We are going to have a rubella epidemic." We put some more money in for rubella, and it did not happen.

Now, this is preventive medicine, and it will do a great deal for the health of the Nation. I am so glad that the leadership decided in a busy schedule to bring up this legislation because of the importance of passing it quickly, if for no other reason than the one I just suggested. I am sure the Senate is going to respond.

Mr. Pearsox. Mr. President, S. 3149, the Toxic Substances Control Act, represents a long sought and critically needed piece of legislation. Final congressional passage now of this legislation would first, come at a time when the need to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution, use or disposal of chemical substances has never been greater; second, close an untenable chasm in Federal legislation designed to protect human health and the environment, and third, culminate over 5 years of congressional consideration of and background work on legislation designed to control toxic substances.

The wide spread introduction and use of new chemicals into our

daily environment has become a fact of life. It has been estimated that there are presently nearly 2,000,000 recognized chemical compounds in existence and nearly 250,000 new compounds produced every year. Although the vast majority of these compounds are never commercially produced, the Environmental Protection Agency has recently estimated that nearly 1,000 new chemical substances are introduced yearly into the marketplace and subsequently find their way into the environment. Many of these substances pose unknown and potentially high risks to human health and the environment.

While no one can argue that tremendous benefits have not accrued as a result of many of these new chemicals, we have only recently begun to recognize that serious human health and environmental hazards are associated with the use of many of these chemicals. A partial listing of commonly utilized and widely dispersed chemicals that have been found to pose significant human health and environmental dangers includes fluorocarbons, PCB's, kepone, vinyl chloride, asbestos, mercury, and other heavy metals. Controlling the adverse effects such toxic chemicals have upon the environment and human health is perhaps the most critical environmental issue facing this Nation.

This Nation can no longer afford to accept the tragic human suffering that has resulted from our continued failure to adequately control the manufacture and use of toxic substances. The National Cancer Institute has recently estimated that 60 to 90 percent of all cancers occurring in this country result from environmental contaminants. It is thus not surprising that the highest incidence of cancer is found, almost without exception, in large industrial areas where vast quantities of industrial chemicals are manufactured and consumed. Many birth defects and occupational illnesses have also been linked to exposure to toxic substances. The costs, both in economic and human

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terms, associated with the harmful health and environmental effects resulting from exposure to toxic substances are simply no longer acceptable. Passage of S. 3149 would provide a means by which the public interest would be protected by assuring that safe and beneficial chemicals continue to be introduced into the marketplace while insuring that these chemical substances that have unacceptable health and environmental cost associated with them are properly restricted.

Existing Federal legislation simply does not provide the means by which adverse effects on human health and the environment can be

ascertained and appropriate action taken before chemical substances are first manufactured and introduced into the marketplace. At present, the only remedy available under such Federal statutes as the Clean Air Act, the Federal Water Pollution Control Act, the Occupational Safety and Health Act, and the Consumer Product Safety Act, is to impose restrictions on toxic substances after they have been first manufactured. The shortcomings in the present system have long been evident; corrective action, as evidenced by the Toxic Substances Control Act, is long overdue.

To correct such deficiencies, the Toxic Substances Control Act provides the EPA Administrator with authority to require essential and critically needed premarket testing of the human health and environmental effects of chemical substances and, where necessary, to regulate chemical substances found to present an unreasonable risk to human health or the environment. The existence within S. 3149 of a strong premarket screening process is a key factor in the effective operation of this legislation. We can no longer operate under the assumption that what we do not know about a chemical substance cannot hurt us. Tragic results associated with too many toxic substances have taught us that lesson all too well. Chemicals, not people, must be put to the test.

Several key factors concerning S. 3149, in addition to the critical provisions regarding premarket review of chemical substances, should be noted. First, the bill would represent the only Federal environmental statute that would exercise direct control over industrial chemicals with respect to their health or environmental effects. Thus increased emphasis and attention will be focused on these very important issues. Second, the bill provides for an ongoing mechanism that would insure that the EPA Administrator would continually have access to new information developed regarding adverse health or environmental effects associated with chemical substances. He would thus be able, on an ongoing basis, to continually evaluate on a timely basis the costs and benefits associated with any chemical substance. Third, the bill provides for both citizens lawsuits and petitions to insure adequate and viable public input with respect to the effective administration of the bill.

I can think of no piece of environmental legislation that is more critically needed than S. 3149. I urge my colleagues to strongly support this legislation.

Mr. Hartke. Mr. President, the Toxic Substances Control Act has now been pending before Congress for 5 years. This is the third time that the Senate will consider the legislation, having passed it twice before only to die in conference.

During the past 5 years, while Congress has struggled to enact toxic substances control legislation, the chemical threat has continued to

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grow. For example, approximately 5,000 new chemical substances have reached commercial fruition during this period. The hazards associated with chemicals like vinyl chloride, BCME, PCB's, and asbestos have all dramatically illustrated how important it is to get early warning with respect to new chemical substances and to have the opportunity for gathering test data and taking regulatory action with respect to chemicals at the earliest possible time.

During this 5-year period there have also been in excess of 1 million deaths in this country from cancer. Over a million infants have been born with physical or mental damage. The latter figure represents 7 percent of all births.

Mr. President, it is extremely important that these kinds of statistics not continue to mount. While many of the grave health risks to which human beings have declined in recent years, cancer statistics have done just the opposite. In fact, the incidence of cancer was estimated in 1975 to be some 21/2 percent above the previous year.

The National Cancer Institute and the World Health Organization have estimated that from 60 to 80 percent of cancer is environmentally induced. It is estimated that cancer costs alone in this country exceed \$18 billion annually.

It is no accident that the hot spots for cancer in this country are in close proximity to those locations where the chemical industry is most highly concentrated. For example, excess bladder, lung, liver, and other cancers among males are all concentrated in those counties of the United States where the chemical industry is most concentrated.

It is indeed unfortunate that most adverse effects associated with chemical substances first appear in the workplace. It is tragic that those who rely upon the industry for jobs have essentially become guinea pigs for discovering the adverse effects of chemical substances. It is also tragic that much of the information which has shown the cancer producing potential of many chemicals has come from death records of employees. For example, of 1 million current and former American asbestos workers who still survive, fully 800,000 have been projected to die of cancer. This death rate is 50 percent higher than

that of the United States population at large.

It is the goal of this legislation to provide a means of preventing this suffering and death rather than merely reacting to it or treating it medically after the fact.

One of the chief stumbling blocks in the past which prevented agreement between the House and the Senate was the strong Senate position with respect to premarket notification for new chemical substances. And the House and Senate seem to be moving together on this issue. It is this provision which offers the greatest potential for discovering the threats from chemical substances at a very early date and providing a sufficient data base to take appropriate early action. None of the other environmental health statutes, except pesticides and drug and food additives law, provide for premarket review by appropriate regulatory officials. In fact, this is probably the most important provision of the act, for it will enable us to limit chemical threats before they become manifest, not after.

Quite frankly, I had reservations about earlier versions of the Toxic Substances Control Act. But in my view, the Committee on Commerce acted extremely responsibly in unanimously ordering this legislation

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favorably reported. I am extremely pleased to join the Senator from California in being an original cosponsor of the bill reported by the Committee.

In my view, the bill provides all of the essential elements for a proper regulatory program. The premarket screening authority will provide early warning systems for hazards to health and the environment. The bill appropriately limits the authority of the EPA Administrator under the major regulatory provisions. The bill recognizes other Federal authority and provides direction for the EPA Administrator in addressing hazards which might be reachable under other Federal statutes.

It is worth dwelling for a brief moment on the economic burdens that this legislation might impose and the manner in which the committee has addressed these types of concerns.

There have been widely varying estimates from the chemical industry of the total cost to the industry of this legislation. Estimates have

ranged from the Dow Chemical estimate of \$2 billion per year down to the low estimate of the Manufacturing Chemists Association of \$340 million per year. The Environmental Protection Agency, on the other hand, estimated that the total annual cost to the chemical industry from this legislation would range only from \$80 to \$140 million per year.

At the request of the committee, the General Accounting Office examined these estimates. The GAO report seriously questioned the high estimate of Dow Chemical and the Manufacturing Chemists Association and stated that EPA's estimates were more reliable and realistic and would cost the chemical industry between \$100 to \$200 million per year.

It is extremely important to note that in the testing section and in the key regulatory sections it is specifically required that the Administrator evaluate the risks and benefits of his actions before taking action. Thus, costs are not to be incurred unless the Administrator has determined they are offset by benefits of at least the same magnitude. Obviously it is not feasible to reach these kinds of decisions just on the basis of quantitative comparisons and the burdens of human suffering and premature death are extraordinary. It is important to note, however, that the economic burdens to be imposed by the legislation have been recognized and appropriately dealt with.

Russell Train, Administrator of EPA, has stated :

It is time we started putting chemicals to the test, not people. It is time we gave the people of this country some reason to believe that every time they take a breath or eat or drink or touch, they are not taking their life into their hands.

Mr. President, I agree wholeheartedly with Mr. Train and I urge the Senate to pass S. 3149, the Toxic Substances Control Act.

Mr. President, I pay special tribute to the chairman of the Commerce Committee for demonstrating humane concern for the health of this Nation which is embodied in this legislation.

I also compliment the Senator from California (Mr. Tunney) who has been working on this legislation for all these many years, who conducted long hearings, frequently doing it in a solitary operation, in which he was able to provide for a continued interest in the committee, and making sure that we did something affirmatively to control the detrimental effect of toxic chemicals in American society.

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One thing is quite clear from what the chairman has said. We have had the help of the people who have been involved in the committee. During the markup of the bill the Senator from Kansas again demonstrated his effective leadership by helping us out of what appeared to be some very difficult situations, and doing it in a rather remarkably fast time. Yet at the same time preserving, not only the essential elements of the health protection embodied in the bill, but also the protection of the individual rights of all the people who could be adversely affected.

A worker himself is directly affected and he has to make that tremendously difficult choice as to whether or not he is going to work in an environment under conditions which might affect his health. He knows very well that if he is too critical of what happens inside his own operation with regard to the safety and health conditions that he may in the long run be cutting his paycheck off. On the other side, he knows he may be cutting his life off.

There is an immediate danger to him. He probably has a tendency to go ahead and take the chance on his life because his paycheck is needed every Friday night. The difficulty of making sure he has a job, and at the same time that he can live with some type of decency, presents him with a difficult challenge.

That is very much a part of what is involved in this bill.

The other side of the conflict always comes from the industry or the business which is involved in manufacturing the chemicals. They see themselves perhaps placed in a position where they are dealt with rather harshly in an area in which they may sincerely dispute what is going on.

I think the essential element of this legislation is that it has attempted to provide for the individual - not only who works, but for the rest of American society - the right to know what is in store as far as the toxicity of chemicals is concerned.

The fact of it is that not only do the workers not know and the general public not know, but in many cases the manufacturers and distributors and business people do not know.

'What we are trying to do here is to provide some type of good judgment and common sense to improve the quality of American life.

We have come into an age in which most people, maybe for the first time in the history of man, have had a chance to spend some of their life in somethinsr other than the mere and sheer operation of trying to provide food, shelter and clothing. Yet when we sfet into that type position as a result of the technological and scientific age we live in, we still find ourselves in the situation where people are suffering the adverse aspects of that type of complex and, progressive society.

I would like to say that this legislation is the type of legislation which I think has the essential element of beinir, first, lefifislation which we should pass and, second, T hope, legislation which the President will feel compelled to sign. I hope the House and Senate can join hands in making sure the environment of this country is much more desirable and that the health of this country is protected. And that as far as the working people are concerned, that they no longer have the fear and uncertaintv about their workinjj environment. The Nation will reap the benefits of having healthier people by merely going

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ahead and, making sure that we know and regulate toxic conditions in chemical manufacturing distribution.

Mr. Tux NET. I wish to say that in response to the comments of the chairman of the committee and the Senator from Indiana, there is no way, in my view, the legislation could have gotten through either the Commerce Committee this year or through the Senate if it had not been for the work of the Senator from Indiana.

The Senator from Indiana was a very important catalyst in developing solutions where we had opposition. He was able to achieve accommodations which in no way kept this legislation from being strong and progressive in its regulatory initiatives, but, on the other hand, did provide for some changes in the language to keep the bill from being oppressive to industry.

It can certainly be said that the Senator from Indiana played a critical role in getting this legislation into the shape it is, which makes it more acceptable, in my view, to this body as a whole.

I also wish to say that the Senator from Kansas, as the ranking

minority member of the Commerce Committee, played a vital role. If it had not been for his cooperation, time and again, I do not think we could have had this bill here today.

I know this to be true because, constantly, he was prepared to reason with those on the other side of the aisle at a time that lesser men, perhaps, would have been satisfied to posture and to make political points.

So the Senator from Kansas and others on the Republican side also played a vital role here.

Mr. Pearson. I thank the Senator.

Mr. TUNNEY. Mr. President, I have a letter in my hand which I am going to have printed in the Record, but I also am going to be quoting from it from time to time during the debate - if there should be any sharp challenge to the efficacy and legitimacy of this legislation.

It is a letter from Dow Chemical U.S.A. It appears over the signature of Earle B. Barnes.

But the letter is addressed to a number of different people, perhaps 30 in number, and it goes on to say :

Before long we will want to encourage the broadest and strongest possible grass roots political action campaign in opposition to Toxic Substances legislation. Hopefully, it will be based on mail to and calls on Senators and Representatives from employees, relatives, friends, distributors, vendors, customers, state organizations, etc. The objectives are to kill the bills or to register a minority vote sufficient to sustain a hoped-for veto or, as a last resort, to get the bills moderated significantly through floor amendments in the House.

During the past summer we asked for mail to be directed primarily to senators because the situation in the Senate was then at a critical stage. The response (3,000 or more letters) was very gratifying. Many senators realized for the first time that important numbers of their constituents were strongly opposed to this largely unnecessary piece of bad legislation.

Now, the time is near for our big push. We are not alone in this effort. Numerous other companies are also rallying grass roots campaigns ; the National Association of Manufacturers has taken a strong stand in opposition, and the MCA is now strongly opposed to the two key bills which are, in the Senate, S. 776 and, in the House, H.R. 10318. The latter replaced H.R. 7229, H.R. 7548 and H.R. 7664.

So, with all this in mind, you will find the attached package of information helpful in extending our request for action to the whole Dow U.S.A. "family"

plus others. Included are -

1. Summaries of the two bills in their current state.

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2. Table of Existing Laws showing the overlap of a few present laws with key features of the proposed Toxic Substances Control Act.

3. Representative paragraphs and sentences which people may wish to draw upon in framing their own letters on their own (non-Dow) stationery. We suggest that form letters not be used.

4. Lists of all Senators and Representatives plus rosters of the two committees who have responsibility for this legislation, along with suggested forms for addressing letters to Senators and Representatives.

5. Tips on writing your Representative or Senator.

Advance briefing and planning sessions will be held with various Government Relations managers. Then, we will write, Telex or call them when it is time to launch this all-out effort. In the meantime, I hope you will take the necessary preparatory action.

If you need more information, please call me or Chet Otis.

Thanks for your help, and good luck.
Very truly yours,

Earle B. Barnes.

So Dow Chemical was planning an enthusiastic, spontaneous effort, in which prepared paragraphs which employees could draw upon, to bombard their Senators and Representatives to show that there was strong adverse feeling on the part of a representative group of constituents. It is this kind of effort, Mr. President, which for the past 5 years has kept this legislation from going through the Congress and being signed into law by the President.

I think when the kind of activities that they have engaged in are exposed, such as they are today by reading this letter into the Record, we realize the effort on the part of the Dow Chemical Co., left at least by Mr. Barnes speaking for the Dow Chemical Co., was not to address the issue or the issues involved in the legislation based upon reason,

based upon the merit of the arguments, but simply to use a propaganda thrust, a political persuasion which is in no way related to the merits of the legislation.

I think it is this kind of effort which is going to do the industry in when it comes to the effectiveness of their approach in trying to block the legislation. I think the time has arrived for control of toxic substances. Lord knows, the last thing we need is more regulation where it is not necessary.

One of the things that certainly I feel, and many other Senators do. is that overregulation of industry can stifle productivity, inhibit creativity, and helps to keep the free enterprise system from operating in a fashion that it should. But when we talk about regulation of toxic substances and the prevention of these substances, these carcinogens, from getting into the environment, and protecting the health of our citizens, there can be no question, in my mind, that any society would want to have its government provide the safeguards that this legislation does. It is a miracle to me that it has taken so long to get to this point.

Mr. Tuxxey. Mr. President, I send an amendment to the desk and ask for its immediate consideration. I offer this amendment for myself and Senator Kennedy.

The Assistant legislative clerk pro tempore. The amendment will be stated.

The assistant legislative clerk read as follows :

The Senator from California (Mr. Tunney), for himself, and Mr. Kennedy, proposes an amendment.

The amendment is as follows :

On page 5, line 7 [sec. 3], immediately following "(vi)" insert "(A)", and strike "or" the second time it appears.

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On page 5, line 8, strike "any".

On page 5, line 10, strike " (A) ".

On page 5, line 11. strike "or as any".

On page 5, line 12, strike "such", and immediately following "(B)" insert "any substance".

On page 5, line 14, strike "or as any such".

Mr. Tuxx^{EY}. Mr. President, I have sent to the desk a series of clarifying amendments and I ask unanimous consent that they be considered en bloc.

The Acting President pro tempore. Is there objection? Without objection, it is so ordered.

Mr. Tun^{XEY}. Mr. President, the amendments are very minor and only serve to clarify the manner in which substances used in or on foods, drugs, cosmetics, or devices are excluded from the definition of a chemical substance. Under the existing language, it is not fully clear as to whether substances produced for research and development purposes and intended only for use in or on foods, drugs, cosmetics, and devices were sufficiently excluded. As these substances are now or will be covered by the Federal Food, Drug and Cosmetic Act, it is appropriate that they not be covered here. What this amendment does is merely to clarify the exclusion that we intended to have written into the bill as it came out of the committee.

Mr. Pearson. Mr. President, this amendment refers to several places in the bill, as the Senator indicates, and it is technical in nature. We have no objection.

The Acting President pro tempore. The question is on agreeing to the amendment.

The amendment was agreed to.

The Acting President pro tempore. Are there any further amendments?

Mr. Helms. Mr. President, I send an amendment to the desk and ask for its immediate consideration.

The Acting President pro tempore. The amendment will be stated. The assistant legislative clerk read as follows:

The Senator from North Carolina (Mr. Helms) proposes an amendment: Beginning on page 90, line 22 [sec 23], strike out all through line 6 on page 92.

Mr. Helms. Mr. President, this amendment would delete the so-called employment protection provision of the act, section 23(f),

Avhich is clearly unnecessary and unwise. It has nothing to do with any discussion about toxic substances.

In the first place, section 23(f) imposes onerous bureaucratic burdens on both the Environmental Protection Agency and the Employer that will unnecessarily increase the costs of administration and compliance. This section provides that "Any employee who is discharged or whose employment is otherwise interrupted, or is threatened with discharge or such interruption, or otherwise discriminated against by any person because of the results of any rule or order issued under this act, or a representative of such employee, may request the Administrator to conduct a full investigation of the matter." This section provides further that the Administrator "shall hold a public hearing on no less than 5 days notice, and shall at such hearings require the parties, including the employer involved, to present information related to the actual or potential effect of such rule."

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In other words, Mr. President, this section requires the Administrator of the Environmental Protection Agency to conduct a full-scale adjudicatory hearing whenever he is requested to do so by any employee or employee representative, such as a labor union official, who thinks that a ruling issued under the Toxic Substances Control Act may endanger his employment, either permanently or temporarily. The employer would in turn be required to appear at the hearing and supply information, with only 5 days notice, relating to the effect of a ruling on his employees. The employer, of course, will bear the cost of making these appearances, which he will pass along to the consumer - and the consumer ought to make no mistake about that - and the Federal agency will bear the cost of the hearings, which it will pass along to the American taxpayer.

No matter how you look at it, the American people are going to be paying for all of this expensive Federal bureaucratic paperwork, and I submit, Mr. President, that the taxpayers and the small businessmen of this country are almost crushed under such a deluge already.

And what would it all accomplish? If past experience with similar regulatory measures is our guide, the act will simply produce more bureaucratic harassment of the business community. Employers will undoubtedly be placed on the defensive by the threat of innumerable hearings demanding that they justify each and every layoff and employment reduction. It requires no great imagination to see that many

layoffs and employment reductions, whether real or imaginary, will be attributed to rulings of the EPA, and that employers will be induced to keep unnecessary employees in order to avoid bureaucratic proceedings. The added cost of labor will simply be passed along to the American people, increasing prices and adding to inflation.

That is something this country does not need, Mr. President.

In an industry employing more than a million persons, where some 1,000 new chemicals are introduced into the market each year, opportunities under section 23(f) for initiating these costly proceedings seem almost unlimited.

Now, contrary to all of the concepts of justice that I understand and appreciate! Mr. President, section 23(f) also discriminates against the employer and denies him equal treatment under the act. The manufacturer of a chemical may have his product banned without being afforded a full, trial-type hearing under the act, but every employee who receives a possible job layoff must receive a full hearing, complete with proper adjudicatory procedures. This, frankly, is not my understanding of justice in the American system of law, Mr. President, and I am confident that my colleagues will join with me in opposing section 23(f) in recognition of its inequitable features.

In the second place, section 23(f) is unnecessary because it is duplicative, under section 6(c) (1) of the act. The Administrator is required to make findings with respect to the economic consequences of any rules of the EPA regulating chemical substances that are allegedly, an unreasonable risk to the public health or environment. But surely, Mr. President, one of the most obvious economic consequences of any rule is the potential of employment reductions: and this is the very subject which section 23(f) commands the Administrator to evaluate constantly and continually. Section 23(f) is thus redundant, in

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the opinion of the Senator from North Carolina, and I believe it should be eliminated.

Mr. President, the principles of fairness, the interests of economy, and pride in legislative draftsmanship demand that we delete section 23(f) from this bill. I urge my colleagues to uphold these standards by joining in support of this amendment. I hope that the distinguished manager of the bill will agree with me and accept by suggestion.

Mr. Tux NET. Mr. President. I wish I could find in the amendment the merits that I know the Senator from North Carolina feels that it has. I would point out to my friend that this language is identical to a provision in the Water Pollution Act that was passed in 1972 and is now on the statute books, and there has been only one case that has been brought to the attention of the Committee on Commerce in which the EPA used its authority, in the 4 years that this statute has been on the books, to investigate alleged intimidation against a worker. It never even got to the hearing stage. It involved a paper mill in Alaska, and apparently when the employee made the charge to the Environmental Protection Agency alleging discrimination by the employer, the employer backed down and the man retained his job.

So there has been only one case in 4 years under an exactly similar provision in the Water Pollution Control Act.

Let me tell you what we were trying to obviate by this language in this bill. I am going to quote from a letter that was directed to me and to another Senator on the committee. It was a handwritten letter, directed to at least the two of us ; it may have been directed to more. But it goes like this :

I thought that you would like to know of the reaction to S. 776. Toxic Substances Control Act. I am in the chemical industry, and there is much pressure on us to write and" oppose this bill. In fact, there is downright intimidation. We are asked to write or phone to the committee members, and our names are written down by our bosses and the list, in turn, given to their bosses. For what purpose I don't know, but a lot of people are afraid not to do as they are told.

I do not think that this is fair of industry, to put pressure like this on their workers, and I would appreciate someone in the Senate speaking out against this form of "support."

Mr. Helms. If the Senator will yield

Mr. TuxNET. This was written in February, the middle of February of 1976. I would be happy to yield, but I do have some other points I would like to make.

Mr. Helms. Well, will the Senator yield at that point on my time?

Mr. TuxNET. Yes.

Mr. Helms. The Senator is making a great deal of a company's effort to oppose this bill, and I know the Senator is concerned about that, but this is a part of the political process, is it not ? Labor unions do it. but I have not heard the Senator complain about labor unions

putting pressure on their members.

I hear from union members all the time, who say to me : "Senator, I agree with you on a piece of legislation, but I would catch the devil from my union bosses if I opposed their position."- So it cuts both ways, and I do not think the Senator ought to complain too much about efforts by the business community to oppose this bill. Second, I think it is fair to point out that the Senator does not know for certain whether the facts of this letter are true : it may have been written by

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an aggravated employee, or someone else. I think that the Senator is not justified, if he will forgive me, in stressing the importance of this letter.

The only fact I am pointing out to the Senator, and I say this to all of the Members of the Senate, is that if this amendment is not adopted, there will be harassment, intimidation, and increased costs, and the Senator will hear from it later. This is why I am opposed to this part of the bill.

Mr. TUNNEY. Well, as I have mentioned, in 4 years, under a similar provision, there has been one case brought to the EPA, and that did not even get to the hearing stage. So I do not quite understand how the Senator from North Carolina feels that this is going to result in extraordinary cost. I can understand, if we had not had any experience under similar legislation, such fears might be reasonable. But with the experience that we have had of 4 years under the Water Pollution Control Act. I would suggest to the Senator that the empirical evidence is such that there is not much merit in the proposition that the Senator is making today.

Mr. Helms. I understand what the Senator is saying, but I do not understand how he relates water to an industry involving the introduction of a thousand new substances a year, each of which could have an effect along the lines that we are discussing here.

Mr. President, I ask for the yeas and nays.

The PRESIDING Officer (Mr. Nelson). Is there a sufficient second? There is a sufficient second.

The yeas and nays were ordered.

Mr. Pearson. Mr. President, will the Senator yield for a question?
Mr. Helms. Yes.

Mr. Pearson. I wonder if the Senator intends in his amendment to strike subparagraph 1, starting at line 22 on page 90 [sec. 23(f)(1)]. I am advised that there is in another part of the bill a requirement of the Administrator to make an evaluation of the economic impact of this particular legislation. That is general in nature. This is meant to be specific or enforcing language. It has provisions as to continuing economic implications, the shifts and reductions of employment, and so forth, under the rules and under the act.

We are advised that that particular subparagraph is one in which industry is very vitally concerned. I wonder if the Senator feels that that also is a matter which should be stricken out in his amendment.

Mr. Helms. Mr. President, will the Senator identify the section to which he refers?

Mr. TUNNEY. Section 23(f) assures that the Administrator of EPA will assess the job impact resulting from the issuance of any rule or order under the Toxic Substances Control Act, and that is what the Senator from Kansas was referring to when he indicated that this is desirable from the point of view of industry, because we should not have an administrator issuing rules that could result in the layoffs of hundreds or maybe thousands of persons without evaluating that impact upon the workers and upon the community in which they work.

The Administrator also, under the provision, will in appropriate circumstances investigate allegations that employers are discriminat-

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intra-against employees as a result of any rule or order issued under the act.

I think that the Senator in his amendment is really referring to this portion of section 23(f). Section 23(f)(2) clearly states that the EPA will only investigate, hold a hearing on an employee's complaint, and make findings of fact.

Therefore, the Administrator is required to take this action if he believes that an employee complaint of alleged employment effects is

"because of the results of any rule or order issued under the act."

I might point out that the Administrator can hold a hearing, and make findings of fact and that is it. He can publicize the results of the hearings, but he cannot order the employer to reinstate the employee under subsection (f). I think that the manager of the company ought to take the heat that comes with public exposure of that kind of discrimination.

Mr. Helms. Mr. President, I ask for the yeas and nays.

Mr. Tuxxey. The yeas and nays have been ordered.

The Presiding Officer. All time is yielded back. The question is on agreeing to the amendment of the Senator from North Carolina. The yeas and nays have been ordered, and the clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. Robert C. Byrd. I announce that the Senator from Indiana (Mr. Bayh), the Senator from Texas (Mr. Bentsen), the Senator from Delaware (Mr. Biden), the Senator from Mississippi (Mr. Eastland), the Senator from Alaska (Mr. Gravel), the Senator from Michigan (Mr. Hart), the Senator from Colorado (Mr. Haskell), the Senator from Hawaii (Mr. Inouye), the Senator from Washington (Mr. Jackson), the Senator from Arkansas (Mr. McClellan), the Senator from Wyoming (Mr. McGee), the Senator from South Dakota (Mr. McGovern), the Senator from New Hampshire (Mr. McIntyre), the Senator from New Mexico (Mr. Montoya), the Senator from Utah (Mr. Moss), the Senator from Mississippi (Mr. Stennis), and the Senator from Missouri (Mr. Symington), are necessarily absent.

I also announce that the Senator from Vermont (Mr. Leahy), and the Senator from Louisiana (Mr. Long), are absent on official business.

I further announce that, if present and voting the Senator from Washington (Mr. Jackson), would vote "nay".

Mr. Tolson. I announce that the Senator from Tennessee (Mr. Brock), the Senator from Massachusetts (Mr. Brooke), the Senator from New York (Mr. Buckley), the Senator from Arizona (Mr. Fannin), the Senator from Arizona (Mr. Goldwater), the Senator from Michigan (Mr. Griffin), the Senator from Oregon (Mr. Hatfield), the Senator from Nebraska (Mr. Hruska), the Senator from Nevada (Mr. Laxalt), the Senator from Maryland (Mr. Mathias), the Senator from Pennsylvania (Mr. Hugh Scott), the Senator from Virginia (Mr. William L. Scott), the Senator from Vermont (Mr. Stafford),

and the Senator from Connecticut (Mr. Weicker), are necessarily absent.

I further announce that, if present and voting, the Senator from Oregon (Mr. Hatfield), and the Senator from Pennsylvania (Mr. Hugh Scott) , would each vote "nay."

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The result was announced - ^yeas 13, nays 54, as follows :

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Leahy

Stafford

Goldwater

Long

Stennis

Gravel

Mathias

Symington

Griffin

McClellan

Weicker

So Mr. Helms' amendment was rejected.

The Presiding Officer. The Senator from New Jersey is recognized.

Mr. Tunney. Mr. President, will the Senator yield? I ask for the yeas and nays on final passage.

The Presiding Officer. Is there a sufficient second? There is a sufficient second.

The yeas and nays were ordered.

Mr. Case. Mr. President, I have an amendment at the desk, on behalf of myself and my colleague. Senator Williams, and I ask that it be reported, but may it be reported in the form which I now hand to the desk.

The Presiding Officer. The clerk will report the amendment. The second assistant legislative clerk proceeded to read the amendment.

The amendment is as follows :

On page 93, between lines 8 and 9, insert the following new section :

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STATE DEMONSTRATION PROGRAMS

Sec 25(a). Establishment of Program. - The Administrator is authorized to assist no more than three states in establishing demonstration. Programs by such states to protect against unreasonable risks to health or the environment associated with chemical substances and mixtures. Such programs shall -

(A) identify and inventory chemical substances and mixtures within such

state, including their manufacture, processing, distribution, use, and disposal :

(B) monitor the extent to which such chemical substances or mixtures are present in the environment of any such state and the human exposure to such substances or mixtures within such state :

(C) establish a program to (1) prevent or eliminate unreasonable risks to health or the environment presented by chemical substances or mixtures
Hi) integrate the control of chemical substances and mixtures under this section with other programs of environmental and public health protection within such state so as to appropriately minimize the overall pollution of the environment within such state: and (iii) identify the appropriate governmental institutions and processes necessary to implement a program for the prevention of unreasonable risks to health or the environment presented by chemical substances and mixtures ;

(D) analyze and evaluate the results of such programs through annual reports to the Administrator ; and

(E) complement and in no way reduce Federal efforts under this Act in such state.

(b) Reports. – The Administrator shall submit a report to the appropriate committees of Congress not later than July 1 of each calendar year. Such report shall include (1) a description of progress with respect to programs assisted under this section and any suggestions for improvement in such program. (2) recommendations as to the manner by which programs within the states for the prevention of unreasonable risk to health or the environment presented by chemical substances may feasibly be implemented, and (3) the extent to which the Administrator has disseminated information regarding programs authorized under this section to other interested states and other persons.

(c) Authorization for Appropriations. – For the purposes of providing assistance under this section, there are hereby authorized to be appropriated not to exceed \$2,000,000 for the fiscal year ending September 30, 1977: \$2,000,000 for the fiscal year ending September 30, 1975, and \$2,000,000 for the fiscal year ending on September 30, 1970. Any funds appropriated under the authority of this subsection shall remain available until expended. Funds available under this section shall not be available for programs which would duplicate any authority or requirements of the Administrator under this Act, including sections 4, 5, 6 and 9(c). Funds available under the authority of this section shall support not more than 75 percent of the costs of any such program described under subsection (a) engaged in by the State .

(d) Priorities. – Assistance afforded under this section shall be available (subject to the requirements of subsection (a)) to those states which can establish a priority need for such assistance, as determined by the rules of the

Administrator. In establishing such rules, the Administrator shall consider the existence of serious health effects associated with chemical substances within such state including cancer, birth defects, and gene mutations : the extent to which chemical substances and mixtures are manufactured, processed, distributed in commerce, used and disposed of within such state : and the extent of exposure of human beings and the environment to chemical substances and mixtures within such State. The Administrator shall approve all such programs and establish a mechanism for monitoring such programs.

(e) DISCLAIMER.— Nothing contained in this section shall affect any provision of section 18 of this Act.

Mr. Case.]Mr. President, the amendment we propose would be of significant benefit in implementing the mandates of the Toxic Substances Control Act. It would enable selected States to develop demonstration programs to protect against unreasonable risks to health or the environment associated with chemical substances and mixtures.

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Through a demonstration program, States like New Jersey could obtain the data necessary to make reasoned decisions as to the dangers to humans resulting from exposure to toxic substances. It would also provide the basis for State management measures to be proposed in the demonstration States and elsewhere. Especially important, it would coordinate State programs with Federal programs, demonstrating methods to minimize the burden upon industry in the requirements for submission of information and data to the several levels of government that are involved in toxic and other environmental programs.

Our amendment would provide for State demonstration grants in no less than one, and no more than three States. The key elements of such State programs would be :

First, to identify and inventory chemical substances and mixtures in the State at various stages in their cycle of use ;

Second, to monitor the extent to which such chemical substances or mixtures are present in the environment of such State, and the extent to which human beings in that State are exposed to them ;

Third, to establish a State program that would prevent or eliminate unreasonable risks to health or the environment from chemical sub-

stances of mixtures, to integrate toxic substances management programs with other environmental and public health programs so as to minimize the overall pollution of the State's environment, and to identify the appropriate governmental institutions and processes necessary to implement such a program.

This point is of particular importance. For too long we have seen pollution control technologies which merely serve to transfer the problem from one medium to another – such as air pollution technologies which remove contaminants from the air and put them into the water cycle instead. This is hardly a solution.

Fourth, to analyze and evaluate the results of such programs through annual reports to the Administrator of EPA.

The Administrator of EPA, in turn, must submit annual report to the Congress on the progress of the demonstration projects, recommended ways for other States to implement toxic substances management programs, and recommend additional legislation if necessary. The Administrator's report must describe the extent to which he has disseminated the information derived from the demonstration programs to other interested States and persons.

This is not a demonstration program to be funded and then forgotten. EPA will be under a mandate to study, evaluate, and make known what has been learned from the demonstrations, so that others will benefit.

There is authorized for each fiscal year, 1977, 1978, and 1979, \$2 million, with the Federal share of the program not to exceed 75 percent.

There are explicit provisions that these funds will not be used to duplicate other requirements and programs. As I stated earlier, one of the primary objectives of this demonstration program is Federal-State coordination so as to minimize the burdens on industry.

Other amendment would give priority for grants under this section to those States where the problem of the effects of toxic substances are most acute. Specifically, the Administrator's project selection must

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consider: First, the existence of serious health effects associated with

chemical substances within such State, including cancer, birth defects, and gene mutations ; second, the extent to which chemical substances and mixtures are manufactured, processed, distributed in commerce, used and disposed of within such State ; and third, the extent of exposure of human beings and the environment to chemical substances and mixtures within such State.

Finally, this amendment assures that nothing in this new section increases or decreases the authorities of a State, as established under section 18, preemption.

New Jerseyans were shocked to learn earlier this year that our State has the highest rate of cancer in the country, not for one, but for all types of cancer. We were totally unprepared for this news.

We know that exposure to certain chemicals can cause cancer, but there remain many, too many, unanswered questions. We need to identify- these chemicals, find out what qualities of them pose a hazard, and - most important - we must find out what we can do to reduce the risk to New Jerseyans.

It seems to us that adoption of this amendment to the toxic substances bill would provide the means to find answers to these questions.

This amendment would be of great significance in helping our State and other States with similar problems to develop demonstration programs to protect against unreasonable risks to health or the environment associated with chemical substances and mixtures. It provides for demonstration programs with Federal participation jointly with the States. It authorizes \$2 million a year for 3 years, and the States must participate to the extent of 25 percent.

I understand that the amendment is agreeable to the minority and the majority.

Mr. Williams. Mr. President, I am pleased to join with Senator Case in offering this amendment to the Toxic Substances Control Act. The amendment would authorize the EPA to establish up to three State demonstration programs in selected States to complement the Federal toxic substances control program. The State programs would in no way reduce or replace Federal efforts to control toxic substances under the act. The demonstration programs would allow a State to inventory chemical substances within its borders and monitor the extent of human and environmental exposure to these substances.

The State would be required to integrate its program for controlling toxic substances with other State environmental and public health programs, and to coordinate its efforts with those of other levels of government.

ernment. By requiring the coordination of State and Federal efforts to control toxic substances, the amendment would help to reduce duplicative regulation. It would help to create greater stability of expectations in industry and end the arbitrary and often conflicting requirements imposed by various authorities which have adverse effects on investment decisions.

Senator Case and I represent a State where the need for such a program is manifest. New Jersey has both the highest concentration of chemical plants and the highest cancer death rate in the Nation. According to the National Cancer Institute, this is no coincidence. A study done by the National Cancer Institute found a high correlation between cancer deaths and densely concentrated industry. New Jer-

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sey's 21 counties were found to be in the top 10 percent of all counties in the Nation for the rate of cancer deaths. Salem County, N.J., where 25 percent of the males work in the chemical industry, has the Nation's highest rate of bladder cancer - an occupational disease associated with chemical exposure. These figures are no less than alarming. This legislation and this amendment together address this critical matter in a comprehensive and coordinated way.

The immediate need at the State level is to begin to determine the types and quantities of toxic substances already present in the environment. This cannot be done with the monitoring systems already in place. EPA would collect the data on various chemical substances, but it would be up to the State to follow these substances through the circle of their use - manufacture, processing, distribution, use, and disposal. While the amendment will not give the States any authority to regulate workplace exposures or duplicate any authority under the Occupational Safety and Health Act, information gathered under the amendment could complement Federal efforts under OSHA.

Like most other States, New Jersey now has an extensive monitoring network in both air and water. These systems are designed to monitor the air and water for so-called classical pollutants. This network is the major method by which New Jersey's Department of Environmental Protection has been able to define the extent of the State's environmental problems, as well as improvements in environmental quality.

But for toxic substances, new monitoring stations must be estab-

lished according to different criteria, and analytical techniques must be utilized which are much more complex and time-consuming than those currently utilized.

The results of such a State demonstration program would be evaluated at both the State and Federal level and would be used as a model for other States to build their own programs.

The final result of such a demonstration program, it is hoped, would be to reduce the rate and prevalence of cancer and other environmentally related diseases.

Mr. TuNNEY. I am authorized by my distinguished friend from Kansas (Mr. Pearson) to indicate that this amendment is acceptable to both the minority and the majority on the committee. This is an amendment that will allow States the leeway in certain circumstances to structure programs to meet particularly acute local and regional problems and, therefore, I am prepared to yield back the remainder of my time.

The Presiding Officer. All time yielded back. The question is on agreeing to the amendment of the Senator from New Jersey. The amendment was agreed to.

Mr. Case. Mr. President, I move to reconsider the vote by which the amendment was agreed to.

Mr. TuNNEY. I move to lay that motion on the table. The motion to lay on the table was agreed to.

Mr. Allen. Mr. President, I call up an amendment which I have at the desk.

The Presiding Officer. The amendment will be stated. The second assistant legislative clerk proceeded to read the amendment.

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The amendment is as follows :

On page 9, line 2, [Sec 3], after the period add the following :

"(15) The term 'unreasonable adverse effects on the environment' means any

unreasonable risk to man or to the environment taking into account the economic social, and environmental costs and benefits of the use of any chemical substance."

On page 52, line 5, strike out all after the word "show" down to and including the period at the end of line 11 on page 52 and substitute in lieu thereof the following : "that a situation exists in which the continued use of a chemical substance would be likely to result in unreasonable adverse effects on the environment or will involve an unreasonable hazard to the survival of a species declared endangered by the Secretary of the Interior under Public Law 91-135."

Mr. Allen. Mr. President, the amendment I have introduced is designed to provide the Administrator of the Environmental Protection Agency with the same definition of "imminent hazard" and "unreasonable adverse effects" in the Toxic Substances Control Act as are contained in the existing law which regulates the testing and registration of pesticides, the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, Public Law 92-516 and Public Law 94-140. My amendment does not in any way weaken the ability of the Administrator to restrict the use of toxic chemical substances but it would provide the consistency needed for even-handed administration of two laws, both of which would have the same intent and both of which would regulate in most instances the same industries and essentially the same subject matter.

Mr. President, when the legislation which led to the Federal Insecticide, Fungicide, and Rodenticide Act was first introduced in the Senate, it was referred jointly to the Senate Committee on Commerce and to the Senate Committee on Agriculture and Forestry. This joint referral evidenced the dual jurisdiction which exists with respect to legislation affecting the chemical industry. I would remind Senators in this connection that Senate rule XXV 1(b) specifies that all proposed legislation relating to "agricultural and industrial chemistry" shall be referred to the Committee on Agriculture and Forestry. Although no similar language is contained in rule XXV 1(f) which sets forth the jurisdiction of the Senate Committee on Commerce, very properly committee jurisdiction over the legislation which led to the enactment of the Federal Insecticide, Fungicide, and Rodenticide Act was shared with the Committee on Commerce. Mr. President, regrettably such was not the case in the present instance. Had committee jurisdiction over toxic substance control legislation been likewise shared. I am confident the inconsistencies between the bill reported by the Senate Committee on Commerce and existing laws could have been eliminated without the necessity of extensive floor amendment.

Mr. President, I believe it is vitally important that S. 3149, the Toxic Substance Control Act, if enacted, be consistent with existing law in the standards to be used by the Administrator and his staff in

administer in the law regulating the use of chemicals. The administrator and his staff have had the opportunity[^] to apply the existing standards contained in the Federal Insecticide, Fungicide, and Rodenticide Act in actions taken by the Agency in regulating the registration and use of pesticides. It would not seem prudent or logical for the Agency, which would be responsible for the administration of two separate laws governing toxic chemicals, to be saddled with conflicting language in the two laws.

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I recently had occasion to preside at 4 days of hearings before the Senate Subcommittee on Agricultural Research and General Legislation of the Senate Committee on Agriculture and Forestry during the course of that subcommittee's investigation of the kepone contamination of the James Kiver in the vicinity of Hopewell, Va. During those hearings I became somewhat familiar with the composition and use of the pesticide kepone. It should be no revelation that toxic chemicals are used as components of agricultural poisons, such as kepone, or that pesticides are themselves often components of toxic substances which are manufactured for entirely different uses. The questions at issue in examining the use or registration of pesticides, fungicides, and rodenticides, therefore, differ little if at all from those posed with respect to other toxic substances.

Many manufacturers who are producing pesticides are also producing other toxic chemical compounds, and it would be confusing and frustrating for a manufacturer of chemical substances to be subjected to two different standards or requirements. For example, any chemical or toxic substance would first be subject to the provisions of this act, and yet when it becomes a component of a pesticide, it would be subject to FIFRA. In many instances, the manufacturer of the component is also the manufacturer and registrant of the pesticide. It is unreasonable to expect either the Administrator or the manufacturer to carry out properly their responsibilities in the presence of conflicting legislative language regulating chemical substances.

Throughout the bill, numerous references are made to "unreasonable risk" without providing a definition of the term. The term is also used in connection with other qualifying phrases which have dissimilar connotations and which could create problems and confusion in the administration of the two statutes. These phrases include:

"Cause or contribute to an unreasonable risk of injury to health or

the environment'" ; "present an unreasonable risk to human health and the environment"; and "is likely to present an unreasonable risk to health or the environment."

My amendment would provide that, whenever the term "unreasonable risk" is used it will be in accord with the meaning of "unreasonable adverse effects" as defined in my amendment and as defined in the Federal Insecticide, Fungicide, and Rodenticide Act. Similarly, and for the same reasons, the definition of "imminent hazard" is brought in line with the definition of that term in the Federal Insecticide, Fungicide, and Rodenticide Act.

Mr. President, I am convinced that consistency is a desirable goal in the regulation of the use of chemical substances. Since my amendment would not in any way weaken the Administrator's authority in regulating those uses, I urge that the amendment be adopted.

Mr. President, the rules state, specifically rule XXY states, that all legislation relating to agriculture and agricultural chemistry should be within the jurisdiction of the Agriculture Committee. To that end legislation having to do with FIFRA, the Federal Insecticide, Fungicide, and Rodenticide Act, having to do with pesticide legislation has always gone to the Agriculture Committee.

This bill, however, was not referred jointly to the Commerce and Agriculture Committees. I believe that the Agriculture Committee, if it had had the bill referred to it, would have made as its main con-

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tribution the reconciling of the rules with respect to the application of the rules governing the toxic substances to the FIFRA legislation so that the EPA, in administering two a very closely related acts, would not have different definitions in connection with their enforcement.

All this amendment does is to conform the definitions in the toxic substances bill to the established definitions under the FIFRA legislation which has served the EPA well and under which it now operates.

I believe the amendment is satisfactory to the manager of the bill. I have discussed it with him, and I am hopeful that he will endorse the amendment

Mr. Tux NET. The Senator from Alabama has, in my view, stated the

situation correctly, that his amendment is merely an amendment which makes the language in this legislation conform with the Pesticides Control Act as it relates to the imminent hazards, and I think it is important that we do have on the statute books language such as the Senator from Alabama has suggested.

Mr. Talmadgk. I commend the Senator from Alabama for introducing his amendment, and I commend the distinguished manager and his counterpart, the Senator from Kansas, for accepting it. I think it is important to have toxic substances and pesticides measured by the same yardstick. That is what the Senator's amendment would do.

Mr. TuNNEY. I thank my friend from Georgia, and I agree with his statement. I think we should have the same yardstick in various statutes.

Mr. Pearson. Mr. President, we find the amendment conforming and we accept it.

The Pr?:sii)ing Officer. The question is on agreeing to the amendment of the Senator from Alabama.
The amendment was agreed to.

Mr. Nelson. INfr. President, I send an amendment to the desk and ask for its immediate consideration.

The Presiding Officer. The clerk will report the amendment.

The second assistant legislative clerk proceeded to read the amendment.

The amendment is as follows :

On page 64, line 13 [Sec 10], insert immediately after the period, "In accordance with s\uh responsibilities, the Administrator shall undertake and supi)ort programs of research and monitoring of polyehlorinated biphenyls to the extent necessary to develop safe methods of disjjosal of polyehlorinated biphenyls and for the control of risks of injury to health or the environment associated with poly-chh)rinated biphenyls,"

On page 52, between lines 2 and 3 [Sec. 6], insert the following new subsection :

"(e) I'oLYCiiLORiNATED BIPHENYLS. (1) Effective 1 year after the date of enactment of this Act, it shall be unlawful to manufacture, process, distribute in connerce. or use any polyehlorinated biphenyl in any manner other than in a totally enclosed manner, except that the Administrator may, by rule promulgated in accordance with subsection (o){2), authorize the manufacture, proc-

essing, distribution in commerce, or use of any polychlorinated biphenyl in other than a totally enclosed manner if the Administrator finds that no unreasonable risk of injury to health or the environment is presented.

"(2) Effective 2 years after the date of enactment of this Act, it shall be unlawful to manufacture any polychlorinated biphenyl, and effective 2 1/2 years after such date, it shall be unlawful to process or distribute in commerce any polychlorinated biphenyl, except that the Administrator may authorize, by rule promulgated in accordance with subsection (c) (2), such manufacture, processing,

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or distribution in commerce after such time period if the Administrator finds that no unreasonable risk of injury to health or the environment is presented.

"(3) Within 6 months after the date of enactment of this Act, the Administrator shall promulgate rules under subsection (a) which shall (A) prescribe methods for the disposal of polychlorinated biphenyls in accordance with the requirements of that subsection and (B) specify the manner in which polychlorinated biphenyls shall be marked with clear and adequate warnings and instructions with respect to their processing, distribution in commerce, use, or disposal. Any such rules shall be consistent with the requirements of paragraphs (1) and (2) of this subsection or rules issued thereunder.

"(4) For the purposes of this subsection, the term 'totally enclosed manner' means any manner which will ensure that any leakage of a polychlorinated biphenyl from its enclosure will be insignificant, as defined in rules of the Administrator."

On page 71, line 13 [Sec. 151, immediately following "5" insert "or 6."

Mr. Nelson. Mr. President, this amendment provides over a period of time the elimination of the use in open or closed systems of PCB's, polychlorinated biphenyls, unless the EPA administrator finds that there is not a serious health hazard.

He also has to weigh, of course, under the provisions of the statute, the question of cost-benefit ratio.

It is my understanding that the manager of the bill and Senator

Pearson are acquainted with the proposed amendment and find it acceptable.

Mr. President, it has become clear that PCB's present a serious pollution problem.

Therefore, I am offering this amendment.

First. It bans the manufacture, processing, distribution and use of nonenclosed PCB's 1 year after enactment, unless the Administrator of the Environmental Protection Agency - EPA - finds there is no unreasonable risk of injury to health or environment from continuing such uses. These include: uses in carbonless paper, paints, coatings, soaps, and copying ink toners.

Second. The manufacture of all PCB's would be banned effective 2 years from the date of enactment ; and the processing and distribution of all PCB's would be banned 6 months after that- 2 1/2 years after enactment - unless the administrator finds that no reasonable risk of injury to health or the environment is presented by PCB's. This would effectively ban all PCB use, including closed uses, such as in electrical capacitors and transformers.

Third. Within 6 months after enactment, EPA is required to issue regulations for the first, disposal of PCB's and second, labelling Avith warnings and instructions of all products containing PCB's with respect to their use and disposal.

Fourth. The amendment defines "totally enclosed manner" so as to insure that "any leakage of a PCB from its enclosure will be insignificant, as defined in rules" by EPA.

All imported PCB's would be subject to the same restrictions.

This amendment is patterned after one that I introduced on December 19, 1975, which Senator Bumpers joined in sponsoring.

Under the. amendment, the continued use of PCB's would be allowed if the EPA Administrator finds that "no unreasonable risk of injury to health or the environment" exists. In making such a finding, it is implicit that consideration be given to the availability of substitutes for PCB's, presumably having less risk.

In addition, to the extent that PCB's continue to be authorized for use, it is assumed that EPA will regulate any recycling of them.

Mr. President, scientific evidence makes it imperative that we no longer wait to regulate and eliminate this toxic substance. The risks to human health and the environment appear to exceed the benefits of these substances, which, like DDT, are not readily biodegradable and tend to accumulate in the food chain.

According to a report on PCB's prepared by the Legislative Research Service, Library of Congress :

PCBs have been used extensively in industry for a variety of applications for 45 years. Until the mid Sixties, it was not fully recognized that large amounts of PCBs were escaping into the environment and that the substance might cause hazard to human health and the environment. High levels of PCBs are now found in carnivorous fish taken from the Great Lakes and some other areas. Levels are so high, in fact, that serious doubts have been raised over the safety of humans consuming these fish. Sports fishing programs, such as the Coho Salmon restocking projects in the Great Lakes and the commercial fishing industry in these areas are at stake. PCBs are found at low levels in human adipose tissue in all parts of the country, illustrating how pervasive and widespread the pollution has become.

"Although Monsanto, the sole United States producer of PCBs, has voluntarily limited PCB sale to a few companies for use in electrical closed systems, the problem of more PCBs entering the environment through these routes, from existing equipment containing PCBs, and from imported stocks, still exists. It has been suggested that PCB use be totally eliminated in the United States, or alternately, that its use be more tightly controlled.

The Library report further notes :

The possibility of adverse effects upon human health from PCBs was highlighted in October of 1968. In the Fukuoka prefecture in western Japan, accidental contamination by PCBs of edible rice-bran oil caused an outbreak of toxic symptoms, the "Yusho" poisoning incident. Soon afterward, PCBs were detected by the U.S. Food and Drug Administration (FDA) in milk, poultry, and other foods due to accidental leakage of PCBs from machines and PCB food packaging made from recycled paper, and in fish exposed to PCBs in the environment.

Action (tolerance) levels for PCB contamination of food, feed, and food packaging were established by FDA. The EPA initiated a test program and monitoring of PCB levels in the environment and proposed regulations governing the discharge of PCBs into waterways as an industrial effluent (under the Clean Water Act). Meanwhile, on the state level, actions were taken against point source discharges of PCBs.

The widespread occurrence of PCBs in the environment, the bioaccumulation of PCB in the food chain of fish found in the human diet, and the persistence of the chemical compounds assure that PCB environmental contamination will continue to be a problem for many years to come.

Here are the facts :

PCBs have been found, in scientific tests, to cause severe skin and liver problems in humans. University of Wisconsin Medical School researchers Dr. James R. Allen and Deborah Barsotti. have demonstrated that very low PCB levels are dangerous to primates, causing facial swelling, loss of hair, acne lesions within one month, birth defects, miscarriages, stillbirths, and death.

A 1972 report by a Federal interdepartmental task force urged a ban on all PCB uses except in closed electrical systems, restricting them to "essential or nonreplaceable uses which involve minimum direct human exposure, since they can have adverse effects on human health."

The commercial fishing industry in the Great Lakes and elsewhere are threatened with extinction, unless the PCB problem can be alleviated or eliminated. Thousands of pounds of Great Lakes fish have been condemned as unsafe because of PCB contamination, and New York State conservation officials warn against eating Hudson River fish.

Water supplies throughout the Nation are contaminated far in excess of safe drinking criteria.

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There has not been adequate monitoring of the extent of the pollution, nor of the sources of the pollution.

At least 10 million pounds of PCBs are lost into the environment each year through vaporization, leaks, and spills, according to estimates reported by Thomas E. Kopp, a chemist with the EPA's Office of Toxic Substances.

At least 10 plants are dumping PCBs into U.S. waterways and another two are discharging the chemicals in municipal sewage treatment systems, according to the EPA.

PCBs have been banned for most uses in Japan – after the 1968 poisoning of more than 1,000 persons who had eaten PCB-tainted rice cooking oil.

Alternatives have been instituted in Japan, and are being developed in the

United States. For example, air-filled transformers have been used for years instead of PCB-filled transformers.

Use of alternatives to PCBs may require retooling and redesigning of some electrical products and equipment which now use PCBs.

PCBs are used in about 5% of all transformers and in almost all industrial capacitors in the United States.

PCBs can be destroyed in special incinerators at very high temperatures.

PCBs can be recycled.

There is no dispute over their toxicity to wildlife and to humans.

This amendment would allow time for the phasing out of the manufacture and use of PCB's over years.

It is preferable not to enact legislation on a substance-by-substance basis but rather generically, as the Toxic Substances bill proposes to do. However, the PCB problem shows no sign of abating and it has become so severe that it is necessary to address the problem head on, as we were forced to do with DDT.

Mr. President, I ask unanimous consent to have printed in the Record three articles illustrating the extent of the problem and the commercial impact on the Great Lakes fishing industry as well as in New York State, as a result of PCB pollution in the Hudson River and Lake Ontario.

There being no objection, the articles were ordered to be printed in the Record, as follows :

[From Wisconsin Natural Resources, January/February 1976]

Sources of Polychlorinated Biphenyls in Wisconsin

Wisconsin's interest in PCBs began in the late 1960's when interfering substances were detected in fish being tested for DDT. Later we were to learn these interfering substances were PCBs.

In 1970, the Department collected fish samples along the Mississippi River bordering Wisconsin. Analysis revealed that between Prescott and Pepin fish commonly exceeded the Food and Drug Administration (FDA) tolerance level of 5 parts per million (ppm). During 1971, Lake Michigan fish were collected and later tested. Mean concentrations of PCBs in these fish ranged from 2.7 ppm in smelt to 15 ppm in lake trout. Subsequent studies confirmed the presence of PCBs in fish in Lake Michigan and other waters of Wisconsin.

The search for PCBs in water was also underway at this time. An analysis of water from the Milwaukee River indicated that PCBs were present from West Bend to Lake Michigan and being discharged through municipal and industrial effluents. In 1971, eleven municipal wastewater treatment plant effluents in Wisconsin were sampled and nine contained PCBs. Studies of the Cedarburg wastewater treatment plant indicated that more than 70 percent of the PCBs coming into the plant were removed during the treatment process and comparatively high concentrations were found in the digester and primary settling sludges.

The Department surveyed many municipal wastewater treatment plan effluents in Wisconsin from 1972 through 1974. PCBs were detected in concentrations exceeding .05 parts per billion (ppb) in more than half of those tested even where there were no suspected industrial sources. In most cases, the discharge was well below 1 ppb and .01 ponds per day. However, higher concentrations were found in effluents from industrial areas.

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Tracing sources of PCBs reaching a large municipal wastewater treatment plant is difficult and time consuming. The Department is attempting to trace sources of PCBs reaching treatment systems where the final effluent exceeds 1 ppb. At present we know of only two municipal wastewater treatment plants in Wisconsin which exceed 1 ppb - Sheboygan and Portage.

Main source of PCBs at Portage was found to be a facility that had used PCBs in the manufacture of carbonless copy papers prior to the summer of 1971. After ceasing the use and after repeated cleanings of holding tanks the discharge was substantially reduced. Residuals still remain, however, in the sewer system and the sewer sludges, resulting in an effluent of several ppb at the municipal sewage treatment plant. We are continuing to check sources of discharge at Sheboygan.

The Department has checked effluents from iron and steel foundries and aluminum foundries. Cooling water effluents from five of seven aluminum foundries contained PCBs ranging from 11.5 to 335 ppb. Close investigation revealed the common source to be leaking hydraulic fluids used in die cast machines. We are working with company officials to correct this. PCBs have been found in the cooling water effluent of only one of nine iron and steel foundries checked to date and that at a concentration of .9 ppb.

DNR has tested effluents of 17 pulp and paper mills. Nine mills which recycle wastepapers had measurable discharges ranging from .1 to more than 25 ppb. Mill representatives indicate that the paper industry no longer uses PCBs and those found in wastepapers come primarily from carbonless copy papers which

were produced prior to 1972. The old carbonless copy papers were widely used in forms and continue to enter the wastepaper market as old files are discarded. Because their solubility in water is low, we believe that most of the PCBs discharged from wastepaper mills are absorbed on fibers and other particulate matter. Mill wastewater treatment systems which effectively remove particulate matter should also remove PCBs.

The electrical industry continues to use PCBs as dielectric fluids in some capacitors and transformers. Although the units are sealed some fluids may be lost as a result of accidents or disposal practices. In March 1975, the Department corresponded with major electrical companies in Wisconsin to determine current handling practices. This was followed by visits to many facilities. The companies contacted were aware of the problems, but some were not aware of recommended Guidelines of the American National Standards Institute for handling and disposal. We also found that some were storing defective capacitors until a proper disposal method could be found. As a result specific guidance was given to Wisconsin electric utilities for the proper handling and disposal.

Snow samples were collected early in 1975 to determine if PCBs were deposited on land and water as fallout from the air. Analysis of snow melt water from Racine, Kenosha, Madison and Milwaukee revealed concentrations from .17 to .24 ppb. These values suggest that fallout of PCBs from the air may be a principal source of PCBs entering the waters of the state.

PCBs are present in sediments in harbors and streams near industrial areas. The sediments act as a reservoir from which PCBs may be released slowly over a long period of time. Sediment samples have tested 3.5 ppm in the Milwaukee River near the Capitol Drive Bridge, 9 ppm in Superior Harbor, and 72 ppm in the Fox River below the outfall of the Portage sewage treatment plant.

We have tried to work out a materials balance for PCBs entering the environment using the domestic sales figures provided by the Monsanto Company and other data. So many pieces are missing from the puzzle, however, that these efforts have been unsuccessful. However, some general comments can be made.

1. PCBs have been sold by the Monsanto Company for more than 45 years. The company reported domestic sales of 795 million pounds from 1957 through 1974. In 1974 Monsanto's domestic sales were reported to be 34 million pounds for use in closed electrical systems. In addition, the Office of Toxic Substances EPA has reported that foreign sales of PCBs in the United States in 1974 exceeded 375,000.

2. The PCB problem in Wisconsin is a fishery problem caused because residues have accumulated in certain fish in Green Bay and Lake Michigan and the Upper Mississippi River in excess of the FDA tolerance level of 5 ppm. Laboratory experiments have shown that fish accumulate PCBs more than 100,000 times levels present in the water. Therefore, even parts per trillion (ppt) levels have significance to the fishery resource.

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3. Our data indicates that levels of PCBs in fish in the Upper Mississippi River have declined in recent years. We have not detected a corresponding decline in levels in Lake Michigan fish.

If Lake Michigan water contains an average of 10 ppt PCB then there are more than 100,000 pounds in solution and probably a much larger poundage in the sediments. We have tested the major effluents of both municipalities and industries discharging to the Lake Michigan drainage in Wisconsin and estimate a discharge of about two pounds per day or 730 pounds of PCBs per year to Wisconsin's drainage to Lake Michigan. Most PCBs identified in our testing of major effluents occur in the wastewaters of pulp and paper mills which recycle wastepapers.

Discharges of PCBs from pulp and paper mills, which recycle wastepapers, will diminish as the mills meet discharge permit requirements. Wisconsin mills which recycle wastepapers are required to reduce discharge of suspended solids from 131,000 pound per day (for calendar year 1973) to 45,000 pound per day by the 1977 compliance date. Recently one mill in the state, which uses only recycled paper, began a new treatment system that has reduced the discharge of suspended solids from 40,000 pounds per day to 3,000 pounds. Tests at this facility revealed 39 ppb PCB entering the treatment system with only 1 ppb being discharged in the final effluent.

4. In our search for sources of PCBs entering the environment, we have not looked closely enough at fallout from the air. Our testing of snow melt suggests that fallout may be contributing much greater amounts of PCBs than are being contributed by industrial and municipal effluents. Trace concentrations in fallout over Lake Michigan and its watershed which cover 67,900 square miles could result in appreciable amounts entering Lake Michigan.

Because PCBs are stable compounds with low vapor pressures, little loss is expected to occur through vaporization from disposal sites where capacitors and other equipment and materials have been disposed and covered with overburden. Entry into the air may be expected to occur at locations where papers are incinerated, at foundries where imported casting waxes containing PCBs are heated to high temperatures and at manufacturing facilities. PCBs adsorbed on fine particulate matter may also be entering the air as windblown dust.

5. Further information is needed to define the amount contributed to Lake Michigan and other waters through past accumulation in sediment. A University of Wisconsin study is currently underway in Southern Lake Michigan, which

should provide some answers.

DNR does not have the authority to regulate the sale or use of PCBs, but can adopt affluent standards.

In December the Natural Resources Board voted to severely limit PCB discharge. This action will be reviewed by the state legislature before it can become effective. The board also proposed legislation that would limit the sale and use of PCB's in Wisconsin.

[From Bulletin of the Lake Michigan Federation, January-February 1976]
PCBs Cost Jobs, Too
(By Elizabeth Botts)

Consumers aren't the only victims of PCB contamination in Great Lakes fish and waters. Fishermen had their livelihoods abruptly cut off when the Food and Drug Administration issued a ban on their contaminated produce last August. A group from Green Bay, Wisconsin, reported to the Federation that they plan to make their grievances publicly known.

Mrs. James Hermes, of Green Bay, wrote to the Federation last October to ask for help in stopping the sources of PCB pollution in her area. "As long as little is done to stop the source, not merely the result," wrote Mrs. Hermes, "many more will suffer."

But stopping the sources is a generous impulse that will help others, nor the Hermes family. "If PCB discharge is stopped, then how do we clean up the existing poison they have left with us?" she asked. "I'm sure the industries won't volunteer. They have gotten rich at everyone's expense but their own.

Although there is growing concern in various government agencies on the effects of PCBs, the FDA is presently the only Federal agency with authority over their use, and can only ban contaminated wildlife that are harvested and proc-

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essed for food consumption. That's why the Hermes' fisheries and other small fishing businesses like them were the only ones to suffer a federal injunction against their fishing activities. The sources of the Lakes' PCBs. e.g.. paper-recycling mills, are free from penalties.

The Hermes are fourth-generation commercial fishermen. Ever since Jim

Hermes' great-grandfather came to Wisconsin from Germany, before the turn of the century, the family has been sailing out of Green Bay. Now there are two Hermes fisheries. Jane and Jim Hermes caught Lake Michigan carp and shipped them to Missouri as stock for private and municipal fishing ponds in and around St. Louis. Jim's cousin, Lee, and his wife, Glory, sold to canneries around Green Bay. Then, without warning, both groups were ordered to stop working.

Not only could they not sell their fish, the St. Louis municipal authorities had to poison all species of fish in the city's private and public fishing ponds to be sure of removing the Hermes carp.

Lee Botts, then Federation Director, responded to Mrs. Hermes appeal, by arranging for both Hermes families to attend the National Technical Conference on PCBs organized by the EPA and other Federal agencies and held in Chicago last November. They told their story at the conference and on WGN-TV, pointing out that even if a ban were imposed immediately it would be years before PCB levels in fish went down enough to permit harvesting.

Things don't look good for the Hermes family. "We don't know what we're going to do," says Mrs. Hermes. "My husband and his cousin are going to try to work on some of the inland lakes where the PCB levels are low, but there aren't a lot of fish there. I don't know what will happen." Jane and Jim have four children and Lee and Glory have seven, so "it's quite a large family to lose their livelihood."

The Hermes fisheries and others in the Green Bay area tried to get themselves declared a disaster area so they would qualify for Small Business Administration loans, but the request was denied.

The Wisconsin Department of Natural Resources doesn't have a lot of help for the Hermes either. According to Ron Poff, of the Great Lakes fishing section of the DNR, the Wisconsin Natural Resources Board had decided to call for stiff discharge limits and to draft legislation for a total ban on manufacture and sale of PCBs, but neither of these measures - if they are carried out - will be effective until 1977. There are powerful interests, including the Wisconsin Paper Council, who can be expected to oppose them. "Considering what paper means in Wisconsin," Poff says, "it's pretty substantial action. And it's the only action we can legally take."

The only immediate help the DNR can offer to Green Bay fishermen is to look for areas where levels may be low enough to allow harvesting. Poff says a few fisheries are already back at work on the Bay's far western edge.

Still, it's probably too late for the Hermes, though Mrs. Hermes hasn't lost her anger or her determination. She's circulating a petition calling for a ban on PCB discharge, and hopes that this is one issue on which the sports and commercial fishermen of Lake Michigan can get together.

The Hermes have retained a lawyer and are investigating the possibility of a lawsuit, but "there are so many dumping we wouldn't know where to start " And despite her hopelessness over her own situation, Mrs. Hermes still believes that something can be done about PCBs in Lake Michigan.

"It's too late for us," she says now, "but maybe it won't be too late for some others.

[From the American Medical News. Mar. 5. 1976]
PCB Discovery Leads to Fish Ban

Polychlorinated biphenyls (PCBs) from industrial pollution have contaminated fish in the Hudson River and Lake Ontario. As a result, New York State has banned commercial fishing in the Hudson, and advised sportsfishermen to restrict their consumption of fish caught in these waters. The ban does not include shad ; analysis of these fish have shown low PCB levels.

The FDA has set a ceiling of 5 parts per million (ppm) as the limit of PCB permissible in fish to be consumed by humans. PCBs cause an acne-like skin eruption, pigmentation of the skin and nails, excessive eye discharge, and swelling of the eyelids.

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FDA has found PCB levels as high as 31.3 ppm in fish caught in the Hudson and 24.6 ppm for salmon from Lake Ontario.

Mr. TUNNEY. Mr. President, I have had the opportunity to look at this amendment. It was submitted by the Senator from Wisconsin yesterday. I commend him in his efforts to control the hazards associated with the PCB's. We know how dangerous they can be.

I think the Senator's amendment strengthens the legislation and I am prepared to accept it for both minority and majority on the Commerce Committee.

Mr. President, I commend the distinguished Senator from Wisconsin on his efforts to control the hazards associated with PCB's. PCB's have long been of concern to the Committee on Commerce as evidenced by hearings held on the subject by the Subcommittee on the Environment last October 24.

Those hearings documented the fact that despite assurances from the sole domestic manufacturer of PCB's, they are still escaping into the environment in awesome quantities, in fact some 10 million pounds per year. Although an agreement several years ago by the Monsanto Co. supposedly restricted PCB's use to closed systems, ^Monsanto obviously has no control over those to whom it sells PCB's nor does Monsanto have any control over those who import PCB's. Thus, PCB's are still being used for nonclosed system uses.

At the same time, PCB's have been shown to cause cancer in one study, and to interfere with reproduction.

In my view, the amendment of the Senator from Wisconsin is indeed appropriate. It phases PCB's out by eliminating nonclosed system uses within 1 year and eliminating PCB's altogether within 2 years. There are mechanisms for authorizing uses of PCB's beyond these time limits should that be appropriate so that we do not create worse problems than those we solve.

In my view, the amendment is a fine addition to the bill, and I urge its adoption.

The Presiding Officer. The question is on agreeing to the amendment of the Senator from Wisconsin.
The agreement was agreed to.

Mr. Cancox. Mr. President, I send an amendment to the desk and ask for its immediate consideration.

The Presiding Officer. The amendment will be stated.
The second assistant legislative clerk read as follows :

The Senator from Nevada (Mr. Cannon) proposes an amendment :
On page 36, line 17, [Sec. 6(a)(1)], insert the following:

After the word "risk," insert a comma and the words "using the least burdensome effective controls."

Mr. Cancox. Mr. President, I ask unanimous consent that Senator Johnston be included as a cosponsor.

The Presiding Officer. Without objection, it is so ordered.

Mr. Cancox. Mr. President, this is simply a clarifying amendment to be sure that the administrator does use the least burdensome effective procedure. I hope the Senator will be willing to accept it.

Mr. Beall. Mr. President, I rise to support S. 3149, the Toxic Sub-

stances Control Act, and hope that the Senate will give its overwhelming endorsement to this measure.

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Twice before, in 1972 and 1973, the Senate passed toxic substances legislation, only to be frustrated in our efforts to reach agreement with the House of Representatives on this matter. This year, however, indications are that chances for Senate-House agreement are good, and thus we will be able to place a strong toxic substances bill on the President's desk prior to adjournment of the 94th Congress.

I can think of no more persuasive argument in favor of this legislation than the stories which have appeared almost daily in the press regarding the serious chemical hazards now present in our environment. In recent months, we in this country have become painfully aware of the catastrophic long-term effects that such chemicals as kepone, vinyl chloride, mercury, and PCB's may have on humans. In fact, approximately 1,000 new chemicals are marketed each year, to find their way into our environment. These chemicals need to be pre-tested before they enter the market, and this bill accomplishes that purpose in a reasonable and responsible manner.

The committee has also made great efforts in this legislation to balance the health needs of our people with economic realities. Throughout the bill, the Administrator of the Environmental Protection Agency is required to fully consider the reasonably ascertainable economic effects of his actions and publish them for the public record.

Mr. President, the terrible effects of toxic chemicals are often not evident until many years after initial exposure. Russell Train, Administrator of the EPA, recently pointed out that Americans were, without either their knowledge or consent, often engaging in a grim game of chemical roulette. This legislation seeks to end that game, which can have no winners, and I urge the Senate to give its strong support to this much-needed and long-awaited legislation.

Mr. President, I have had an opportunity to review the amendment that is being offered by the Senator from Nevada and I would like to ask him a question with respect to it.

If the Senator's amendment is agreed to and is made a part of the law, unreasonable risks must still be prevented and protected against, must they not?

Mr. Caxnox. Is the Senator talking about the amendment we just acted upon or the other amendment we are considering ?

Mr. TuNNEY. I am talking about the amendment the Senator offered, after the word "risk," insert a comma and the words "using the least burdensome of effective controls."

The Presiding Officer. The Chair advises the Senator, that is the pending amendment, it is now pending.

Mr. Caxxon. Yes; the answer to the Senator's question is "Yes."

Mr. TuNXXY. Fine.

Then under those circumstances. I do not see any reason at all that this amendment should not be accepted. I feel that as long as it is very clear in the Record that unreasonable risks must still be prevented under the regulatory framework, certainly it would be important to use the least burdensome of effective controls to effectuate that desired result.

So I accept the amendment.

Mr. Pearson'. Mr. President, it is my understanding the effective control is still the essentiality of what the Administrator will do.

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Mr. Cannon. Yes.

Mr. Pearson. And this amendment just seeks the least burdensome procedure to get there ?

Mr. Cannon. The Senator is correct.

Mr. Pearson. I find it acceptable.

Mr. Cannon. We do not want to give the Administrator unlimited authority and let him say, "I will impose this control," if there are other controls that are effective and are less burdensome on the industry.

That is really what is intended.

The Presiding Officer. The question is on agreeing to the amendment.

The amendment was agreed to.

Mr. Cannon. Mr. President, I send an amendment to the desk and ask for its immediate consideration.

The Presiding Officer. The amendment will be stated.
The second assistant legislative clerk read as follows :

The Senator from Nevada (Mr. Cannon) for himself, Senator Laxalt, and Senator Johnston proposes an amendment :

On page 5, line 2, [Sec. 6(d)(2)] after "(3) insert "in those situations where compliance with the requirements of subsection (c) (2) or (3) would present an unreasonable risk of death, serious or substantial personal injury (including illness) or serious or substantial environmental harm."

Mr. Cannon. Mr. President, in the Commerce Committee several members expressed concern that a provision in the bill authorizing the Administrator to make rules regulating chemical substances immediately effective was too broad. Efforts were made to narrow that authority to those situations where the public interest required, and an existing provision in the Administrative Procedure Act was referenced.

Unfortunately, the language in the APA is somewhat ambiguous and could be interpreted to permit the EPA Administrator to waive the due process requirements of the rulemaking provisions at whim. That certainly was not the intent.

Therefore, this amendment that is submitted is perfecting the language of section 6(d)(2) of the bill.

The perfecting language prohibits the Administrator from waiving the due process requirements of section 6 rulemaking unless compliance would present an unreasonable risk of serious or substantial injury to health or the environment. This limits the authority to put rules into effect quickly to those cases where there is real need to protect the public health or environment immediately and I think carries out better the intent of the Committee and particularly my intent in offering the original amendment in committee.

I would hope that the amendment would be agreed to, Mr. President.

Mr. Hartke. Mr. President, let me say about the amendment submitted by the Senator from Nevada that I think this amendment should

be satisfactory to the committee and also to the manager of the bill. This was the heart of a lot of discussion in the Senate Commerce Committee. I think the Senator from Nevada has correctly stated the situation. We want to make sure that the Administrator has the authority ; we want to make sure that due process is protected ; we want to make sure that there is not an unreasonable delay in absolute prohibition in case it needs to be done.

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On the other side of the coin we wanted to make sure there was not some type of arbitrary decision by the Administrator. I believe the amendment by the Senator from Nevada does carry out the intent of the committee at the time. We had long discussions about this matter. I do think possibly it could be misinterpreted or be ambiguous in the way it was originally drafted.

Mr. Tuxen. I want to thank my friend from Indiana for that explanation. I am impressed by his comments, and by what the Senator from Nevada said.

I would like to ask the Senator from Nevada a question. What is meant by serious and substantial personal injury as it is contained here, or serious or substantial environmental harm ?

Mr. Cannon. A "serious" illness would be one causing a high degree of illness to a relatively small number of people whereas a substantial illness would be one involving a lesser degree of illness but affecting a large portion of the population.

Mr. Tunney. I have no objections to the amendment and I am prepared to accept it. I am authorized to accept it for the minority.

The Presiding Officer. The question is on agreeing to the amendment.

The amendment was agreed to.

The bill is open to further amendment. If there be no further amendment to be proposed, the question is on the engrossment and third reading of the bill.

The bill was ordered to be engrossed for a third reading and was read the third time.

Mr. Thurmond. Mr. President, I have received numerous letters from companies operating in my State, and some out of the State, concerning this bill.

I would like to call to the attention of the Senate a few of these letters.

Certainly, I want to take every step possible to protect our people, but it appears that this bill goes further than necessary.

I have a letter in my hand from [^]filliken Chemicals, which I would like to read into the Record.

The Toxic Substances Control Act is probably the most serious threat the chemical industry has ever faced. This bill could require that before any chemical is sold, even in research quantities, it be subjected to all the tests required of a new drug.

The tests that could be required would easily cost \$100,000 and. in many cases much more. The authority to determine just how many tests and what tests would be run will reside with the administrator of the EPA. While it is possible that a reasonable administrator would not be too severe, it is undesirable to have the welfare of one's business hang on the whim of an administrator. Furthermore, according to the bill, any person may initiate a civil action for injunctive relief. Therefore, any manufacturer is not only at the mercy of the administrator but is also at the mercy of any citizen who has an "axe to grind".

Five reasons for you to oppose this bad piece of legislation :

1. It is unnecessary : We already have 27 health and environmental laws which cover the "toxic chemicals" that this bill would regulate.
2. It will be inflationary : It will increase the cost of production because of the severe testing required. It will reduce the number of products available and require the use of more expensive products in many cases.
3. It will stifle progress : Unnecessary restrictions will seriously hamper the flow of new products and we will be frozen into products we now have – some of which products have serious limitations and which could be improved if research and development were allowed to continue with reasonable caution.

4. It will drive industry overseas : Many companies will be forced to take their research and production to other countries where laws are less oppressive.

5. It is vague. The bill gives an EPA Administrator very broad authority with very few restrictions.

6. It probably won't work. Even one who supports the bill admits, "this bill will not, of course, catch all of the dangers. Some of the adverse effects occur in such unique circumstances or after very long times (up to 20 years in some cases) that it would be extremely difficult to diagnose their dangers. Very long-term testing would be very costly to industry and would seriously delay use of some valuable new chemicals." The logic here is inescapable.

This bill will have a serious effect throughout industry. Even those who use specialty chemicals or buy products that require specialty chemicals in their manufacture will have problems.

The large companies may be able to meet the excessive costs and red tape involved but it is bound to increase their costs. It is questionable if the small company can survive.

I appeal to you to seriously consider the reasons outlined in this letter and put the face of your office behind the effort to defeat this proposed legislation.
Sincerely,

C. M. Butler,
General Manager.

Mr. President, I have another letter here from a smaller company, the Graniteville Co. in Graniteville, S.C. It reads:

Dear Senator Thurmond : I am writing you about my deep concern over the Toxic Substances Control Bill that is presently in the final draft stage of the Senate and House Subcommittees. It is quite evident that if the Tunney Bill is passed in its present form, many chemical companies, both large and small, could possibly be out of business in short order. The textile industry has had to wrestle with many new government regulations in the last few years, many of which have been most beneficial, while others have taxed the sanity of most corporate management.

As I am sure you are aware, Graniteville Company has had a small wholly-owned subsidiary which manufactures dyes and chemicals. This Bill would require a ninety-day notice for manufacture or import of new chemicals, a ninety-day notice on change in formulations or on new uses of existing chemicals, and has broad powers to stop the manufacture of any chemical or finished product. In addition, the cost of testing each new chemical would approximate \$100,000 to \$300,000 and would increase the operating costs of our subsidiary by millions of dollars if this law were strictly enforced. I strongly believe that almost every

business has worked closely with and survived OSHA, EPA and other government agencies, but we cannot survive if this Bill is passed and enforced in its present form.

Mr. President, those letters are typical of others I have received, and I ask unanimous consent that a number of additional letters be printed in the Record following these.

There being no objection, the letters were ordered to be printed in the Record, as follows :

Monsanto Textiles Co.,
Greenwood, S.C, J, anuary 19, 1976.

Hon. Strom Thurmond,
U.S. Senate,
Washington, D.C.

Dear Senator Thurmond : As manager of Monsanto's plant in Greenwood, I want to express my strong opposition to the all-encompassing nature of toxic substances legislation currently being considered by committees in the Congress. The bills could seriously impact 2100 people, engaged in the manufacture of nylon at our Greenwood location, plus another 278 Monsanto employes working elsewhere in South Carolina.

I do support appropriate legislation on toxic substances for the pubhc's welfare, but the pending bills (S. 3149 and H.R. 10318) are overly burdensome to industry and detrimental to the public interest. It seems to me that this is another example of the overregulation which concerns us all today.

Specifically, the bills could impose costly and unnecessary testing requirements, on new and existing chemical substances without regard to the risk which may be involved. They also require regulations on the manufacture and use of sub-

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stances, based on the mere possibility of an unreasonable risk, without requiring an economic impact statement, even though the rules could ban production, shut down plants, and terminate jobs. Uncertainty in enforcement would occur since duplicative actions by different Federal agencies are encountered.

These defects can be corrected. A bill which meets many of these concerns has been introduced by Rep. John McCollister, H.R. 7664). I urge you to actively support legislaticni like the McCollister bill, and work against bills which threaten

entire industries and payrolls with needless over-regulation. I hope you will also voice your concern to committee members now considering toxic substances bill.

Congratulations on again becoming a proud father. I know Nancy got first class treatment at the hospital here and your son was very photogenic !
Sincerely,

R. T. Phelps, Jr.,

Plant Manager.

Exxon Chemical Co., U.S.A.,
Summerville, S.C., January 22, 1976.

Hon. Strom Thurmond,

U.S. Senate, Senate Office Building, Washington, D.C.

Dear Senator Thurmond : As a follow-up to my telephone call of today to Mr. John Steer, I would like to set forth in somewhat more detail my company's concerns regarding the Toxic Substances Control Legislation (S. 3149) (H.R. 10318) now before the Senate (House).

We support appropriate legislation in this area but are convinced that this bill, if enacted, would be overly burdensome (particularly to the small companies which comprise the bulk of the chemical industry), would unnecessarily increase costs, would stifle innovation and, ultimately, would make the U.S. chemical industry much less competitive than its strong counterparts in Europe and Japan.

This legislation could impose costly and unnecessary testing requirements with respect to new and existing chemical substances, in many cases without regard to the relative level of risk which may be involved. It requires the promulgation of rules governing the production and use of chemical substances on the mere possibility that these substances may present an unreasonable risk. It doesn't even require the preparation of an economic impact statement although the regulations could ban the production of a chemical, shut down the plants making it or using it, and terminate the jobs involved. The bill would also create uncertainty in the enforcement of Federal laws by encouraging duplicative action by different Federal agencies and would permit the EPA to pick and choose among potentially applicable laws.

My company believes that a law as broadly drawn as this would be, giving vast powers to the Administrator of the EPA without his being required to consider and weigh the economic consequences of his actions, is neither necessary nor appropriate to control toxic substances. In our view, appropriate legislation

is exemplified by H.R. 7664, which has been introduced in the current Congress by Rep. John McCollister. It is similar to a bill passed by the House in the last Congress and provides adequate means of controlling toxic substances without needless and costly overregulation. I hope you will support this kind of legislation rather than S. 3149 (H.R. 10318) which could result in such adverse consequences to industry without offering added assurance of public safety.

I am attaching a summary of some of the major concerns of the chemical industry regarding the bills now before Congressional committees, as compiled by the Manufacturing Chemists Association. If you wish additional information, I'll be happy to provide it.

Sincerely yours,

J. J. Jamison.

Firestone Steel Products Co.,
Spartanburg, S.C., January 19, 1976.

Hon. J. Strom Thurmond,
U.S. Senate,
Washington, D.C.

Dear Senator Thurmond : Despite the firm commitment of The Firestone Tire & Rubber Company to the prevention of undue risk to human health and the environment at its manufacturing plants, I am deeply concerned about certain provisions

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sions of the toxic substances control bills currently before the Committees of the

^"our company supports appropriate legislation in this area, but the pending bills (S. 3149 and H.R. 10318) are unduly burdensome to industry and could be detrimental to the public interest for the following reasons : , . , ,

1 By imposition of costly and unnecessary testing requirements with respect to new and existing chemical substances, in many cases without regard to the relative level of risks which may be involved ; , ^ . ^

2 By requiring the promulgation of rules governing the production and use of chemical substances on the mere possibility that these substances may present an unreasonable risk, without recourse to an economic impact statement ;

3 By creating uncertainty and duplication of Federal law enforcement under a plan which permits the EPA to pick and choose among potentially applicable statutes. . , . , ^ „ , ,

These are all correctible defects. In fact legislation which met many of these concerns passed the House of Representatives in the last Congress. A similar bill, H.R. 7664, has been introduced in the current Congress by Rep. John McCollister. I urge Members of Congress to actively support legislation like the Mc(V)llister bill, H.R. 7664, and to work against the enactment of legislation which would threaten entire industries with needless regulation without offering added assurance of public safety.

I hope you will also voice your concern to members of the committee now considering toxic substances control bills.

Sincerely,

D. E. Oldham,
Plant Manager.

W. R. Grace & Co.,

ZONOLITE,

Enoree, S.C., January 19, 1916.

Hon. Strom Thurmond,
U.S. Senate,
Washington, D.C.

Dear Sir : As Manager of W. R. Grace & Co.'s Kearney Plant at Enoree, South Carolina, I wish to express to you my views concerning some bills now before the Congress.

Our plant produces vermiculite, and at present employs approximately 115 men and women.

Despite the firm commitment of the chemical industry to the prevention of undue risk to human health and the environment from exposure to toxic chemicals, we are deeply disturbed and concerned about the provisions of the toxic substances control bills currently under consideration by the Committees of the Congress.

We support appropriate legislation in this area, but the pending bills (S. 3149 and H.R. 10318) are overly burdensome to industry and detrimental to the public interest. They could impose costly and unnecessary testing requirements with respect to new and existing chemical substances, in many cases without regard to

the relative level of risk which may be involved. They require the promulgation of rules governing the production and use of chemical substances on the mere possibility that these substances may present an unreasonable risk, and do not even require the preparation of an economic impact statement, although the regulations could ban the production of a chemical, shut down the plants making it or using it, and terminate the jobs involved. The bills would also create uncertainty in the enforcement of Federal laws by encouraging duplicative action by different Federal agencies and would permit the EPA to pick and choose among potentially applicable laws.

These are correctible defects. In fact, legislation which met many of these concerns passed the House of Representatives in the last Congress. A similar bill, H.R. 7664, has been introduced in the current Congress by Re.p. John McCollister. We urge Members of Congress to actively support legislation like the McCollister bill, H.R. 7664, and to work against the enactment of legislation which would threaten entire industries with needless regulation without offering added assurance of public safety.

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I hope you will also voice your concern to Members of the Committee now considering toxic substances control bills.

May I count on your help?

Yours very truly,

O. F. Stewabt,

Manager.

Fiber Industries, Inc.,

January 19, 1976.

Hon. J. Strom Thurmond,
Dirk sen Senate Office Building,
Washington, D.C.

Dear Senator Thurmond : As the Plant Manager of the Greenville Plant of Fiber Industries, Inc., situated in Greenville, S.C.. I wish to follow up the conversation between Hugh RoUinson, Technical Manager and Mr. John Steer, in expressing our opposition to S. 3149, the Toxic Substances Control Bill, in its present form. This measure is now before the Senate Commerce Committee.

S. 3149 requires premarket testing and screening. I'm not opposed to this broad

concept. As one well versed in the chemical industry I have consistently supported legislation that would require reasonable testing and premarket screening of chemical substances which are likely to pose a "substantial" danger to health and the environment. By "substantial" danger, I mean unreasonable risk of death or severe personal injury or illness as well as widespread or severe harm to the environment.

I am opposed to S. 3149 because I believe it would retard basic research, the development of new products and the development of new uses for existing products by requiring excessive and routine long term testing and premarket screening requirements for individual chemical substances or classes or such substances.

S. 3149 requires all new substances which "may present" [Sec 4(a) (1) (A) (i)] an unreasonable risk to public health be tested and screened in accordance with E.P.A. procedures. I have earned over the year that testing for chronic effects to determine the carcinogenic potential of materials is long term taking two to four years to complete with costs from \$300-\$750,000.

I'm not in favor of trade-off testing at the expense of safety but I do believe that unnecessary testing and screening is not only wasteful of the valuable time of a limited number of highly qualified technicians we have in our company but wasteful of financial resources, for these activities neither contribute to protecting health or the environment and impede research and development.

The term "unreasonable risk" used throughout the bill and in my judgment is too broad and needs to be strictly defined in a meaningful way as I suggested earlier. With such a guide or standard, testing and screening would be limited to those products presenting significant risks and the likelihood of excessive and unreasonable testing would be minimized. In the same vein, it seems to me that the language "may present" should be changed to "present" to require action based upon fact rather than a mere possibility of fact.

I believe that toxic substances legislation should be limited to gap areas not covered by other laws. It seems to me that S. 8149 goes far beyond the gap areas and overlap laws such as the Clean Air Act and the Water Act. I feel this legislation should be operative only when a risk to health and the environment cannot be scientifically presented or reduced by other Federal laws.

An Amendment has been offered to S. 3149. The Amendment No. 21 would permit the granting of equitable relief where there is a risk to human health without requiring proof by the plaintiff rather the burden of proof would be shifted to the defendant to demonstrate that no harm to human health exists. This seems to me to be an impossible legal and scientific burden and should be eliminated.

Any added costs from unnecessary and impractical testing requirements will be felt throughout the host of vital consumer related industries dependent upon

the chemical industry for their essential raw materials. Therefore, I believe that Section 6 of S. 3149, the section which provides authority to restrict or limit manufacturing and sales, should have language added to it to the effect that

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when regulations and other major actions are initiated under the proposed act that they are evaluated for their impact upon jobs and upon the economy.

I would welcome the opportunity to speak with you or Mr. John Steer further on this matter at your convenience. Please do not hesitate to call me if I can be of any help in this matter.

Yours sincerely,

Burton E. Cash,

Plant Manager.

E. I. DU Pont de Nemours & Company,

Flcyrence, S.C., January 19, 1976.

Re Toxic Substances Control Legislation.

Hon. J. Strom Thurmond,

U.S. Senate,

Dirkscti Office BuiMing,

Washington, B.C.

Dear Strom : You will recall from your visits to our plant that we employ 650 people at this location. Our product is "MYLAR" ^ a tough plastic film used by the following industries : magnetic tape, electrical insulation, packaging, micro-film, engineering drawings, and laminating. Our new Plant Manager is Dr. R. D. Pruett and lam writing you at his request.

Despite the firm commitment of the chemical industry to the prevention of undue risk to human health and the environment from exposure to toxic chemicals, we are deeply disturbed and concerned about the provisions of the toxic substances control bills currently under consideration by the Committees of the Congress.

We support appropriate legislation in this area, but the pending bills (S. 3149

and H.R. 10318) are overly burdensome to industry and detrimental to the public interest. They would impose costly and unnecessary testing requirements with respect to new and existing chemical substances, in many cases without regard to the relative level of risk which may be involved. They require the promulgation of rules governing the production and use of chemical substances on the mere possibility that these substances may present an unreasonable risk, and do not even require the preparation of an economic impact statement although the regulations could ban the production of a chemical, shut down the plants making it or using it. and terminate the jobs involved. The bills would also create uncertainty in the enforcement of Federal laws by encouraging duplicative action by different Federal agencies and would permit the EPA to pick and choose among potentially applicable laws.

These are correctible defects. In fact, legislation which met many of these concerns passed the House of Representatives in the last Congress. A similar bill, H.R. 7664, has been introduced in the current Congress by Rep. John McCollister. We urge Members of Congress to actively support legislation like the McCollister bill, H.R. 7664. and to work against the enactment of legislation which would threaten entire industries with needless regulation without offering added assurance of public safety.

I hope you will also voice your concern to Members of the Committee now considering toxic substances control bills. Should you want more details on our concerns. I will supply it.

We know that we can always depend on you to take a realistic position on such issues.

Sincerely,

R. D. Pruett,

Plant Manager.

Per: M. B. Wallace, Jr.,

Employee Relations Superintendent.

1 Reg. U.S. Patent Office for rhi Pon't polyester film.

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Fiber Industries, Inc.,

January 19, 1976.

Hon. J. Strom Thurmond, ^
U.S. Senate Office Building,
Washi7ifftoti, D.C.

Dear Senator Thurmond : I am writing to you as Plant Manager of Fiber Industries Palmetto Plant located in Darlington County concerning certain op-
position to S. 3149 (Toxic Substances Control Bill) which is now before the Senate Commerce Committee.

I am certainly in favor of sound legislation for control of toxic substances to the greatest extent possible through existing regulatory agencies. S. 3140 in its present form would, however, encourage duplication and uncertainty with respect to laws administered by the administrator.

The term "unreasonable risk" is used throughout the bill and seems to me to be too broad which, along with the term "may present," will very probably result in unnecessarily, costly and progress-stifling requirements for testing and screening.

Any added costs from unnecessary testing requirements will be felt throughout the vital consumer-related industries such as ourselves which dei^end on the chemical industry for their raw materials. I believe, therefore, that Section should have hinguage to the effect that when regulations and other major actions are initiated they be evaluated for their impact on jobs and upon the economy as well as health risk.

In summary, I hope that correctable general and vague language will be changed so that unreasonable burdens are not placed where unreasonable risks do not in fact pose substantial danger.

Yours truly,

E. J. Scott, Plant Manager.

Anderson, S.C, Mareh 15, 1916.

U.S. Senator Strom Thurmond,
Senate Office Building,
Washington, D.C.

Dear Senator Thurmond : I am greatly concerned over the phenomenal growth of reguhitions and regulatory agencies. It api)ears that Congress and the Presi-
dent have only one approach to solving our problems as a nation and that is to create more regulations and agencies to administer these. What we need today is less rather than more governmental regulation of our business and individual hves.

As a typical citizen, it is obvious to me that Congress has put little thought into the total ramifications and consequences of a given regulation or set of regulations. In most cases an extensive, inefficient, bungling federal agency is created. Further the citizen and business in the U.S. must bear the brunt of more red tape. And in terms of business, many regulations will be indirectly responsible for the slow death of capitalism.

Specifically I am opposed to the proposed toxic substances legislation presently before Congress. There are already in excess of 25 health and environmental laws presently in effect. These laws give the federal government adequate authority to control dangerous substances.

The Environmental Protection Agency would be given near absolute control of the chemical industry. In effect making the administrator of this group a dictator over the chemical industry.

This legislation would have an inflationary impact through increased cost of goods to the consumer. It would also reduce the discovery of new chemical products. And finally, it would reduce the number of jobs available.

As one of your constituents. I would appreciate knowing your position on this proposed legislation and if you believe it will become law. Thank you for your kind indulgence.

Respectfully,

Dr. Herbert L. Whitaker, Jr.

79-313 0 - 77 - 17

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Whitestone Chemical, a Department of BASF Wyandotte Corp.,

Spartanburg, S.C., January 19, 1976.

Hon. Strom Thurmond,
U.S. Senator, Aiken, S.C.

Dear Senator Thurmond : Whitestone Chemical, a Department of BASF-Wyandotte Corporation, is a manufacturer of specialty chemicals for the textile,

paper, leather and other industries here in Spartanburg. Current employment is forty-one with an annual payroll of approximately \$500,000. Whitestone is a significant contributor to the economic well-being of the Spartanburg area.

My company is firmly committed to the prevention of undue risk to human health and the environment from exposure to toxic chemicals. We are, however, deeply disturbed and concerned about the provisions of certain toxic substances control legislation, S. 3149 and H.R. 10318, currently under consideration by the Senate Commerce Committee and the House Interstate and Foreign Commerce Committee.

Review of the controls now in existence on toxic substances does convince us that some additional legislation is appropriate. However, S. 3149 and H.R. 10318 represent, in our opinion, legislative overkill. We believe they go far beyond what is required to provide reasonable protection to chemical workers, consumers and the general public and would burden all of these groups with costly and unnecessary testing requirements with respect to existing and new chemical substances. These bills lack standards for exercising good judgment as to the relative level of risk that may be involved ; rather, they would condemn all chemicals without regard to historic data, the relative level of risk that may be involved or the economic impact that would result. Appropriate legislation must provide for taking the economic impact into account because the cost of complying with the legislation will fall on consumers and the general public and our country in total.

As stated previously, we do believe, that some further legislation is required and H.P. 7664 introduced into the current Congress by Representative John McCollister would accomplish what we believe is needed. H.R. 7664 would provide necessary protection at reasonable cost. We urge you to support actively the McCollister bill and to oppose S. 3149 and H.R 10318.

Even though Whitestone is a department of BASF- Wyandotte Corporation, we operate as a separate company and therefore must pay our own way. The economic impact associated with the toxic substances control bills could be extremely detrimental to the continued operation of Whitestone, and many other small chemical companies in South Carolina.

If you share our concerns, we hope that you will voice them to the members of the Senate Committee now considering toxic substances control bills. We would appreciate learning your position on this legislation.
Sincerely.

T. W. Beal, Plant Manager.

E. I. DU Pont de Nemot'rs & Co..
Florence, S.C, January 10, 1976.

Re Toxic Substances Control Legislation.
Hon. J. Strom Thurmond,
U.S. Senate, Dirkscn Office Building,
Washington, B.C.

Dear Strom : You will recall from your visits to our plant that we employ 650 people at this location. Our product is "MYLAR"*, a tough plastic film used by the following industries : magnetic tape, electrical insulation, packaging, microfilm, engineering drawings, and laminating. Our new Plant Manager is Dr. R. D. Pruett and I am writing you at his request.

Despite the firm commitment of the chemical industry to the prevention of undue risk to human health and the environment from exposure to toxic chemicals, we are deeply disturbed and concerned about the provisions of the toxic substances control bills currently under consideration by the Committees of the Congress.

We support appropriate legislation in this area, but the impending bills (S. 3149 and H.R. 10318) are overly burdensome to industry and detrimental to the public interest. They could impose costly and unnecessary testing requirements with respect to new and existing chemical substances, in many cases without regard to the relative level of risk which may be involved. They require the promulgation

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of rules governing the production and use of chemical substances on the mere possibility that these substances may present an unreasonable risk, and do not even require the preparation of an economic impact statement although the regulations could ban the production of a chemical, shut down the plants making it or using it, and terminate the jobs involved. The bill would also create uncertainty in the enforcement of Federal laws by encouraging duplicative action by different Federal agencies and would permit the EPA to pick and choose among potentially applicable laws.

These are correctible defects. In fact, legislation which met many of these concerns passed the House of Representatives in the last Congress, A similar bill, H.R. 7664, has been introduced in the current Congress by Rep. John McCollister. We urge Members of Congress to actively support legislation like the McCollister bill, H.R. 7664, and to work against the enactment of legislation which would threaten entire industries with needless regulation without offering added assurance of public safety.

I hope you will also voice your concern to Members of the Committee now considering toxic substances control bills. Should you want more details on our con-

cerns, I will supply it.

We know that we can always depend on you to take a realistic position on such issues.

Sincerely,

R. D. Pruett.

Plant Manager.

Per: M. B. Wallace, Jr.,

2'Employee Relations Superintendent.

Ashland Chemical Co.,
DiviMon of Ashland Oil, Inc.,
Charlotte, N.C., February 2, 1976.

Hon. Strom Thurmond,
U.S. Senate,

Dirkscn Senate Office Building, Washington, D.C.

Dear Senator Thurmond : As regional manager of the Industrial Chemicals »& Solvents Division of Ashland Chemical Company stationed in Charlotte, N.C., I am very much concerned about the so-called Toxic Substance Control measures, which are currently under consideration by the Committees of the Congress. Included under my jurisdiction are the two Carolinas; and the havoc that would be raised, not only in this area but industry-wide if the bills in question should be enacted into law, would be monumental. Once again, therefore, I am seeking your assistance.

Despite the firm commitment of the chemical industry to the prevention of undue risk to human health and the environment from exposure to toxic chemicals - and we support legislation in this area - the provisions of the pending measures, Senate bill 3149, introduced by Senator John Tunney. and House Bill 10318, introduced by Representative Bob Eckhardt, are objectionable as being both overly burdensome to industry and detrimental to the public interest.

These bills could impose costly and unnecessary testing requirements with respect to the new and existing chemical substances, in many cases without regard to the relative level of risk which may be involved. They require the promulgation of rules governing the production and use of chemical substances on the mere possibility that these substances may present an unreasonable risk, and do not even require the preparation of an economic impact statement although the regulations could ban the production of a chemical, shut down the plants making it or using it, and terminate the jobs involved. The bills also

would create uncertainty in the enforcement of Federal laws by encouraging duplicative action by different Federal agencies and would permit the EPA to pick and choose among potentially applicable laws.

These are correctible defects. In fact, legislation which met many of these concerns passed the House of Representatives in the last Congress. A similar bill, H.R. 7664, has been introduced in the current Congress by Rep. John McCollister. We urge Members of Congress to support, actively legislation like the McCollister bill, H.R. 7664, and to work against the enactment of legislation which would threaten entire industries with needless regulation without offering added assurance of public safety.

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I hope that you also will voice your concern to Members of the Committee now considering toxic substances control bills.

I am enclosing a summary of industry's concerns over the aforementioned bills which provides more detailed information with respect to such concerns. In addition, I shall be most happy to discuss them with you at any time you are in this area.

Thank you for your assistance.
Sincerely yours,

A. T. MOEPHY.

Summary of Some of the Major Concerns With Toxic Substances Control

Legislation

(H.R. 10318 (Eckhardt)- S. 3149 (Tunney))

1. Testing. [Sec 4] The Administrator of EPA should be permitted to require testing of chemical substances where necessary to protect against an unreasonable risk to health or the environment. However, both H.R. 10318 and S. 3149 require the Administrator to order testing if a chemical substance "may present" an unreasonable risk, and they thus threaten unnecessary testing which is both costly and time-consuming. Both bills contain undesirable provisions for establishment of extensive public priority lists of suspect chemicals, without appropriate procedural safeguards, which arbitrarily restrict the EPA Administrator's authority and could unfairly damage or destroy a product's trade

acceptance and reputation before recommended testing could be completed.

2. Premarket Screening. [Sec. 5] Premarket screening, which for all practical purposes results in an EPA premarket approval, should be limited to those chemicals that are likely to pose a substantial danger – an unreasonable risk of death or severe or widespread harm. S. 3149 requires premarket screening – and threatens indefinite delay of new product development and marketing – with respect to all new chemical substances and significant new uses of established substances, regardless of the risks involved. Under H.R. 10318 screening jjiay be required on the mere possibility of an unreasonable risk.

3. Regulation. [Sec. 6] A sound, balanced approach to controlling toxic substances should require that regulatory actions be aimed at the distribution and use of those substances only when necessary to prevent an unreasonable risk to health or the environment. Both pending bills require the promulgation of such rules on the mere possibility that a chemical substance presents or contributes to an unreasonable risk. Under certain circumstances they can be put into effect immediately. They do not require the Administrator to use the least burdensome regulation required to prevent the risk. They do not require the Administrator to include an economic impact statement in any such rule, even if the rule bans the production of a substance, shuts down the plant making and using it, and ends the jobs involved in manufacture and use.

4. Unreasonable Risk. [Sec. 6] S. 3149 attempts a legislative definition of "unreasonable risk to human health and the environment." The definition proposed by S. 3149 is both vague and unworkable. H.R. 10318 also unwisely and unnecessarily broadens the concept of unreasonable risk by making the concept applicable even if the substances make a minute contribution to any risk, even a naturally occurring one.

5. Imminent Hazard. [Sec. 7] Of serious concern is that the total impact of Sections 4, 5, 6, and 7 of H.R. 10318 and S. 3149 is in the direction of a zero risk concept, that is, protection of society from all possible health hazards. Yet all social progress is predicated on some level of risk assumption. Our good quality and style of life today would never have been achieved by a no-risk approach to progress. What is essential is that we avoid unreasonable risks and we support legislation to this effect – not legislation reflecting a zero risk, no-hazard approach.

6. Reporting. [Sec. 8] Toxic substances control legislation should empower the regulatory agency to obtain information from manufacturers as necessary to facilitate its administration of the law, but avoid overburdensome paperwork requirements. S. 3149 unreasonably requires both the immediate transmittal to EPA and the retention of all health and safety data, including any letters from anyone concerning an alleged adverse effect of a chemical substance and any report of illness allegedly related to chemical exposure. H.R. 10318 imposes crimi-

nal penalties for violation of the impossibly vague requirement that a manufacturer immediately inform the Administrator about any information which "reasonably supports" the conclusion that a chemical substance presents an unreasonable risk. In addition, both bills require manufacturers to prepare a list of all chemical studies conducted by or for them, regardless of their need, significance, or validity.

7. Citizen Petitions. [Sec. 21] H.R. 10318 and S. 3149 give any person the right to petition the Administrator to commence a proceeding for the issuance of a rule under various sections of the legislation, and, more remarkably, give any such person the right to a de novo trial in Federal district court if the Administrator does not accede to the request. This means that every Federal court could be turned into a mini-EPA, forced to hear complex, scientific testimony presented by any person with whom EPA disagreed. This is not judicial review of agency action ; there is no weight given to the Administrator's discretion or expertise. Moreover, the very existence of this type review threat further erodes the likelihood that the Administrator will be in a position to make reasonable and prudent judgments in discretionary areas - judgments which are essential in administering any of the proposed bills because of the severe economic and social consequences that could result from any significant action.

8. Overlapping Lairs. [Sec. 9] Sound legislation should provide for the control of toxic substances, to the greatest extent possible, through existing regulatory authorities. H.R. 10318 and S. 3149 would create uncertainty in the enforcement of Federal laws by encouraging duplicative action by Federal agencies and, with respect to laws administered by the Administrator, would permit the Administrator to "pick and choose" among potentially applicable laws.

9. Scope and Coverage. [Sec. 3] Both S. 3149 and H.R. 10318 are, at least potentially, applicable to every chemical substance and every mixture of chemical substances. Since every substance, product or commodity is covered by the bill's definitions of chemical substance and mixture, great care must be taken in drafting the legislation to prevent its unfair and unnecessary application to chemicals that do not present significant risks. Neither bill reflects this care. It is unnecessary for the legislation to cover mixtures of chemical substances, research and test chemicals, reagents, or catalysts, unless they pose an unreasonable risk.

10. Confidential Industry Data. [Sec. 14] To prevent unfair competitive damage, the legislation must provide careful protection against public disclosure for confidential company data with respect to production, chemical composition, marketing plans and other business secrets,

11. All of the above concerns are correctable defects. In fact, legislation which met many of these concerns passed the House of Representatives in the last Congress. A similar bill, H.R. 7664, has been introduced in the current Congress by Rep. John McCollister. We urge Members of Congress to actively support legislation like the McCollister bill, H.R. 7664, and to work against the enactment of legislation which would threaten entire industries with needless regulation without offering added assurance of public safety.

Mr. TIERMOXD. I wish to say too that I think the administration's position on this bill is a sound position. This is the administration's position :

While the Administration has taken the lead since 1971 in urging legislation to control toxic substances, it strongly opposes enactment of this bill.

S. 3149 unnecessarily overburdens both the regulatory agency and the regulated industry by :

Requiring premarket notification on all new substances regardless of whether or not they are even potentially toxic.

Requiring the regulatory agency to make detailed findings even on those substances which it feels need no regulation or further testing.

The bill does not adequately protect against the unauthorized release of trade secrets and proprietary information. Such protection is critical to the effective work of the toxic controlled program. Also provides for citizen petition, citizen civil action against nondiscretionary acts, and compensation for attorney's fees.

These provisions unnecessarily invite further litigation without any major benefit over the normal judicial review procedures in the legislation.

Mr. President. I think the administration is on sound ground here. As it says, the administration has taken the lead since 1971 in urging

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legislation to control toxic substances, but it cannot support this bill, and, in fact, strongly opposes the enactment of the bill for the reasons I have just stated.

For those reasons, Mr. President, and others I shall not take time now to mention, I shall vote against this measure. All of us have a sincere desire to protect the public from toxic chemical substances, but

this legislation goes much further than prudence and the public interest require.

Mr. TuxNEY. Mr. President, I make it clear that the legislation that I hope we pass in a few minutes is designed to assure that chemicals that are used in high volume are going to be tested for safety.

As a matter of fact, even low volume chemicals will be tested if there is concern as to their effect on the environment or on human health.

Section 4 states that if a chemical substance or mixture may present a significant human or environmental exposure because of production in substantial quantities or for other reasons, and the substance or mixture may perhaps present an adverse effect on health and the environment, the Administrator must require testing if there are insufficient data or experience to reasonably determine or predict the effects and testing is necessary to develop the data.

So there should be no question in anyone's mind that, where we have substantial amounts of a chemical being produced and being disbursed throughout the environment, the Administrator is required to order testing where he does not have adequate data to be able to make up his mind on the evidence and where the testing is needed to develop the data.

I think it is very clear.

Mr. Hartke. Mr. President, I quite agree with the Senator from California. There is no question that one of the problems we have in American society today is that we are increasingly using a volume of chemicals which is absolutely going to astonish most individuals and as far as the people are concerned provide for them an exposure which might not otherwise be dangerous but simply by the sheer volume of the chemical exposure present a hazard to the health or to the environment of this Nation.

The Administrator is required to go ahead and deal with this type of situation. In other words, he will, in fact, address himself to this potential hazard and will make the necessary testing, necessary reports, and necessary findings.

I point out that generally speaking we will have in here, as I understand it only one reference to specific items. Generally speaking, I think it is better legislative procedure to keep legislation general and not deal with specific items. For that reason, I think we are justified in not putting an amendment in this bill which really specifically deals with high volume chemicals. On the other hand, I think that if it is omission as a specific amendment could be interpreted as an indication by Congress

that we did not intend to cover such items, then I would feel compelled to make sure that Ave had an amendment of that nature in the bill. But as has been indicated by the Senator from California, under section 4, the testing of chemical substances and mixtures, it is fully anticipated that the Environmental Protection Administrator will require that testing and will act accordingly.

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Mr. TuNKEY. Mr. President, a question has been raised concerning the possibility that a State law, a State effluent standard, for example, established pursuant to the Federal AVater Pollution Act would be preempted if there were in existence a toxic substance rule pertaining to the manufacture, distribution, or disposal of a chemical substance that was subject to the effluent standard. That emphatically is not the case. The State is only preempted under the bill from establishing a standard relating to the manufacture, distribution, or disposal inconsistent with the standards authorized under section 6. State effluent or air pollution standards pursuant to Federal law would not be preempted by section 13.

Mr. Pearson. Mr. President, I ask unanimous consent to have printed in the Record a statement by the distinguished Senator from Connecticut (Mr. Weicker).

The Presiding Officer. Without objection, it is ordered.

Statement of Senator Weicker

I believe the Toxic Substance Contol Act is the most important piece of environmental le^slation to come before the Congress this year. It places the responsibility of proving the safety of new chemicals right where it belongs - on the government. With 500 to 1.000 new chemical substances being introduced into commercial use every year, the government must have the power to act. The illness and death attributed to kepone, vinyl chloride, asbestos, and other chemicals is tragic evidence that that power does not now exist,

I have long supported and I am a cosponsor of this measure which places as one of our greatest environmental priorities the protection of the public against the health hazards associated with dangerous chemicals,

LEGISLATTVE HISTORY TO ACCOMPANY MODEL ATTORNEYS^ FEES PROVISION

Mr. TuNNEV. Mr. President, attorneys' fees provisions appear in a

number of places throughout this legislation [e.g., Sec. 19(c)(3)]. These provisions allow a court to award costs of suit and reasonable fees where "appropriate." These provisions are very important to the proper vindication of rights under this legislation. I would like to offer some explanation which in my opinion will clarify the operation of those provisions.

Until recently, the courts often provided for effective actions by private citizens through the award of costs and fees, even in the absence of specific statutory authorization, under the "private attorney general" rationale. However, in a recent decision, *Alyeska Pipeline Service Co. against Wilderess Society*, the Supreme Court held that -

Courts lacked discretionary power to award attorneys' fees to petitioners who sought to vindicate "important statutory rights for all citizens", . . . unless there was specific statutory authorization for such awards, . . . The circumstances under which attorneys' fees are to be awarded and the range of discretion in the court for making those awards are matters for Congress to determine.

In light of that decision, the fees and costs provisions of this legislation follow the precedent of over 50 Federal statutes in permitting fee shifting by the courts.

This provision would allow an award of fees and costs to any party when "appropriate," a word which should be liberally construed to effectuate the purposes of this act. Thus, in typical circumstances, the court should follow prevailing case law which holds that a successful plain-

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tiff "should ordinarily recover an attorneys' fee unless special circumstances would render such an award unjust." *Newman v. Piggie Park Enterprises, Inc.*, 390 U.S. 400, 402 (1968) (per curiam). "Plaintiff" in this sense is used to mean the parties seeking to enforce the rights granted by this section and can include an intervenor, or a defendant in some cases. See e.g., *Shelley v. Kramer*, 334 U.S. 1 (1948).

In exceptional circumstances, fees and costs might also be awarded to defendants where they must "defend against unreasonable, frivolous, meritless or vexatious actions * * *" *United States Steel Corp. v. United States*, 385 F. Supp. 346, 348 (W.D. Pa. 1974). Where plaintiff's proceeding is brought in good faith or on the advice of competent counsel, fees and costs would ordinarily be denied to a prevailing defendant. *Richardson v. Hotel Corporation of America*. 332 F. Supp.

519 (E.D. La. 1971), aff'd 468 F. 2d 951 (5th Cir. 1972). The standard for awarding fees and costs to a prevailing defendant is not the same as for a plaintiff because, if it were, the risk, to the average citizen of bringing suit under this section would be so great it would discourage such suits.

Fees and costs would be awarded to a "successful plaintiff" under this provision where there was a final court order granting the relief requested by plaintiffs, or as a matter of interim relief pending the outcome of the case. The provision does not require the entry of a final order before fees or costs may be recovered. See *Bradley v. School Board of the City of Richmond*, 416 U.S. 606 (1974) ; *Mills v. Electric Auto-Lite Co.*, 396 U.S. 375 (1970). Such awards are especially important where a party has prevailed on an important matter in the course of the litigation even where he does not ultimately prevail on all the issues. See *Bradley*, supra, and *Mills*, supra. For purposes of the award of fees and costs, it is "appropriate" to make awards where the parties have vindicated rights through a consent judgment, or without formally obtaining relief, or where such award is in the public interest without regard to the outcome of the litigation. *Kopet v. Esquire Realty Co.*, 523 F. 2d 1005 (2d Cir. 1975) ; *ParJiam, v. Southwestern Bell Telephone Co.* 433 F. 2d 421 (8th Cir. 1970) ; *Richards v. Griffith Rubier Mills*. 300 F. Supp. 338 (D. Ore. 1969) ; *Thomas v. Honeybrook Mints, Inc.*, 428 F. 2d 981 (3d Cir. 1970).

By specifying a general rule for the amount of fees to be awarded, this provision requires the method of calculating fees be no different than that now being utilized in other fields of law as, for example, antitrust and securities regulation litigation. The "actual time" spent is that reasonably calculated to advance the client's interest. *The Stanford Daily v. Zurcher*, 64 F.R.I). 680 (N.D. Cal. 1974) , and the amount can be adjusted for factors including, inter alia, the contingent nature of the success or the quality of the work performed. *Lrudy Bros. Builders v. American Radiator* (€ Standard Sanitary Corp.. 487 F. 2d 161 (e3d Cir. 1973), on remand, 382 F. Supp. 999 (E.D. Pa. 1974), or benefits to the public from the suit. *Davis v. County of Los Angeles*, 8 E.P.D. 9444 (CD. Cal. 1974). Fees should not be reduced merely because the attorneys are salaried employees of public interest and/or foundation -funded law firms.

Fees and costs awarded under this provision may be assessed against the United States, including any of its agencies and officers acting in an official capacity, the same as against a private party.

Finally, since expert witnesses are often needed to make an adequate presentation to a court, such fees are also provided for in this statute. They would be in addition to those now provided in 28 U.S.C. 1920 and 28 U.S.C. 1821.

The policy outlined above should apply to the procedures under section 23 to the extent applicable.

Mr. Xelsox. Mr. President, I would like to take this opportunity to elaborate and clarify an important point contained in the committee's report. On page 26, in reference to amendment Xo. 21 [Sec. 17(a)] sponsored by the Senator from Michigan (Mr. Gary Hart), the Senator from Illinois (Mr. Percey), and myself, regarding the burden of proof a plaintiff must sustain in order to gain relief under the laws administered by the Environmental Protection Agency, the report states :

The amendment attempted to rectify a three judge panel decision of the Eighth Circuit concerning relief set against the Reserve Mining Company. As decisions reached by the Courts in subsequent appeals is consistent with the requirements of Amendment No. 21 the amendment is unnecessary.

I believe it has for many years been the law that courts have full authority to protect human life and health when either is seriously threatened. However, some courts have expressed doubts about what the law is, and how it should be interpreted. I believe that any court of law or any governmental administrator when faced with a real risk of serious injury to human beings would have to make sure that the danger is removed.

Amendment Xo. 21 is aimed at those situations where some evidence of a serious potential hazard exists but the evidence is inconclusive. Amendment Xo. 21 would prohibit a court from denying equitable relief under any act administered by the EPA where a risk to public health is alleged and established.

Amendment X'o. 21 attempts to clarify existing law. This legislation does not change the law. If enacted, this legislation would only clarify and reinforce existing tenets of congressional policy and existing law, that precautionary action shall be taken to prevent perceived harm where evidence of a serious potential hazard exists but the conclusive scientific evidence is not yet available.

On the merits of the issue, I agree with the committee that the law is clear and that the Eighth Circuit Court of Appeals sitting en banc, in reviewing the Resen[^]e Mining Co. decision, has indeed rectified

many of the mistakes contained in the original eighth circuit decision. However, subsequent court decisions reveal that the courts are still not clear as to Congress' intent as well as what the law requires in these most serious environmental health cases.

On March 19, 1976, the U.S. Court of Appeals for the District of Columbia sitting en banc affirmed an Environmental Protection Agency regulation regarding the reduction of lead levels in gasoline. The 5 to 4 decision deals specifically with the question addressed by amendment No. 21.

The Administrator determined that leaded gasoline automotive emissions present "a significant risk of harm" to the public health * * *. Based on this finding, the Administrator issued the regulations requiring annual reductions in the lead content of leaded gasoline.

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The Court held that—

In applying the "will endanger" standard the Administrator is authorized to assess risks of harm and, where the risk is found significant, to act to prevent the harm from happening. Thus the regulatory action under this precautionary statute should precede, and hopefully prevent, the perceived harm.

The petitioners in this case argued that the "will endanger" standard requires a high quantum of actual proof, proof of actual harm rather than a "significant risk of harm." The Court stated :

It is our view that the Administrator's interpretation of the standard is the correct one.

The court held —

The meaning of "endanger" is not disputed. Case law and dictionary definition agree that endanger means something less than actual harm. When one is endangered, harm is threatened ; no actual injury need ever occur ... a statute allowing for regulation of the force in danger is, necessarily, a precautionary statute. Regulatory action may be taken before the threatened harm occurs; indeed, the very existence of such precautionary legislation would seem to demand that regulatory action precede, and, optimally, prevent, the perceived threat.

The Court specifically refers to the en banc decision of Reserve, Mining/ Company v. EPA, 514 F. 2d 492 (8th Cir. 1975) (en banc), in interpreting the meaning of "endanger." The eighth circuit's unanimous conclusion fully supports the District of Columbia Appeals Court standard of "will endanger." The eighth circuit held:

In the context of this environmental legislation, we believe that Congress used the term "endangering" in a precautionary or preventive sense, and, therefore, evidence of potential harm as well as actual harm comes within the preview of that term,

(See Reserve Mining Campcmly vs. EPA, supra, 514 F. 2d at 528)

The District of Columbia Appeals Circuit Court held :

. . . based on the meaning of the statute . . . and the Reserve Mining precedent, we conclude that the "will endanger" standard is precautionary in nature and does not require proof of actual harm before regulation is appropriate.

In the Reserve Mining case, the eighth circuit allowed regulation of the daily discharge of 67,000 tons of taconite tailings into Lake Superior on only a "reasonable" or "potential" showing of danger, hardly the probable finding urged by the petitioners in the EPA lead case as a proper reading of the "endanger" language. The appeals court states:

Reserve Mining convincingly demonstrates that the magnitude of risks sufficient to justify regulation is inversely proportional to the harm to be avoided.

Judge Wright, in commenting for the majority of the D.C. circuit regarding lead levels in gasoline, correctly has viewed the congressional policy and has correctly interpreted the law in determining what standard of evidence is required before appropriate relief can be granted. However, Judge Wilkey, who joined with Judge Tamm and Robb in dissent, raised questions regarding what standard of proof is required before relief is granted. His dissent states, in part :

For the Court's opinion to hold that the Administrator can dispense with proof of actual harm, i.e., what has occurred in the past, and can nevertheless somehow determine potential harm, is to grant the plaintiffs license for the widest speculation we have always under scientific conclusions, above all demand that proof by events recorded and observed.

Apparently, the law is not sufficiently clear if our judges on the District of Columbia Circuit Court of Appeals specifically disagreed with what burden of proof must be sustained by a plaintiff before appropriate relief may be granted. How clear the Eighth Circuit Court of Appeals and the majority of the District Court of Appeals and Members of Congress believe the law is, as currently drafted, clarification would be helpful. Amendment No. 21 is not as unnecessary as the committee report would indicate. There is question in the judiciary as to what the law is. I believe the law is clear, and I hope this legislative history will help the courts in understanding Congress intent to protect the public's health before significant harm can occur. At the very least, the dissent by Judge Wright and others reemphasize the merit in enacting legislation to make Congress intent unmistakably clear.

Mr. President, I ask unanimous consent that a Library of Congress American Law Division opinion on this issue be printed in the Record.

There being no objection, the material was ordered to be printed in the Record, as follows :

Congressional Research Service,

Washington, D.C., March 25, 1976.

To : Hon. Gaylord Nelson, Attention : Jeff Nedelman.

From : American Law Division,

Subject : Reserve Mining and Ethyl Corporation Interpretation of Findings Necessary to Show That a Pollutant is "Endangering" the Public Health.

This responds to your request for an analysis of the above-noted subject as interpreted by the decision of the United States Court of Appeals for the Eighth Circuit in *Reserve Mining Co. v. United States*, 417 F.2d 492 (8th Cir. 1975) (en banc), and by the decision of the United States Court of Appeals for the District of Columbia in *Ethyl Corp. v. Environmental Protection Agency*, No. 78-2205, March 19, 1970 (en banc). The 5-judge panel of the Eighth Circuit was unanimous in its decision ; the 9-judge panel of the District of Columbia Circuit was split 5 to 4.

Both the 8th Circuit and the majority of the D.C. Circuit agreed that the concept of endangerment includes a precautionary or preventive element, so that proof of potential harm can establish endangerment, and it is not necessary to establish that actual harm has already occurred. In this context the language at issue in *Reserve Mining* was former section 1160(g) (1) of Title 33, U.S.C. Code, predicating an abatement action on a finding that "pollution of water ... is endangering the health or welfare . . ." At issue in *Ethyl Corp.* was section 211 of the Clean Air Act, 42 U.S.C. § 1857f-6c, permitting the Administrator of EPA to regulate a fuel additive "if any emission products of such fuel or fuel additive will endanger the public health or welfare."

The following analysis appears in the 8th Circuit's opinion in *Reserve Mining*, 514 F.2d at 528-529;

[20] An action under the FWPCA requires proof of an additional element. The United States must establish that the water pollution which is violative of state water quality standards is also "endangering the health or welfare of persons." § 1160(g) (1).

In this review, we must determine whether "endangering" within the meaning of the FWPCA encompasses the potential of harm to public health in the degree shown here.

[21, 22] Provisions of the FWPCA are aimed at the prevention as well as the cure of water pollution. The initial sentence of the FWPCA reads :

The purpose of this chapter is to enhance the quality and value of our water resources and to establish a national policy for the prevention, control, and abatement of water pollution. [33 U.S.C. § 1151(a).]

The term "endangering," as used by Congress in § 1160(g) (1), connotes a lesser risk of harm than the phrase "imminent and substantial endangerment to the health of persons" as used by Congress in the 1972 amendments to the FWPCA, 33 U.S.C. § 1364 (Supp. 1974).

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[23] In the context of this environmental legislation, we believe that Congress used the term "endangering" in a precautionary or preventive sense, and therefore, evidences of potential harm as well as actual harm comes within the purview of that term. We are fortified in this view by the flexible provisions for injunctive relief which permit a court "to enter such judgment and orders enforcing such judgment as the public interest and the equities of the case may require." 33 U.S.C. § 1160(c) (5).

We deem pertinent the interpretation given to the term "endanger" by Judge Wright of the District of Columbia Circuit in his analysis of the congressional use of the word "endanger" in the context of a provision of the Clean Air Act. 42 U.S.C. § 1857f-6c(c) (1) (A) (1970).

Judge Wright observed :

The meaning of "endanger" is, I believe, beyond dispute. Case law and dictionary definition agree that endanger means something less than actual harm. When one

is endangered, harm is threatened; no actual injury need ever occur.

"Endanger," * * * is not a standard prone to factual proof alone. Danger is a risk, and so can only be decided by assessment of risks.

***** * *

[A] risk may be assessed from suspected, but not completely substantiated, relationships between facts, from trends among facts, from theoretical projections from imperfect data, or from probative preliminary data not yet certifiable

as "fact." [Ethyl Corporation v. Environmental Protection Agency, F. 2d

, (D.C. Cir., Jan. 28, 1975) (dissenting op. at ,) (emphasis in

original) (footnote omitted).]

Although the Supreme Court has not interpreted the concept of "endangering" in the context of an environmental lawsuit, it has emphasized the importance of giving environmental legislation a "common-sense" interpretation. Mr. Justice Douglas, writing for the Court, said :

"This case comes to us at a time in the Nation's history when there is greater concern than ever over pollution - one of the main threats to our free-flowing rivers and to our lakes as well * * * [W]hatever may be said of the rule of strict construction, it cannot provide a substitute for common sense, , precedent, and legislative history." [United States v. Standard Oil Co., 384 U.S. 224, 225, 86 S.Ct. 1427, 1428, 16 L.Ed.2d 492 (1966) .]

See United States v. Republic Steel Corp., 362 U.S. 482, 491, 80 S.Ct. 884, 4 L.Ed. 2d 903 (1960).

[24, 25] The record shows that Reserve is discharging a substance into Lake Superior waters which under an acceptable but "unproved medical theory may be considered as carcinogenic. As previously discussed, this discharge gives rise to a reasonable medical concern over the public health. We sustain the district court's determination that Reserve's discharge into Lake Superior constitutes pollution of waters "endangering the health or welfare of persons" within the terms of §§ 1160(c) (5) and (g) (1) of the Federal Water Pollution Control Act and is subject to abatement.

The Ethyl Corp. decision cited in Reserve Mining, supra, was vacated. Judge Wright, whose dissent in the vacated decision is quoted above in Reserve Mining, wrote the majority opinion in the March 19, 1976 en banc decision in Ethyl Corp. Judge Wright reiterated his previous analysis, and provided the following summary (slip opinion, pp. 53-56) ;

These cases, recognizing as they do the developing nature of environmental medicine, fortify our analysis of the "will endanger" language of Section 211. Where a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect the public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect. Such proof may be impossible to obtain if the precautionary purpose of the statute is to be served. Of course, we are not suggesting that the Administrator has the power to act on hunches or wild guesses. Amoco makes it quite clear that his conclusions must be rationally justified. *Amoco Oil Co. v. EPA*, 163 U.S. App. D.C. at 180-181, 501 F.2d at 740-741. However, we do hold that in such cases the Administrator may assess risks. He must take account of available facts.

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of course, but his inquiry does not end there. The Administrator may apply his expertise to draw conclusions from suspected but not completely substantiated, relationships between facts, from trends among facts, from theoretical projections from imperfect data, from probative preliminary data not yet certifiable as "fact," and the like. We believe that a conclusion so drawn – a risk assessment – may, if rational, form the basis for health-related regulations under the "will endanger" language of Section 211."*

All of this is not to say that Congress left the Administrator free to set policy of his own terms. To the contrary, the policy guidelines are largely set, both in the statutory term "will endanger" and in the relationship of that term to other sections of the Clean Air Act. These prescriptions direct the administrator's actions. Operating within the prescribed guidelines, he must consider all the information available to him. Some of the information will be factual, but much of it will be more speculative – scientific estimates and "guesstimates" of probable harm, hypotheses based on still-developing data, etc. Ultimately he must act, in part on "factual issues," but largely "on choices of policy, on an assessment of risks, [and] on predictions dealing with matters on the frontiers of scientific knowledge * * *." *Amoco Oil Co. v. EPA*, supra, 163 U.S. App. D.C. at 181, 501 F.2d at 741. A standard of danger – fear of uncertain or unknown harm – contemplates no more.

That other interpretations of the "will endanger" or "endangering" standard are possible is apparent from a reading of Judge Wilkey's dissent in *Ethyl Corp.*, joined by Judges Tamm and Robb. Judge Wilkey rejected the distinction "between actual and potential between past and future harm." and continued :

The Administrator is dealing with a continuing situation. If there can be found potential harm from lead in exhaust emissions, the best (and only convincing)

proof of such potential harm is what has occurred in the past (either in 50 years of practical usage or in laboratory experimentation), from which the Administrator can logically deduce that the same factors will produce the same harm in the future. For the court's opinion to hold that the Administrator can dispense with proof of actual harm, i.e., what has occurred in the past, and can nevertheless somehow determine potential harm, is to grant the plainest license for the

^ It bears emphasis that what is herein describe as "assesment of risk" is neither unprecedented nor unique to this area of law. To the contrary, assessment of risk is a normal part of judicial and administrative fact-finding. Thus KPA is not attempting to expand its powers ; rather, petitioners seek to constrict, the usual flexibility of the fact-finding process. Petitioners argue that the Administrator must decide that lead emissions "will endanger" the public health solely on "facts," or, in the words of the division majority, by a "chain of scientific facts or reasoning leading (the Administrator) inevitably to this conclusion * * *." Division op. at 59. Petitioners demand sole reliance on scientific facts on evidence that reputable scientific techniques certify as certain. Typically, a scientist will not so certify evidence unless the probability of error, by standard statistical measurement, is less than 5 percent. That is, scientific fact is at least 95 percent certain.

Such certainty has never characterized the judicial or the administrative process. It may be that the "beyond a reasonable doubt" standard of criminal law demands 95 percent certainty. Cf. *McGill v. United States*, 121 U.S. App.D.C. 179, 185 n.6, 348 F.2d 791, 797 n.f) (1965) But the standard of ordinary civil litigation, a preponderance of the evidence,, demands only 51 percent certainty. A jury may weigh conflicting evidence and certify as adjudicative (although not scientific) fact that which it believes is more likely" than not. Since *Rectierve Mining* was adjudicated in court, this standard applied to the court's fact-finding. Inherently, such a standard is flexible ; inherently, it allows the fact-finder to assess risks, to measure probabilities, to make subjective judgments. Nonetheless, the ultimate finding will be treated, as law. as fact and will be affirmed if based on substantial evidence, or if made by a judge, not clearly erroneous.

The standard before administrative agencies is no less flexible. Agencies are not limited to scientific fact, to 95 percent certainties. Rather, they have at least the same fact-finding powers as a jury, particularly when, as here, they are engaged in rule-making.

Looking to the future, and commanded by Congress to make policy, a rule-making agency necessarily deals less with "evidentiary" disputes than with normative conflicts, projections from imperfect data, experiments and simulations, educated predictions, diffe

r-
ing assessments of possible risks, and the like.

Adwco Oil Co. V. EPA. supra note 2, 16.S U.S. App.D.C. at 175, 501 F.2d at 735. An agency's finding of fact differs from that of a jury or trial judge primarily in that it is accorded more deference by a reviewing court. See note 74 infra. Thus, as a matter of administrative law, the Administrator found as fact that lead emissions "will endanger" the public health. That in so doing he did not have to rely solely on proved scientific fact is inherent in the requirements of legal fact-finding. Petitioners' assertions of the need to rely on on "fact" confuse the two terminologies. We must deal with the terminology of law, not science. At law, unless the administrative or judicial task is peculiarly factual in nature, or Congress expressly commands a more rigorous finding, see 21 TT.S.C. § ,355 (d) :
cf. pages 4,3-45 supra, assessment of risks as herein described typifies both the administrative and the judicial fact-finding function, and is not the novel or unprecedented theory that petitioners contend.

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wildest speculation. We have always thought scientific conclusions, above all, demanded proof by events recorded and observed.

The court's second asserted dichotomy, risks versus facts, is equally indefensible in logic. All true risk assessment is based on fact and nothing else. Those professional risk-assessors, the professional sports gambling fraternity, would smile at any other theory. To the extent that a hunch and intuition enter into any final decision, these are separate factors outside of any scientific risk calculation.

Our colleagues apparently find it necessary to legitimize the Administrator playing hunches. They assert, "Danger is a risk, and so must be decided by assessment of risk as well as by proof of facts." Of course the Administrator assesses risk - from the facts as he knows them. The question here is how much he knows. To the extent the agency found it necessary to make an "assessment of risk as well as [rely on] proof of facts," the agency was frankly just speculating. No reviewing court can countenance this. If such agency decision is not "arbitrary and capricious," what decision could be? It is precisely a devotion of facts, not hunches, that distinguishes the professionals from the amateurs in assessing risks ; we deem the Administrator to have been intended by Congress to be a "professional."

Geoege Costello,
Legislative Attorney.

Mr. Baker. Mr. President, American society has just recently realized the pervasiveness of the toxic chemical problem. The public is being exposed to substances that are potentially toxic during normal daily activities.

Our present pollution laws do no guard effectively against this threat until these substances are already present in the environment. Government regulatory agencies in general have no authority to prevent exposure until after the substances have been manufactured and are in use.

The measure before us today is an innovative legislative effort to evaluate and control these substances before they have a chance to become a problem.

The bill provides a mechanism to evaluate these elements prior to production, thus halting the chain of events before it is started. It is hoped that this preventive action will yield an opportunity to the consumer, who has no resources to judge the long-range consequences of these chemicals. This creates a mechanism to sort out the risks and benefits of these substances before harmful exposure.

But while this regulatory approach is generally sound, it carries with it the potential for excessive administrative regulation and delay. It is imperative that this legislation not become a tool for causing unnecessary redtape for industry or government.

The premarket screening process [Sec. 5] which is the key to this bill should not be used to cause unnecessary extensive testing in advance of commercial production, preventing production of many needed products. This creates a heavy responsibility on those who administer this act. Care must be taken to assure that the responsibility is carried out with fairness, not an overzealous use of administrative powers.

The Presiding Officer. All time having been yielded back, the question is. Shall the bill pass ?

The yeas and nays have been ordered, and the clerk will call the roll.

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The assistant legislative clerk called the roll.

Mr. Robert C. Byrd. I announce that the Senator from Indiana (Mr. Bayh), the Senator from Texas (Mr. Bentsen) , the Senator from Mississippi (Mr. Eastland), the Senator from Alaska (Mr. Gravel), the Senator from Michigan (Mr. Philip A. Hart), the Senator from Colorado (Mr. Haskell), the Senator from Hawaii (Mr. Inouye), the Senator from Washington (Mr. Jackson), the Senator from Wyoming (Mr. McGee), the Senator from New Hampshire (Mr. McIntyre), the Senator from New Mexico (Mr. Montoya), the Senator from Utah (Mr. Moss), the Senator from Mississippi (Mr. Stennis), and the Senator from Iowa (Mr. Culver) are necessarily absent.

I further announce that the Senator from Vermont (Mr. Leah[^]), and the Senator from Louisiana (Mr. Long) are absent on official business.

I further announced that, if present and voting, the Senator from Washington (Mr. Jackson), the Senator from Vermont (Mr. Leahy) and the Senator from Iowa (Mr. Culver) would each vote "'yea."

Mr. Griffix. I announce that the Senator from Tennessee (Mr. Brock), the Senator from Massachusetts (Mr. Brooke), the Senator from New York (Mr. Buckley), the Senator from Arizona (Mr. Fannin), the Senator from Oregon (Mr. Hatfield), the Senator from Nebraska (Mr. Hruska), the Senator from Nevada (Mr. Laxalt), the Senator from Maryland (Mr. Matliias), the Senator from Pennsylvania (Mr. Hugh Scott), the Senator from Virginia (Mr. Scott), and the Senator from Connecticut (Mr. Weicker) are necessarily absent.

I further announce that, if present and voting, the Senator from Oregon (Mr. Hatfield), the Senator from Pennsylvania (Mr. Hugh Scott), and the Senator from Connecticut (Mr. Weicker) would each vote "yea."

The result was announced – yeas 60, nays 13, as follows :

[Rollcall Vote No. 103 Leg.]
YEAS- 60

Abourezk

Glenn

Xunn

Allen

Griffin

l*ackwood

Baker

Hart, Gary

Pastore

Beall

Hartke

Pearson

Biden

Hathaway

Pell

Bumlers

Hollings

Percy

Burdick

Huddleston

Proxmire

Byrd, Harry F., Jr.

Humphrey

Randolph

Byrd, Robert C.

Javits

Ribicofif

Cannon

Johnston

Roth

Case

Kennedy

Schweiker

Chiles

Magnuson

Sparkman

Church

Mansfield

Stafford

Clark

McClellan

Stevens

Cranston

McGovern

Stevenson

Dole

Metcalf

Stone

Durkin

Mondale

Taft

Eagleton

Morgan

Talmadge

Fong

Muskie

Tunney

Ford

Nelson

Williams

264

NAYS- 13

Bartlett

Bellmon

Curtis

Domenici

Garn

Goldwater

Hansen

Helms

McClure

Symington

Thurmond

Tower

Young

Bayh

Bentsen

Brock

Brooke

Buckley

Culver

Eastland

Fannin

Gravel

NOT VOTING- 27

Hart, Philip A.

Haskell

Hatfield

Hruska

Inouye

Jackson

Laxalt

Leahy

Long

Mathias

McGee

McIntyre

Montoya

Moss

Scott, Hugh

Scott, William L.

Stennis

Weicker

So the bill (S. 3149) was passed, as follows:

S. 3149

Be it enacted hp the Senate and House of Representatives of the United States
of America in Congress assembled,

SHORT TITLE AND TABLE OF CONTENTS

Section 1. This Act may be cited as the "Toxic Substances Control Act".

TABLE OF CONTENTS

Sec. 1. Short title and table of contents.

Sec. 2. Findings, policy, and intent.

Sec. 3. Definitions and exclusions.

Sec. 4. Testing of chemical substances and mixtures.

Sec. 5. Premarket notification of chemical substances.

Sec. 6. Regulation of chemical substances and mixtures.

Sec. 7. Imminent hazards.

Sec. 8. Reporting and retention of information.

Sec. 9. Relationship to other Federal laws.

Sec. 10. Research, collection, dissemination, and utilization data.

Sec. 11. Inspections and subpoenas.

Sec. 12. Expo'-L.

Sec. 13. Entry into customs territory of the United States.

Sec. 14. Disclosure of data.

Sec. 15. Prohibited acts.

Sec. 16. Penalties.

Sec. 17. Specific enforcement and seizure.

Sec. 18. Pre-emption.

Sec. 19. Judicial review.

Sec. 20. Citizen's civil action.

Sec. 21. Citizen's petitions.

Sec. 22. National defense waiver.

Sec. 23. Employee protection.

Sec. 24. Studies.

- Sec. 25. State demonstration programs.
- Sec. 26. Administration of Act.
- Sec. 27. Authorization for appropriations.
- Sec. 28. Annual report.

FINDINGS, POLICY, AND INTEREST

Sec. 2. (a) Findings. – The Congress finds that –

- (1) humans and the environment are being exposed to a large number of chemical substances and mixtures each year ;
- (2) among the many chemical substances and mixtures constantly being developed and produced are some whose manufacture, processing, distribution in commerce, use, or disposal may cause or contribute to an unreasonable risk of injury to health or the environment ; and
- (3) the effective regulation of such chemical substances and mixtures in interstate commerce necessitates the regulation of such chemical substances and mixtures in intrastate commerce as well.

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(b) Policy. – It is the policy of the United States that –

- (1) adequate data should be developed with respect to chemical substances and mixtures concerning their effect on human health and the environment and that such data development should be the responsibility of those who manufacture and those who process such chemical substances and mixtures ;
- (2) adequate authority should exist to regulate chemical substances and mixtures which cause or contribute to an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards ; and
- (3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not cause or contribute to an unreasonable risk of injury to health or the environment.

(c) INTENT OF Congress. – It is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this Act.

DEFINITIONS AND EXCLUSIONS

Sec. 3. (a) Definitions. – As used in this Act :

(1) The term "Administrator" means the Administrator of the Environmental Protection Agency.

(2) (A) Except as provided in subparagraph (B), the term "chemical substance" means –

(i) any organic or inorganic substance of a particular molecular identity including a combination of such substances occurring as a result of a chemical reaction, or

(ii) any element or uncombined radical.

(B) Such term does not include –

(i) any mixture,

(ii) any pesticide (as defined in the Federal Insecticide, Fungicide and Rodenticide Act) when manufactured or distributed in commerce for use as a pesticide,

(iii) tobacco or any tobacco product.

(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act) .

(v) any article which, if sold by the manufacturer, would be subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code) , and

(vi) (A) any substance found in or on any food, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured or distributed in commerce for use in or any such food, drug, cosmetic, or device, or (B) any substance produced for research and development purposes and intended only for use in or on any such food, drug, cosmetic, or device.

The term "food" as used in clause (vi) of this subparagraph includes poultry

and poultry products (as defined in sections 4(e) and 4(f) of the Poultry Products Inspection Act), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act).

(3) The term "commerce" means trade, traffic, or transportation (A) between a place in a State and any place outside of such State, or (B) which affects such trade, traffic or transportation.

(4) The term "distribute in commerce" or "distribution in commerce" which used to describe an action taken with respect to a chemical substance, or the introduction or delivery for introduction into commerce of. the substance or mixture; or to hold, or the holding of, the substance or mixture after its introduction into commerce.

(5) The term "environment" includes humans and their environment, water, atmosphere, and land and the interrelationships which exist among and between these.

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(6) The term "health and safety study" means any study of any effects of a chemical substance or mixture on health or the environment, including epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act.

(7) The term "manufacture" means to import, produce, or manufacture for commercial purposes.

(8) The term "mixture" means any combination of two or more chemical substances if such substances (A) do not react chemically with each other and if the combination is not the result of a chemical reaction, or (B) occur in nature.

(9) The term "new chemical substance" means any chemical substance not included in the chemical substance list compiled and published under section 8(b).

(10) The term "process" means the preparation of a chemical substance or mixture for distribution in commerce -

(A) in the same form or physical state, or in a different form or physical state from that in which it was received by the person making such preparation, or

(B) as part of an article containing the chemical substance or mixture.

(11) The term "processor" means any person who processes a chemical substance or mixture.

(12) The term "standards for the development of test data" means a prescription of -

(A) the-

(i) health and environmental effects, and

(ii) type of information relating to toxicity, persistence, and other characteristics which relate to effects on health and the environment

for which test data for a chemical substance or mixture are to be developed and any analysis that is to be performed on such data, and

(B) to the extent necessary to assure that such data are reliable and adequate, the manner in which such data are to be developed, the specification of any test protocol or methodology to be employed in the development of data respecting such effects and characteristics, and such other requirements as are necessary to provide such assurance.

(13) The term "State" means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, or the Trust Territory of the Pacific Islands.

(14) The term "United States", when used in the geographic sense, means all the States.

(15) The term "unreasonable adverse effects on the environment" means any unreasonable risk to man or to the environment taking into account the economic, social, and environmental costs and benefits of the use of any chemical substance.

(b) Exclusions. - The Administrator may exclude from coverage of this Act or any provision of this Act any chemical substance or mixture if the Administrator determines, by rule, that such substance or mixture does not present an unreasonable risk of injury to health or the environment, except that any such exclusion shall not apply to section 7 or 8(e). Any such rule shall (A) be promulgated pursuant to the procedures specified in section 6(c) (2), (3), (4), and (5) and (B) may be modified, amended, or revoked in accordance with the requirements of this subsection and pursuant to the procedures specified in such

section 6(c) (2), (3), (4), and (5).

TESTING OF CHEMICAL SUBSTANCES AND MIXTURES

Sec. 4. (a) Testing Requirements. – If the Administrator finds that –

(1)(A)(i) the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture may present an unreasonable risk of injury to health or the environment, or (ii) (I) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture may present significant human or environmental exposure because it is or will be produced in substantial quantities or for other reasons, and (II) that such substance or mixture may perhaps present an adverse effect on health or the environment.

(B) there are insufficient data or experience upon which the effects of such manufacture, processing, distribution in commerce, use, or disposal on health or the environment can reasonably be determined or predicted, and

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(C) testing of such substance or mixture with respect to such effects is necessary to develop such data ; and

(2) in the case of a mixture, the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing chemical substances which comprise the mixture : the Administrator shall by rule require that testing be conducted on such substance or mixture to develop data with respect to the health and environmental effects for which there is an insufficiency of data or experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture does or does not contribute to an unreasonable risk of injury to health or the environment. In requiring tests under this subsection, the Administrator shall consider the reasonably ascertainable costs and other burdens associated with conducting such tests in light of the possible risks of injury to health or the environment and shall publish the same in the Federal Register. The finding in paragraph (1) (A) (ii) (II) shall be presumed if the Administrator has no reliable data or experience available to him concerning the chemical substance or mixture. The finding in paragraph (1)(ii)(II) shall not be subject to judicial review on any ground other than the fact that such finding was not made.

(b)(1) Testing Requirement Rule. - ,A rule under subsection (a) requiring the testing of a chemical substance or mixture shall include -

(A) identification of the substance or mixture for which testing is required.

(B) standards for the development of test data for such substance or mixture, and

((') with respect to chemical substances which are not new chemical substances a specification of the i)eriod (which period may not be of un-reasonable duration) within which the persons required to conduct the testing shall submit to the Administrator data developed in accordance with the standards referred to in subparagraph (B). Such a rule may require the submission of preliminary data during the period prescribed under subparagraph (C).

(2) (A) The health and environmental effects for which standards for the develoi)ment of test data may be prescribed include carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may cause or contribute to an unreasonable risk of injury to health or the environment, and the characteristics of chemical substances and mixtures for which such standards may be prescribed include persistence, acute toxicity, .subacute toxicity, chronic toxicity, and any other characteristic which may cause or contribute to such a risk of injury. The methodologies that may be prescribed in such standards include epidemiology, serial, or hierarchical tests : in vitro tests ; and whole animal tests.

(B) From time to time, but not less than once each 12 months, the Admin-istrator shall review the adequacy of tlie standards for development of data prescribed in rule.s under subsection (a) and shall, if necessary, institute pro-ceedings to make appropriate revisions of such standards.

(3) (A) A rule under subsection (a) respecting a chemical substance or mix-ture shall require the persons described in subparagraph (B) to conduct tests and submit data on such substance or mixture, except that the Administrator may permit two or more of such per.sons to designate one such i)erson or a quali-fied third party to conduct such tests and submit .such data on behalf of the persons making the designation.

(B) Tlie following persons shall be vcquired to conduct tests and submit data on a chemical substance or mixture .subject to a rule under sub.section (a) :

(i) Each person who manufactures or intends to manufacture such sub-stance or mixture if the Administrator made a finding described in sub-section (a)(1)(B) with respect to the manufacture of the substance or mixture which such person is engaged in or intends to engage in.

(ii) Each person who processes or intends to process such substance or mixture if the Administrator made a finding described in subsection (a)(1)(B) with respect to the processing of the substance which such person is engaged in or intends to engage in.

(iii) Each person who manufactures or processes or intends to manufacture or process such substance or mixture if, with respect to the dis-

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tribution in commerce, disposal or use of such substance or mixture manufactured or processed by such person, the Administrator made a finding described in subsection (a)(1)(B).

(4) Rules issued under subsection (a) (and any amendment thereto or repeal thereof) shall be promulgated pursuant to section 553 of title 5, United States Code, except that in promulgating, amending, or repealing any such rule (A) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions ; and (B) a transcript shall be made of any oral presentation.

(c) Exemption. - (1) Any person required by a rule under subsection (a) to conduct tests and submit data on a chemical substance or mixture may apply to the Administrator (in such form and manner as the Administrator shall prescribe) for an exemption from such requirement.

(2) If, upon receipt of an application under paragraph (1), the Administrator determines that -

(A) the chemical substance or mixture with respect to which such application was submitted is equivalent to a chemical substance or mixture for which data has been submitted to the Administrator in accordance with a rule under subsection (a) or for which data is being developed pursuant to such a rule, and

(B) submission of data by the applicant on such substance or mixture would be duplicative of data which has been submitted to the Administrator in accordance with such rule or which is being developed pursuant to such rule.

the Administrator shall exempt, in accordance with paragraph (3) or (4), the applicant from conducting tests and submitting data on such substance or mixture.

(3) (A) If the exemption of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the existence of previously submitted test data and if such exemption is granted during the reimbursement period for such test data (as prescribed by subparagraph (B)), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator) -

(i) to the person who previously submitted such test data, for a portion of the costs incurred by such person in complying with the requirement to submit such data, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on competition within the chemical industry and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph for purposes of judicial review shall be considered final agency action.

(B) For purposes of subparagraph (A), the reimbursement period for any test data for a chemical substance or mixture is a period -

(i) beginning on the date such data was submitted in accordance with a rule promulgated under subsection (a) , and

(ii) ending -

(I) two years after the date referred to in clause (i) , or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later.

(4) (A) If the exemption of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the fact that test data is being developed by one or more persons pursuant to

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a rule promulgated under subsection (a), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall issue an order to the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator) -

(i) to each such person who is developing such test data, for a portion of the costs incurred by each such person in complying with such rule, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to the costs of complying with such rule, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on competition within the chemical industry and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph for purposes of judicial review shall be considered final agency action.

(B) If an exemption is granted on the basis of the fact that one or more persons are developing test data pursuant to a rule promulgated under subsection (a) and if after such exemption is granted the Administrator determines that no such person has complied with such rule, the Administrator shall (i) after providing written notice to the person who holds such exemption and an opportunity for a hearing, by order terminate such exemption, and (ii) notify in writing such person of the requirements of the rule with respect to which such exemption was granted.

(C) If a person provides reimbursement pursuant to an order issued under paragraph (3) (A) or (4) (A) in connection with an exemption from a rule promulgated under subsection (a), such person may, subject to section 14, have access to test data the submission or development of which was the basis for such exemption.

(d) Notice. - Upon the receipt of any test data pursuant to a rule under subsection (a), the Administrator shall (subject to section 14) publish a notice of the receipt of such data in the Federal Register and make the data available to the public within 15 days of receipt. Each such notice shall (1) identify the chemical substance or mixture for which data have been received; (2) list

the uses or intended uses of such substance or mixture and the information required by the applicable standards for the development of test data; and (3) describe the nature of the test data developed.

(e) PRIORITY LIST. - (1) (A) There is established a committee to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of a rule under subsection (a). In making such a determination with respect to any chemical substance or mixture, the committee shall consider all relevant factors, including -

(i) the quantities in which the substance or mixture is or will be manufactured, •

(ii) the quantities in which the substance or mixture enters or will enter the environment,

(iii) the number of persons who are or will be exposed to the substance or mixture in their places of employment and the duration of such exposure,

(iv) the extent to which humans are or will be exposed to the substance or mixture.

(v) the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to cause or contribute to an unreasonable risk to health or the environment.

(vi) the existence of data concerning the effects of the substance or mixture on health or the environment, and

(vii) the extent to which testing of the substance or mixture may result in the development of data upon which the effects of the substance or mixture on health or the environment can reasonably be determined or predicted.

The recommendations of the committee shall be in the form of a list of chemical substances and mixtures which shall be listed, either by individual substance or

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mixture or by groups of substances or mixtures, in the order in which the committee determines the Administrator should take action under subsection (a) with respect to the substances and mixtures. The committee shall give priority attention in establishing such list to those chemical substances and mixtures

which are known or are suspected of causing or contributing to (i) cancer, (ii) gene mutations, or (iii) birth defects.

(B) As soon as practicable but not later than nine months after the date of the enactment of this Act, the committee shall publish in the Federal Register the list required by subparagraph (A) together with the reasons for the committee's inclusion of each chemical substance or mixture on the list. At least every 6 months after the publication of the list pursuant to the preceding sentence, the committee shall make such revisions in the list as it determines to be necessary and shall publish the list in the Federal Register with the committee's revisions (if any) and the reasons for the revisions. Within the 12-month period beginning on the date of the inclusion of a chemical substance or mixture on such a list the Administrator shall with respect to such chemical substance or mixture either (i) initiate a rulemaking proceeding under section 4(a) or (ii) if such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reasons for not initiating such a proceeding.

(C) The Administrator may promulgate a rule under subsection (a) with respect to a chemical substance or mixture (i) which is not contained on a list published under this subsection or (ii) whether or the Administrator has published in the Federal Register reasons for not initiating a proceeding under subparagraph (B).

(2) (A) The committee established by paragraph (1) (A) shall consist of seven members as follows :

(i) One member (or designee of the member) appointed from the Department of Commerce by the Secretary.

(ii) One member (or designee of the member) appointed from the Environmental Protection Agency by the Administrator".

(iii) One member (or designee of the member) appointed by the Secretary of Labor from officers of the Department of Labor engaged in the Secretary's activities under the Occupational Safety and Health Act of 1970.

(iv) One member (or designee of the member) appointed from the Council on Environmental Quality by the Chairman of the Council.

(v) One member (or designee of the member) appointed from the National Institute for Occupational Safety and Health by the Director of the Institute.

(vi) One member (or the designee of the member) appointed from the National Institute of Environmental Health Sciences by the Director of the Institute.

(vii) One member (or designee of the member) appointed from the Na-

tional Cancer Institute by the Director of the Institute.

(viii) One member (or designee of the member) appointed from the National Science Foundation by the Director of the Foundation.

A member may designate an individual to serve on the member's behalf only with the approval of the applicable appointing authority and only if the individual is from the entity from which the member was appointed. A vacancy in the committee shall be filled in the same manner in which the original appointment was made.

(B) (i) The term of office of a member of the committee is 4 years, except that of the members first appointed, four members shall have initial terms of 2 years. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of such term. If any member of the committee leaves the office or entity from which the member was appointed, such member's term of office shall be terminated and the member's position shall be considered as being vacant. A member may serve after the expiration of the member's term of office until a successor has taken office. Members may be reappointed.

(ii) Initial appointments to the committee shall be made not later than the 60th day after the date of the enactment of this Act. Not later than the 90th day after such date of enactment the members of the committee shall hold a meeting for the selection of a chairman from among their number and to determine, by lot, the four members who shall have initial terms of 2 years.

(C) (i) No member of the committee, or designee of such member, shall accept employment or compensation from any person subject to any requirement of this

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Act. or rules issued thereunder, for a period of at least 24 months after termination of employment with such agency.

(ii) No person, while serving as a member of such committee, or designee of such member, may own any stocks or bonds, or have any pecuniary interest in any firm, association, or corporation engaged in the manufacture, processing, or distribution of any chemical substance or mixture subject to the provisions of this Act.

(iii) The Administrator or the Attorney General bring an action in the appropriate district court of the United States to restrain any violations of this subparagraph.

(D) The Administrator shall provide the committee such administrative and staff support services as may be necessary for the committee to carry out its functions under this subsection.

(f) Required Actions. - (1) Upon the receipt of (A) any test data required to be submitted under this section or under section o. or (B) any other information available to the Administrator which indicates that a chemical .substance or mixture has the potential, at levels for which human exposure exists or may exist and with appropriate safety margins, to induce in human beings (1) cancer. (2) gene mutations, or (3) birth defects, the Administrator shall take appropriate action under section 5(e), 6(a). or 7, within 180 days after the receipt of such data or information to limit exposure of human beings with respect to such substance or mixture, or he shall publish in the Federal Register his findings that no unreasonable risk of injury is i)resented and rea.sons therefor. Any such finding under this subsection that nounreasonable ri.sk is presented shall be reviewable in accordance with chapter 7 of title 5. United States Code.

(2) Nothing contained in this subsection shall require the Administrator to take action under section Hfe). 6(a). or 7, or publish his reasons for failing to take such action, until 2 years after the date of enactment of this Act.

PREMARKET NOTIFICATION OF CHEMICAL SUBSTANCES

Sec. 5. (a) General. - (1) Commencing 1 year and 30 days after the date of enactment of this Act, a manufacturer shall notify the Administrator, who shall notify the public as required in subsection (c). of any planned manufacture of a new chemical substance, at least 90 days prior to the commencement of such manufacture. Such notice to the Administrator shall be accompanied by all pertinent information referred to in section 8(a)(2), whether or not the Administrator has required the submission thereof under section 8(a)(2), except that with respect to the information referred to under section 8(a) (2) (E), such manufacturer may submit a description of such information, as defined by the Administrator, by rule.

(2) The Administrator shall give priority attention to a chemical substance with respect to which information is received indicating that serious economic or other hardships are likely to result if there is any delay in manufacture. If the Administrator finds that such a substance does not present an unreasonable risk to human health and the environment, he may reduce the number of days, after submission of such information, during which manufacture may not occur. The Administrator shall promptly publish (subject to .section 14) his findings and the basis therefor in the Federal Register.

(b) Submission of Data. - Any manufacturer of a new chemical substance that is covered by section 4(a) shall submit to the Administrator (in addition to the information required in subsection (a) the data developed in accordance with such requirement at least 90 days prior to such manufacture, and the

Administrator shall make it publicly available in accordance with subsection (c).

(c) Data Availability. – "Within 15 days after receipt, the Administrator shall promptly publish in the Federal Register (subject to section 14) the identity of each chemical substance for which a notice has been received under subsection (a) or (b). the intended use or distribution of such substance, and a statement that the data and other information is available. The 90 days referred to in subsections (a) and (b) shall begin upon publication under this subsection in the Federal Register.

(d) Extension. – The Administrator may extend, for an additional period beyond the 90-day period referred to in subsection (a) or (b). the date after which a new chemical substance may be manufactured. Such additional period may not exceed 90 days and shall not be imposed except for good cause shown. Notice of any such extension, and the reasons therefor, shall be published (sub-

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ject to section 14) in the Federal Register. Such an extension shall constitute a final action for purposes of judicial review.

(e) Orders. – (1) (A) If the Administrator finds, during the 90-day period referred to in subsection (a) or (b) or during any extension thereof, with respect to any new chemical substance for which notification is required under this section –

(i) that such new chemical substance is covered by a test requirement under section 4(a), but that such requirement requires additions or revisions with respect to such substance ; or

(ii) that such new chemical substance is not covered by such a requirement under section 4(a), but that such requirement should be established; he shall issue an order in accordance with this subsection. Such an order shall appropriately prohibit or restrict the manufacture, processing, distribution in commerce, use, or disposal of such new chemical substance pending the completion of a rulemaking proceeding under section 4(a) and the submission of any data required thereunder, as described under subparagraph (B) ; shall contain a proposed rule under section 4(a) ; and shall be immediately effective.

(B) Upon the issuance of any order under subparagraph (A), the Administrator shall proceed with a rulemaking procedure as expeditiously as practicable under section 4(a) and in accordance with subparagraph (C). During the course of, or upon the completion of, such rulemaking, the Administrator shall, if neces-

sary, appropriately modify or rescind any order issued under subparagraph (A). If any testing requirements are established as a result of such rulemaking, any provision of such order restricting the manufacture, processing, distribution in commerce, use, or disposal of such substance shall remain in effect, unless modified or rescinded, pending the submission of such data to the Administrator and the completion of procedures described in subsection (b) or any extension imposed under subsection (d).

(C) If the Administrator issues an order under subparagraph (A), the Administrator shall provide interested persons reasonable opportunity, in accordance with section 4(b) (4) to make presentations and submissions with respect to such order. If such presentation or submission is requested, the Administrator shall comply within 30 days from the date such request is made unless the Administrator and the person making the request agree upon a later date. Within 10 days after such presentations and submission are concluded, the Administrator shall consider such presentations and submissions and affirm, modify, or revoke such order.

(2) (A) If the Administrator finds, during the 90-day period referred to in subsection (a) or (b) or during any extension thereof, with respect to any new chemical substance for which notification is required under this section, that a rule is appropriate under section 6(a), he shall issue an order in accordance with this subsection. Such an order shall appropriately prescribe such requirements as are authorized under section 6(a) : shall contain a proposed rule under section 6(a) ; and shall be immediately effective.

(B) Upon the issuance of any order under subparagraph (A), the Administrator shall proceed with a rulemaking procedure as expeditiously as practicable under section 6(a) and in accordance with subparagraph (C). During the course of, or upon the completion of such rulemaking, the Administrator shall, if necessary, appropriately modify or rescind any order issued under subparagraph (A).

(C) If the Administrator issues an order under subparagraph (A), the Administrator shall provide interested persons reasonable opportunity, in accordance with section 6(c) (2) and (3) for an informal hearing with respect to such order. If such hearing is requested, the Administrator shall comply within 30 days from the date such request is made unless the Administrator and the person making the request agree upon a later date. Within 10 days after such hearing is concluded, the Administrator shall consider the information presented at such hearing and affirm, modify, or revoke such order.

(f) Statement of Reasons for Not Taking Action. – Prior to the expiration of 90 days after the date of publication under subsection (c), of data and information with respect to a new chemical substance, or prior to the expiration of such period as extended under subsection (d), the Administrator shall publish a statement of his reasons in the Federal Register, if he decides not to take action under subsection (e) or section 7 with respect to such chemical substance during such period. Manufacture may commence following publication of the

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Administrator's statement. The Administrator's failure to issue such an order under subsection (e) or take action under section 7 is an action subject to judicial review in accordance with section 19. Nothing in this subsection prohibits the Administrator from -

(1) promulgating a rule pursuant to section 6 or 4, with respect to such a substance, after such manufacture has commenced ;

(2) taking action against any chemical substance which is found to be an imminent hazard pursuant to section 7 ; or

(3) taking any other action authorized by this Act.

(g) Exemption. - (1) The Administrator may upon application (made in such form and manner as the Administrator may prescribe) exempt any person from the requirement of subsection (b) or (h) to submit data for a chemical substance or mixture. If, upon receipt of an application under the preceding sentence, the Administrator determines that -

(A) the chemical substance or mixture with respect to which such application was submitted is equivalent to a chemical substance or mixture for which data has been submitted to the Administrator in accordance with subsection (b) or (h), and

(B) submission of data by the applicant with respect to such substance would be duplicative of data which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from submitting such data with respect to such substance. No exemption granted under this subparagraph with respect to the submission of data for a chemical substance or mixture may take effect before the beginning of the reimbursement period applicable to such data.

(2) If the Administrator, under paragraph (1), exempts any person from submitting under subsection (b) or (h) data for a chemical substance or mixture because of the existence of previously submitted data and if such exemption is granted during the reimbursement period for such data, then (unless such person and the persons referred to in subparagraphs (A) and (B) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under the rules of the Administrator) -

(A) to the person who previously submitted the data on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b) or (h) to submit such data, and

(B) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in subparagraphs (A) and (B) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consulting with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on competition within the chemical industry and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph shall be considered final agency action, for purposes of judicial review.

(3) For purposes of this paragraph, the reimbursement period for any previously submitted data for a chemical substance or mixture is a period -

(A) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such data to the Administrator, and

(B) ending -

(i) two years after the date referred to in subparagraph (A), or

(ii) at the expiration of a period which begins on the date referred to in subparagraph (A) and is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later.

(h) Significant New Use. - (1) Within months after the date of enactment of this Act, and from time to time thereafter, the Administrator shall, by rule, establish criteria defining a significant new distribution in commerce, use, or disposal of a chemical substance. In establishing such criteria the Administrator shall take into account -

(A) projected volume of production ;

(B) projected category or categories of uses ;

(C) projected increase in magnitude and duration of human and environmental exposure ;

(D) route or routes of exposure of human beings or of the environment that are attributable to such significant new use : and

(E) the human health and environmental effects thereof.

(2) A chemical substance may not be manufactured or processed for a distribution in commerce use, or disposal that is identified by the Administrator, in a rule, as a significant new distribution in commerce, use, or disposal, unless, at least 90 days prior to such manufacture or processing, the person intending to manufacture or process such substance for such distribution in commerce, use, or disposal submits a notice of his intention to do so and any data required to be developed under section 4(a) to the Administrator. Any such use of such substance shall be subject to all of the provisions of this section.

(i) Special Exemption, - The Administrator may, upon application and by rule, exempt any person from the foregoing requirements of this section -

(1) for the purpose of permitting such person to manufacture, process, distribute in commerce, use, or dispose of a new chemical substance to which a rule under section (a) is applicable for test marketing purposes or specially limited purposes (A) upon a showing by such person that such activity will not cause or contribute to an unreasonable risk of injury to human health or the environment, and (B) under such restrictions as the Administrator considers appropriate ; or

(2) to the extent that such person manufactures chemical substances which are intermediate reaction products formed during the manufacture of other chemical substances and for which there is no exposure to human beings or the environment.

(j) Mixtures. - The Administrator is authorized to specify any mixture which shall be subject to the provisions of this section.

(k) Experimentation. - The requirements of subsections (a), (b), and (h) do not apply to any chemical substance which is manufactured or intended to be manufactured only in small quantities (as defined by the Administrator by rule) solely for scientific experimentation or analysis or for chemical research or analysis, including such research or analysis for the development of a product, except that the Administrator may, by rule, include such chemical substances upon a finding that the manufacture, processing, distribution in

commerce, use, or disposal of such chemical substances may cause or contribute to an unreasonable risk of injury to human health or the environment.

REGULATION OF CHEMICAL SUBSTANCES AND MIXTURES

Sec. 6. (a) Scope of Regulation. - (1) If the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture presents or is likely to present an unreasonable risk of injury to health or the environment, the Administrator shall by rule apply to such substance or mixture one or more of the following requirements as is necessary to adequately protect against such risk using the least burdensome of effective controls :

(A) A requirement prohibiting processing or distribution in commerce of such substance or mixture or limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

(B) A requirement -

(I) prohibiting the manufacture, processing or distribution in commerce of such substance or mixture for (i) a particular use or particular uses or (ii) a particular use or particular uses in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or

(II) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or particular uses or (ii) a particular use or particula uses in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

(C) A requirement regulating the manner or method of use or disposal of such substance or mixture.

(D) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate

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warnings and instructions with respect to its distribution in commerce, use, or disposal. The form and content of such warnings and instructions shall be prescribed by the Administrator.

(E) A requirement directing manufacturers or processors of such substance

or mixture (i) to give notice of such unreasonable risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (ii) to give public notice of such risk of injury, and (iii) to either replace or repurchase such substance or mixture whichever the person to which the requirement is directed elects.

(F) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of this subsection. A requirement imposed under this subsection may be limited in application to specified geographic areas.

(2) Rules limiting the amount of a chemical substance or mixture which may be manufactured, processed, or distributed in commerce, or limiting, the amount of such substance which may be manufactured, processed, or distributed for a particular use shall, upon the petition of any manufacturer, processor, or distributor in commerce thereof, provide for assigning production, processing, and distribution quotas, to the extent necessary with respect to the chemical substance involved. The permissible quota for each person who applies to manufacture, process, or import such substance or to engage in its distribution in commerce shall be determined in accordance with fair and equitable criteria which the Secretary of Commerce, in consultation with the Administrator and the Attorney General, shall prescribe by rule. Such criteria shall take into account all relevant factors, including (A) effects on competition; (B) the market shares, productive capacity and product and raw material inventories of the precursors of the chemical substance or mixture of persons applying for quotas; (C) emergency conditions; and (D) effects on technological innovation.

(3) (A) Prior to the issuance of a quota under paragraph (2) the persons who apply under such paragraph shall attempt to develop a voluntary agreement limiting the quantities which each such person shall manufacture, process, import, or distribute. The availability of immunity from the antitrust laws with respect to the development of such voluntary agreement shall be limited to the provisions of this subsection.

(B) The Secretary of Commerce, with the approval of the Attorney General, after each of them has consulted with the Federal Trade Commission, shall prescribe, by rule, standards and procedures by which persons seeking to manufacture, process, import, or otherwise distribute a chemical substance or mixture for which limitations on quantity have been prescribed pursuant to paragraph (B)(II) of subsection (a) of this section may develop and carry out such voluntary agreements as are permissible pursuant to this subsection.

(C) The standards and procedures prescribed under subparagraph (A) shall include the following requirements:

(i) Meetings held to develop or carry out a voluntary agreement under this subsection shall permit attendance by representatives of Committees of Congress and interested persons, including all persons interested in the chemical substance or mixture involved, and the public: shall be preceded by timely and adequate notice with identification of the agenda of such meeting to the Secretary of Commerce, the Attorney General, the Federal Trade Commission, the Administrator and the public; and shall be chaired by a regular full-time Federal employee.

(ii) A full and complete record, and where practicable a verbatim transcript, shall be kept of any meeting held, and a full and complete record shall be kept of any communication (other than in a meeting) made, between or among participants or potential participants, to develop, or carry out a voluntary agreement under this subsection. Such record or transcript shall be deposited, together with any agreement resulting therefrom, with the Secretary of Commerce and the Administrator and shall be available to the Attorney General and the Federal Trade Commission. Such records or transcripts shall be available for public inspection and copying in accordance with section 552 of title 5, United States Code.

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(D) (i) The Attorney General and the Federal Trade Commission shall participate from the beginning in the development, and when practicable, in the carrying out of voluntary agreements and plans of action authorized under this section. Each may propose any alternative which would void or overcome, to the greatest extent practicable, possible anticompetitive effects while achieving substantially the purpose of this subsection. A voluntary agreement under this subsection may not be carried out unless approved by the Attorney General, after consultation with the Federal Trade Commission. Prior to the expiration of the 20-day period prescribed under clause (ii), the Federal Trade Commission shall transmit to the Attorney General its views as to whether such an agreement or plan of action should be approved, and shall publish such views in the Federal Register. The Attorney General, in consultation with the Federal Trade Commission, and the Secretary, shall have the right to review, amend, modify, disapprove, or revoke, on his own motion or upon the request of the Federal Trade Commission or any interested person, any voluntary agreement at any time, and, if revoked, thereby withdraw prospectively any immunity which may be conferred by subparagraphs (F) or (1).

(ii) Any voluntary agreement entered into pursuant to this section shall be submitted in writing to the Attorney General and the Federal Trade Commission 20 days before being implemented. Any such agreement shall be available for

public inspection and copying, to the extent to which records or transcripts are so available as provided in the last sentence of subparagraph (C) (ii). Any action taken pursuant to such voluntary agreement or plan of action shall be reported to the Attorney General and the Federal Trade Commission pursuant to such regulations as shall be prescribed under clauses (iii) and (iv) of subparagraph (E).

(E) (i) The Attorney General and the Federal Trade Commission shall monitor the development and carrying out of voluntary agreements authorized under this paragraph in order to promote competition and to prevent anticompetitive practices and effects.

(ii) In addition to any requirement specified under subparagraphs (B) and (C) of this paragraph and in order to carry out the purposes of this section, the Attorney General, in consultation with the Federal Trade Commission and the Administrator, shall promulgate rules concerning the maintenance of necessary and appropriate records related to the development and carrying out of voluntary agreements authorized pursuant to this section.

(iii) Persons developing or carrying out voluntary agreements authorized pursuant to this section shall maintain such records as are required by rules promulgated under subparagraph (B). The Attorney General and the Federal Trade Commission shall have access to and the right to copy such records at reasonable times and upon reasonable notice.

(iv) The Attorney General and the Federal Trade Commission may each prescribe such rules as may be necessary or appropriate to carry out their respective responsibilities under this section. They may both utilize for such purposes and for purposes of enforcement any powers conferred upon the Federal Trade Commission or the Department of Justice, or both, by the antitrust laws or the Antitrust Civil Process Act ; and wherever any such law refers to "the purposes of this Act" or like terms, the reference shall be understood to include this subsection.

(F) (i) There shall be available as a defense to any civil or criminal action brought under the antitrust laws (or any similar State law) in respect to actions taken to develop or carry out a voluntary agreement by persons engaged in the business of manufacturing, processing, or distributing such chemical substance or mixture (provided that such actions were not taken for the purpose of injuring competition) that -

(I) such actions were taken in the course of developing a voluntary agreement pursuant to this paragraph to carry out a voluntary agreement authorized and approved in accordance with this section, and

(II) such persons complied with the requirements of this paragraph and the rules promulgated hereunder.

(ii) Persons interposing the defense provided by this paragraph shall have the burden of proof, except that the burden shall be on the person against whom the defense is asserted with respect to whether the actions were taken for the purpose of injuring competition. .

(G) No provision of this section shall be construed as granting immunity for, or as limiting or in any way affecting any remedy or penalty which may result

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from any legal action or proceeding arising from, any act or practice which occurred prior to the date of enactment of this Act or subsequent to its expiration or repeal..

(H) The Attorney General and the Federal Trade Commission shall each submit to the Congress and to the President, at least once each year a report on the impact on competition and on small business of actions authorized by this section.

(I) In any action in any Federal or State court for breach of contract, there shall be available as a defense that the alleged breach of contract was caused predominantly by action taken to carry out a voluntary agreement authorized and approved in accordance with this paragraph.

(J) As used in this paragraph, the term "antitrust laws" includes -

(i) the Act entitled "An Act to protect trade and commerce against unlawful restraints and monopolies", approved July 2, 1890 ;

(ii) the Act entitled "An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes", approved October 15, 1914 ;

(iii) the Federal Trade Commission Act ;

(iv) section 73 and 74 of the Act entitled "An Act to reduce taxation, to provide revenue for the Government, and for other purposes", approved August 27, 1894 : and

(v) the Act of June 19, 1936. chapter 592.

(b) Quality Control. - (1) If the Administrator has good cause to believe that a particular manufacturer or processor is manufacturing or processing a chemical substance or mixture in a manner which causes the adulteration of a

chemical substance or mixture -

(A) the Administrator may by order require such manufacturer or processor to submit a description of the relevant quality and control procedures followed in the manufacturing or processing of such chemical substance or mixture ; and

(B) if the Administrator thereafter determines on the record, after opportunity for hearing in accordance with section 554 of title 5, United States

Code, that such quality control procedures are inadequate to prevent the chemical substance or mixture from causing or contributing to such risk, the Administrator may order the manufacturer or processor to revise such quality control procedures to the extent necessary to remedy such inadequacy.

(2) As used in this section, a chemical substance or mixture is adulterated if the manner in which it is manufactured or processed causes it to contain a particular molecular identity, an uncombined radical, an element, or any combination thereof, which is found by the Administrator to cause or contribute to an unreasonable risk of injury to human health or the environment.

(c) Promulgation of Subsection (a) Rules. - (1) In promulgating any rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider relevant factors and make findings with respect thereto, including -

(A) the risks presented by such substance or mixture to health and the magnitude of human exposure to such substance or mixture.

(B) the risks presented by such substance or mixture to the environment and the magnitude of environmental exposure to such substance or mixture.

(C) the benefits of such substance or mixture for such use or uses and the availability of other substances or mixtures for such use or uses, and

(D) the reasonably ascertainable economic consequences of the rule, including consideration of the effect on the national economy, innovation, the environment, and public health.

Findings made under this paragraph shall be published in the Federal Register.

(2) When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of title 5, United States Code (without regard to any reference in such section to sections 556 and 557 of such title), and shall also (A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule: (B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly

available; (C) provide an opportunity for an informal hearing in accordance with paragraph (3) : and (D) promulgate, if appropriate, a final rule based on the matter in the rulemaking record.

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(3) The Administrator shall conduct informal hearings required by paragraph (2) (C) of this subsection in accordance with the following procedure:

(A) Subject to paragraph (B) of this paragraph, an interested person is entitled -

(i) to present his position orally or by documentary submissions (or both) , and

(ii) if the Administrator determines that there are disputed issues of material fact it is necessary to resolve, to present such rebuttal submissions and to conduct (or have conducted under subparagraph (B)(ii)) such cross-examination of persons as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to such issues.

(B) The Administrator may prescribe such rules and make such rulings concerning proceedings in such hearings to avoid unnecessary costs or delay. Such rules or rulings may include (i) imposition of reasonable time limits on each interested person's oral presentations, and (ii) requirements that any cross-examination to which a person may be entitled under subparagraph (A) be conducted by the Administrator on behalf of that person in such manner as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to disputed issues of material fact.

(C) (i) Except as provided in clause (ii), if a group of persons each of whom under subparagraphs (A) and (B) would be entitled to conduct (or have conducted) cross-examination and who are determined by the Administrator to have the same or similar interests in the proceeding cannot agree upon a single representative of such interests for purposes of cross-examination, the Administrator may make rules and rulings (I) limiting the representation of such interest for such purposes, and (II) governing the manner in which such cross-examination shall be limited.

(ii) When any person who is a member of a group with respect to which the Administrator has made a determination under clause (i) is unable to agree upon group representation with the other members of the group, then such person shall not be denied under the authority of clause (i) the opportunity to con-

duct (or have conducted) cross-examination as to issues affecting his particular interests if (I) he satisfies the Administrator that he has made a reasonable and good faith effort to reach agreement upon group representation with the other members of the group and (II) the Administrator determines that there are substantial and relevant issues which are not adequately presented by the group representative.

(D) A verbatim transcript shall be taken of any oral presentation, and cross-examination, in informal hearings under this subsection. Such transcript shall be available to the public.

(E) A substantive amendment to, or repeal of, a rule promulgated under subsection (a) shall be prescribed, and subject to judicial review, in the same manner as a rule prescribed under such subsection.

(4) Any rule promulgated under this section shall be judicially reviewable in accordance with section 19, except that in addition to any basis for holding unlawful or setting aside the rule under subparagraphs (A), (B), (C), or (D) of section 706(2) of title 5, United States Code, the court shall hold unlawful and shall set aside the rule if the court finds that -

(A) the Administrator's determination under paragraph (3) that the petitioner is not entitled to conduct cross-examination or make rebuttal submissions, or

(B) the Administrator's rule or ruling under paragraph (3) limiting the petitioner's cross-examination or rebuttal submissions, has precluded disclosure of disputed material facts which was necessary for fair determination by the Administrator of the rulemaking proceeding taken as a whole.

(5) (A) The Administrator may pursuant to rules prescribed by him, provide compensation for reasonable attorneys fees, expert witness fees, and other costs of participating in a rulemaking proceeding under this section to any person (i) who has, or represents an interest (I) which would not otherwise be adequately represented in such proceeding and (II) representation of which is necessary" for a fair determination of the rulemaking proceeding taken as a whole, or (ii) who is unable effectively to participate in such proceeding because such person cannot afford to pay costs of making oral presentations, conducting cross-examination, and making rebuttal submission in such proceeding.

(B) The aggregate amount of compensation paid to all persons in any fiscal year under this subsection may not exceed \$1,(X)0,000.

(d) Effective Date. – (1) The Administrator shall specify in any rule under section (a) the date on which it shall take effect, which date shall be as soon as feasible.

(2) Section 553(b) (B) of title 5, United States Code, shall be applicable to rules issued under subsection (a) notwithstanding any requirement of subsection (c) (2) or (3) in those situations where compliance with the requirements of subsection (c) (2) or (3) would present an unreasonable risk of death, serious or substantial personal injury (including illness) or serious or substantial environmental harm.

(e) POLYCHLORINATED BIPHENYLS. – (1) Effective 1 year after the date of enactment of this Act, it shall be unlawful to manufacture, process, distribute in commerce, or use any polychlorinated biphenyl in any manner other than in a totally enclosed manner, except that the Administrator may, by rule promulgated in accordance with subsection (c) (2), authorize the manufacture, processing, distribution in commerce, or use of any polychlorinated biphenyl in other than a totally enclosed manner if the Administrator finds that no unreasonable risk of injury to health or the environment is presented.

(2) Effective 2 years after the date of enactment of this Act, it shall be unlawful to manufacture any polychlorinated biphenyl, and effective 2½ years after such date, it shall be unlawful to process or distribute in commerce any polychlorinated biphenyl, except that the Administrator may authorize, by rule promulgated in accordance with subsection (c)(2), such manufacture, processing, or distribution in commerce after such time period if the Administrator finds that no unreasonable risk of injury to health or the environment is presented.

(3) Within 6 months after the date of enactment of this Act, the Administrator shall promulgate rules under subsection (a) which shall (A) prescribe methods for the disposal of polychlorinated biphenyls in accordance with the requirements of that subsection and (B) specify the manner in which polychlorinated biphenyls shall be marked with clear and adequate warnings and instructions with respect to their processing, distribution in commerce, use, or disposal. Any such rules shall be consistent with the requirements of paragraphs (1) and (2) of this subsection or rules issued thereunder.

(4) For the purposes of this subsection, the term "totally enclosed manner" means any manner which will ensure that any leakage of a polychlorinated bi-

phenyl from its enclosure will be insignificant, as defined in rules of the Administrator.

i IMMINENT HAZARDS

Sec 7. (a) Definition. – An imminent hazard shall be considered to exist when

If the evidence is sufficient to show that a situation exists in which the continued use of a chemical substance would be likely to result in unreasonable adverse effects on the environment or will involve an unreasonable hazard to the survival of a species declared endangered by the Secretary of the Interior under Public Law 91-135.

(b) Actions Authorized.— The Administrator may file an action in a United States district court —

(1) against an imminently hazardous chemical substance or mixture for seizure of such substance or mixture,

(2) against any person who manufactures, processes, distributes in commerce, uses, or disposes of such substance or mixture, or

(3) against both (A) such substance or mixture and (B) such person.

An action under this subsection may be filed notwithstanding the existence of

1 a rule under section 4(a) or 6(a) or an order under section 5(e) and notwithstanding the pendency of any administrative or judicial proceeding under any provision of this Act.

(c) Jurisdiction of Court. — (1) The United States district court in which an action under subsection (b) is brought shall have jurisdiction to grant such

temporary or permanent relief as may be necessary to protect against such unreasonable risk of death, serious illness or serious personal injury, or serious environmental harm presented by the chemical substance or mixture involved in such action.

(2) In the case of an action under subsection (b) brought against a person who manufactures, processes, distributes in commerce, uses, or disposes of a chemical substance or mixture, the relief authorized by paragraph (1) may include the issuance of a mandatory order requiring (A) in the case of purchasers of such substance or mixture known to the defendant, notification to such purchasers of the risk associated with it; (B) public notice of such risk:

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(C) recall; and (D) the replacement or repurchase of such substance or mixture.

(3) In the case of an action under subsection (b) against a chemical substance or mixture, such substance or mixture may be proceeded against by process of libel for its seizure and condemnation. Proceedings in such an action

shall conform as nearly as possible to proceedings in rem in admiralty.

(d) Venue and Consolidation. – (1)(A) An action under subsection (b) against a person who manufactures, processes, distributes in commerce, uses, or disposes of a chemical substance or mixture may be brought in the United States District Court for the District of Columbia or for any judicial district in which any of the defendants is found, resides, or transacts business ; and process in such an action may be served on a defendant in any district in which such defendant resides or may be found. An action under subsection (b) against a chemical substance or mixture may be brought in any United States district court within the jurisdiction of which the substance or mixture is found.

(B) In determining the judicial district in which an action may be brought under subsection (b) in instances in which such action may be brought in more than one judicial district, the Administrator shall take into account the convenience of the parties.

(C) Subpoenas requiring attendance of witnesses in an action brought under subsection (b) may run into any judicial district.

(2) Whenever proceedings under subsection (b) involving the same type of chemical substances or mixtures are pending in courts in two or more judicial districts, they shall be consolidated for trial by order of any such court upon application reasonably made by any party in interest, upon notice to all parties in interest.

(e) Action Under Section 6. – Where appropriate, concurrently with the filing of an action under subsection (b) or as soon thereafter as may be practicable, the Administrator shall initiate a proceeding for the promulgation of a rule under section 6(a).

(f) Representation. – Notwithstanding any other provision of law, in any action under subsection (b), the Administrator may direct attorneys of the Environmental Protection Agency to appear and represent the Administrator in such an action.

reporting and retention of information

Sec. 8. (a) Reports. – (1) The Administrator shall promulgate rules under which –

(A) each person who manufactures or processes or proposes to manufacture or process a chemical substance shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require, and

(B) each person who manufactures or processes or proposes to manufacture or process –

(i) a mixture, or

(ii) a chemical substance in small quantities (as defined by the Administrator by rule) solely for scientific experimentation or analysis or for chemical research or analysis. including such research or analysis for the development of a product, shall maintain records and submit to the Administrator reports but only to the extent the Administrator determines the maintenance of records or submission of reports, or both, is necessary for the effective enforcement of the Act. For purposes of the compilation of the list of chemical substances required under subsection (b), the Administrator shall promulgate rules pursuant to this subsection not later than 180 days after the date of the enactment of this Act.

(2) The Administrator may require under paragraph (1) reporting with respect to the following :

(A) The common name, trade name, the chemical identity, and the molecular structure and identity of each chemical ."substance or mixture for which such a report is required, insofar as known to the person making the report or insofar as reasonably ascertainable.

(B) The categories or proposed categories of use of each such substance or mixture, insofar as known to the person making the report or insofar as reasonably ascertainable.

(C) Reasonable estimates of the amount of each substance and mixture to be manufactured or processed and. insofar as known to the person making the

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report or insofar as reasonably ascertainable, a reasonable estimate of the amount of each such substance and mixture to be manufactured or processed for each of its categories or proposed categories of use.

(D) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture, insofar as known to the person making the report or insofar as reasonably ascertainable.

(E) All existing data concerning the environmental and health effects of such substance or mixture, insofar as known to the person making the report or are reasonably ascertainable.

(F) Estimates of the number of persons who will be exposed to such substance or mixture in their places of employment and the duration of such exposure, insofar as known to the person making the report or are reasonably ascertainable.

(b) Inventory. – The Administrator shall compile, keep current, and publish a list of each chemical substance or mixture which any person reports under subsection (a) or under section 5(a) is manufactured or processed in the United States. The Administrator shall first publish such a list not later than 270 days after the date of enactment of this Act. The Administrator shall not include in such list any chemical substance which is manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for scientific experimentation or analysis or for chemical research or analysis, including such research or analysis for the development of a product.

(c) Records. – Any person who manufactures, processes, or distributes in commerce or intends to manufacture, process, or distribute in commerce any chemical substance or mixture shall maintain records of adverse reactions to health or the environment alleged to have been caused by the substance or mixture. Records of such adverse reactions to the health of employees shall be retained for 30 years from the date such reactions were first reported to or known by the person maintaining such records; and any other record of such adverse reactions shall be retained for 5 years from the date the information contained in the records was first reported to or known by the person maintaining the records. Records under this subsection shall include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source. Upon request of an officer or employee duly designated by the Administrator, each person who is required to maintain records under this subsection shall permit the inspection of such records and shall submit copies of such records.

(d) Health and Safety Studies. – The Administrator shall promulgate rules under which the Administrator requires any person who manufactures, processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce any chemical substance or mixture to submit to the Administrator –

(1) lists of health and safety studies conducted or initiated by or for such person with respect to such substance or mixture at any time or known to such person or are reasonably ascertainable, except that the Administrator may exclude certain types or categories of studies from the requirements of this subsection if he finds that submission of lists of such studies are unnecessary to carry out the purposes of this Act; and

(2) the Administrator may require the submission of any study contained on a list otherwise known by such person.

(e) Notice to Administrator of Unreasonable Risks. – Any person who

manufactures, processes, or distributes in commerce a chemical substance or mixture, and any liability insurer of such person, who obtains information which supports the conclusion that such substance or mixture causes or contributes to an unreasonable risk of injury to health or the environment shall immediately inform the Administrator of such risk unless such person has reason to believe that the Administrator has been adequately informed of such risk.

relationship to other federal laws

Sec. (a) Law's Not Administered by the Administrator. - (1) If the Administrator has reason to believe that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture causes or contributes to, or is likely to cause or contribute to an unreasonable risk of injury to health or the environment, and determines, in his discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under

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a Federal law not administered by the Administrator, the Administrator shall request the agency which administers such law (A) to issue an order declaring whether or not the manufacture, processing, distribution in commerce, use, or disposal of such substance or mixture causes or contributes to or is likely to cause or contribute to such a risk, and (B) if the agency issues an order declaring that such manufacture, processing, distribution in commerce, use, or disposal respecting such substance or mixture causes or contributes to or is likely to cause or contribute to such a risk, to determine if such risk may be prevented or reduced to a sufficient extent by action taken under such law. Any such request shall be published in the Federal Register and shall be accompanied by a detailed statement of the information on which it is based. The agency receiving the request shall consider carefully all data submitted by the Administrator and other information available to it and shall issue an appropriate order upon request, and shall make any resulting determination within such reasonable time as the Administrator specifies in the request, but such time specified may not be less than 90 days from the date the request was made. The report of an agency in response to a request made under this paragraph shall be accompanied by a detailed statement of the findings and conclusions of the agency respecting the order and determination requested to be made.

(2) If the Administrator makes a request under paragraph (1) with respect

to a chemical substance or mixture and the agency to which such request was made either -

(A) issues an order declaring that there is no unreasonable risk of injury to health or the environment associated with such substance or mixture, or

(B) initiates, within 90 days of the publication in the Federal Register of the report of the agency under paragraph (1) in response to such request, action under the law (or laws) administered by such agency to protect against such a risk,

the Administrator may not take any action under section 6 or 7 with respect to the risk associated with such substance or mixture. Nothing contained herein shall prevent the Administrator from (A) making any subsequent request under paragraph (1) with respect to such risks or (B) to take subsequent action under this Act with respect to such risks if the requirements of this subsection are satisfied.

(3) If the Administrator has initiated action under section 6 or 7 with respect to a risk of injury associated with a chemical substance or mixture which was the subject of a request made to an agency under paragraph (1), such agency shall before taking action under the law (or laws) administered by it to protect against such risk consult with the Administrator for the purpose of avoiding duplication of Federal action against such risk.

(b) Laws Administered by the Administrator. - The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. The Administrator shall use the authorities contained in such other Federal laws to protect against any risk to health or the environment associated with a chemical substance or mixture unless the Administrator, in his discretion, determines that such risk may be more appropriately protected against under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws. Nothing contained in this subsection shall (1) affect any final action taken under such other Federal law, or (2) in any way affect the extent to which human health or the environment is to be protected under such other Federal law.

(c) OCCUPATIONAL SAFETY AND HEALTH. - In exercising any authority under this Act, the Administrator shall not, for purposes of section 4(b) (1) of the Occupational Safety and Health Act of 1970, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

(d) Coordination. - In administering this Act, the Administrator shall consult and coordinate with the Secretary of Health, Education, and Welfare and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate insru-

mentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subjects to the Act and for other purposes. The adminis-

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The Administrator shall report annually to the Congress on actions taken to coordinate with such other Federal departments, agencies, or instrumentalities, and on actions taken to coordinate the authority under this Act with the authority granted under other Acts referred to in subsection (b).

(e) Exception. - Nothing contained in this section shall limit any requirement of section 4, 5 (other than section 5(e)(2)), or 8, or rules promulgated thereunder.

RESEARCH. COLLECTION. DISSEMINATION, AND UTILIZATION OF DATA

Sec. 10. (a) Authority. - The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare and with other heads of appropriate agencies, conduct such research and monitoring as is necessary to carry out the purposes of this Act. In accordance with such responsibilities, the Administrator shall undertake and support programs of research and monitoring of polychlorinated biphenyls to the extent necessary to develop safe methods of disposal of polychlorinated biphenyls and for the control of risks of injury to health or the environment associated with polychlorinated biphenyls.

(b) Data Systems. - (1) The Administrator shall establish, administer, and be responsible for the continuing activities of an interagency committee which will (A) design, establish, and coordinate an efficient and effective system, within the Environmental Protection Agency, for the collection, dissemination to other Federal agencies, and use of data submitted to the Administrator under this Act and (B) coordinate the regulation of chemical substances among Federal agencies.

(2) (A) The Administrator shall, in consultation with the Secretary of Health, Education, and Welfare and other heads of appropriate agencies, design, establish, and coordinate an efficient and effective system for the retrieval of toxicological and other scientific data which could be useful to the Administrator in carrying out the purposes of this Act. Systematized retrieval shall be developed for use by all Federal and other agencies with responsibilities in the area of

regulation or study of chemical substances and mixtures and their effect on health, or the environment.

(c) Grants and Contracts. - The Administrator, in consultation with the Secretary of Health, Education, and Welfare, is authorized to make grants and enter into contracts in order to carry out his responsibilities under this section. Contracts may be entered into under this section without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5).

INSPECTIONS AND SUBPOENAS

Sec. 11. (a) Inspections. - (1) For purposes of administering this Act (including any rule or order promulgated under this Act) the Administrator, or any representative of the Administrator duly designated by the Administrator, may inspect any establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after distribution in commerce and any conveyance being used to transport chemical substances or mixtures in connection with distribution in commerce. Such an inspection may only be made upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge of the premises or conveyance to be inspected. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness and shall be conducted at reasonable times, within reasonable limits, and in a reasonable manner.

(2) An inspection under paragraph (1) shall extend to all things within the premises or conveyance inspected (including records, files, papers, processes, controls, and facilities) bearing on whether the requirements of this Act applicable to the chemical substances or mixtures within such premises or conveyance have been complied with.

(b) Subpoenas. - In carrying out his or her duties under the provisions of this Act, the Administrator may by subpoena require the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, or other information that the Administrator deems advisable. Witnesses shall be paid the same fees and mileage that are paid witnesses in the courts of the

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United States. In the event of contumacy, failure, or refusal of any person to obey any such order, any district court of the United States in which venue is proper shall have jurisdiction to order any such person to comply therewith. The failure to obey such order of the Court is punishable by the Court as a contempt

thereof.

EXPORT

Sec. 12. (a) General. – (1) Except as provided in paragraph (2) and subsection (b), this Act (other than section 8) shall not apply to any chemical substance or mixture, if –

(A) it can be shown that such substance or mixture is being manufactured, processed, sold, or held for sale, for export from the United States, unless such substance or mixture is, in fact, manufactured, processed, or distributed in commerce, for use in the United States, and

(B) such substance or mixture, when distributed in commerce, or any container in which it is enclosed when so distributed, bears a stamp or label stating that such substance or mixture, is intended for export.

(2) Paragraph (1) shall not apply to any chemical substance or mixture if the Administrator finds that the substance or mixture will cause or contribute to an unreasonable risk of injury to the health of persons within the United States or to the environment of the United States or may cause or contribute to such risk. The Administrator may require, under section 4, testing of a chemical substance or mixture exempted from this Act by paragraph (1) to determine whether or not such substance or mixture causes or contributes to an unreasonable risk to health within the United States or to the environment of the United States.

(b) Notice. – (1) If any person exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under section 4 or 5, such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of the availability of the data (subject to section 14) submitted to the Administrator under section 4 or 5 for such substance or mixture.

(2) If any person exports or intends to export to a foreign country a chemical substance or mixture for which a rule has been proposed or promulgated under section 5 or 6, or with respect to which an action is pending, or relief has been granted, under section 7, such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of such rule, action, or relief.

ENTRY INTO CUSTOMS TERRITORY OF THE UNITED STATES

Sec. 13. (a) General. – (1) The Secretary of the Treasury shall refuse entry into the customs territory of the United States (as defined in general headnote 2 of the Tariff Schedules of the United States) of any chemical substance or mixture offered for entry if –

(A) it fails to conform with any requirement of this Act or any rule in effect thereunder, or

(B) it is otherwise prohibited pursuant to this Act from being distributed in commerce.

(2) If a chemical substance or mixture is refused entry under paragraph (1), the Secretary of the Treasury shall notify the consignee of such entry refusal, shall not release it to the consignee, and shall cause its disposal or storage (under such regulations as the Secretary of the Treasury may prescribe) if it has not been exported by the consignee within 90 days from the date of receipt of notice of such refusal, except that the Secretary of the Treasury may, pending a review by the Administrator of the entry refusal, release to the consignee such substance or mixture on execution of bond for the amount of the full invoice of such substance or mixture (as such value is set forth in the customs entry), together with the duty thereon. On failure to return such substance or mixture for any cause to the custody of the Secretary of the Treasury when demanded, such consignee shall be liable to the United States for liquidated damages equal to the full amount of such bond. All charges for storage, cartage, and labor on such substances or mixtures which are refused entry or release under this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future entry made by such owner or con-

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signee. Nothing contained herein shall limit any other remedy to which the United States is entitled.

(b) Rules. - The Secretary of the Treasury, after consultation with the Administrator, shall issue rules for the enforcement of subsection (a) of this section.

DISCLOSURE OF DATA

Sec. 14. Any information reported to, or otherwise obtained by, the Administrator or his representatives, under this Act, shall be subject to section 552 of title 5, United States Code; except that such information shall be disclosed -

(1) upon request, to officers or employees of the United States, in connection with their official duties (A) under laws protecting human health or the environment or (B) for specific law enforcement purposes;

(2) to contractors with the United States and employees of such con-

tractors if in the opinion of the Administrator such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States entered into on or after the date of enactment of this Act for the performance of work in connection with this Act and under such conditions as the Administrator may specify ;

(3) whenever the Administrator determines it necessary to protect human health or the environment ; or

(4) to any duly authorized committee of the Congress upon written request of such committee or any chairman thereof.

PROHIBITED ACTS

Sec. 15. It shall be unlawful for any person to -

(1) fail or refuse to comply with (A) any rule or order promulgated under section 4, (B) any requirement prescribed by section 5 or 6, or (C) any rule or order promulgated under section 5 or 6 ;

(2) use or dispose of a chemical substance or mixture which such person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 or a rule or order under section 6 ;

(3) fail or refuse to (A) establish or maintain records, (B) submit reports, notices, or other information, or (C) permit access to or copying of records, as required by this Act or a rule thereunder; or

(4) fail or refuse to permit entry or inspection as required by section 11.

PENALTIES

Sec. 10. (a) Civil. - (1) Any person who violates a provision of section 15 of this Act shall be liable to the United States for a civil penalty in an amount not to exceed \$25,000 for each such violation. Each day such a violation continues shall for purposes of this subsection constitute a separate violation of section 15.

(2) (A) A civil penalty for a violation of section 15 shall be assessed by the Administrator by an order made on the record after opportunity (provided in accordance with this subparagraph) for a hearing in accordance with section 554 of title 5, United States Code. Before issuing such an order, the Administrator shall give written notice to the person to be assessed a civil penalty under such order of the Administrator's proposal to issue such order and providing such person an opportunity to request, within 15 days of the date the notice is received by such person, such a hearing on the order.

(B) In determining the amount of a civil penalty, the Administrator shall take into account the nature, circumstances, extent, and gravity of the violation or

violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Administrator may compromise, modify, or remit, with or without conditions, any civil penalty which may be imposed under this subsection. The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owed by the United States to the person charged.

(3) Any person who requested in accordance with paragraph (2) (A) a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a

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petition may only be filed within the 30-day period beginning on the date the order making such assessment was issued.

(4) If any person fails to pay an assessment of a civil i)enalty after it has become a final and unappealable order, or after a court in an action brought under paragraph (3) has entered final judgment in favor of the Administrator, the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from such date) in any appropriate United States district court. In such action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(b) Criminal.— (1) Any person who knowingly or willfully violates any provision of section 15 shall, in addition to or in lieu of a civil penalty which may be imposed under subsection (a) of this section for such violation, be subject upon conviction, to a fine of not more than \$25,000 for each day of violation, or to imprisonment for not more than 1 year, or both.

(2) For purposes of paragraph (1), the term "knowingly" means having actual knowledge.

SPECIAL ENFORCEMENT AND SEIZURE

Sec. 17. (a) Specific Enforcement. — (1) Upon application of the Administrator or the Attorney General the United States district courts shall have jurisdiction over civil actions to —

(A) restrain any violation of section 15,

(B) restraint any person from manufacturing or processing a chemical substance before the expiration of the period during which such manufacturing or processing is prohibited under section 5,

(C) restrain any person from taking any action prohibited by a requirement prescribed under section 5 or 6 or rules or orders issued thereunder or,

(D) direct any manufacturer or a chemical substance or mixture not in compliance with any order issued under section 5(e) or any rule issued under section 4 or 6, (i) to give notice of such fact to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (ii) to give public notice of such risk of injury, and (iii) to either replace or repurchase such substance or mixture whichever the person to which the requirement is directed elects.

(E) compel the taking of any action required by or under this Act.

(2) A civil action described in paragraph (1) may be brought –

(A) in the case of a civil action described in subparagraph (A) of such paragraph, in the United States district court for the judicial district wherein any act, omission, or transaction constituting a violation of section 15 occurred or wherein the defendant is found or transacts business, or

(B) in the case of any other civil action described in such paragraph, in the United States district court for the judicial district wherein the defendant is found or transacts business.

In any civil action process may be served on a defendant in any judicial district in which a defendant resides or may be found. Subpoenas requiring attendance of witnesses in any such action may run into any judicial district.

(b) Seizure. – Any chemical substance or mixture which was manufactured, processed, or distributed in commerce in violation of this Act or any rule or order promulgated under this Act shall be liable to be proceeded against, by process of libel for the seizure and condemnation of such substance or mixture in any United States district court within the jurisdiction of which such substance or mixture is found. Such proceedings shall conform as nearly as possible to proceedings in rem in admiralty.

pre-emption

Sec. 18. (a) Effect on State Law. – (1) Except as provided in paragraph (2), nothing in this Act shall affect the authority of any State or political subdivision of a State to establish or continue in effect regulation of any chemical substance or mixture containing a chemical substance or mixture.

(2) Except as provided in subsection (b) –

(A) if the Administrator requires by rule promulgated under section 4 the testing of a chemical substance or mixture, no State or political subdivision may, after the effective date of such rule, require the testing of such substance

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or mixture for purposes similar to those for which testing is required under

“(6) If the Administrator prescribes a requirement under section 5 or 6 of this Act which is applicable to a chemical substance or mixture and which is designed to protect against a risk to health or the environment associated with such substance or mixture no State or political subdivision of a State may after the effective date of such requirement, establish or continue in effect a requirement applicable to such substance or mixture and designed to protect against such risk unless such requirement is identical to the requirement prescribed by the Administrator or unless such State or political subdivision prohibits the use or distribution of such substance or mixture within the territorial jurisdiction of the State or political sub-

(b) EXEMPTION.—Upon application of a State or political subdivision of a State, the Administrator may by rule exempt such State or subdivision from subsection (a) (2), under such conditions as may be prescribed in such rule, if—
“(1) compliance with the requirement would not cause the substance or mixture to be in violation of the applicable under this Act described in subsection (a) (2), and . c. ifi

(A) the State or political subdivision requirement (A) provides a significantly higher degree of protection from such risk than the requirement under this Act described in subsection (a) (2), and (B) does not, through difficulties in marketing, distribution, or other factors, unduly burden interstate commerce.

JUDICIAL REVIEW

Sec. 19. (a) General.— Not later than 60 days following the promulgation of any rule under this Act or an order under section 5(e), any interested person may file a petition for judicial review of such rule or order with the United States Court of Appeals for the District of Columbia Circuit, or for the circuit in which such person resides or in which such person's principal place of business is located. Copies of the petition shall be forthwith transmitted by the clerk of such court to the Administrator and to the Attorney General. The Administrator shall transmit to the Attorney General, who shall file in the court, the record

of the proceedings on which the Administrator based such rule or order as provided in section 2112 of title 28, United States Code. For purposes of this section, the term "record" means such rule or order, any transcript required of any oral presentation ; any written submission of interested parties ; and any other information which the Administrator, (m or before the date of the promulgation of such rule or order, published a notice in the Federal Register identifying such information.

(b) Additional Data. - If the petitioner applies to the court for leave to adduce additional data, views, or arguments, and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there are reasonable grounds for the i)etitioner\s failure to adduce such data, views, or arguments in the proceeding before the Administrator, the court may order the Administrator to provide additional opportunity for oral presentation of data, views, or arguments and for written submissions. The Administrator may modify findings or determinations upon which the rule or order, subject to review by such court was based, or make new findings or determinations by reason of the additional data, views, or arguments so taken and shall file such modified or new findings or determinations, and the Administrator's recommendation, if any, for the modification or setting aside of such rule or order, with the return of such additional data, views, or arguments.

(c) Authority and Review Standard. - (1) Upon the filing of a petition under subsection (a), the court shall have jurisdiction (A) to review the rule or order involved in accordance with chapter 7 of title 5, United States Code, and (B) to grant appropriate relief, including interim relief, as provided in such chapter, except that any rule promulgated by the Administrator under section 3(b), 5, or 6 of this Act and reviewed under this section shall be affirmed, unless the rule is not supported by substantial evidence on the record taken as a whole.

(2) The judgment of the court affirming or setting aside, in whole or in part, any rule or order reviewed in accordance with this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 12'54 of title 28, the United States Code.

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(3) The judgment of the court in an action brought pursuant to subsection (a) mav include an award of costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. The Supreme Court of the United States in its decision on a review of a judgment in such an action mav provide for the award of costs in suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(d) Other Remedies.— The remedies provided in this section shall be in addition to and not in lieu of any other remedies provided by law.

citizen's civil action

Sec. 20. (a) In General.— Except as provided in subsection (b), any person may commence a civil action —

(1) against any person (including (A) the United States, and (B) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution) who is alleged to be in violation of this Act or any rule or order prescribed under section 4, 5, or 6(a) to restrain such violation, or

(2) against the Administrator to compel the Administrator to perform any act or duty under this Act which is not discretionary.

Any civil action under paragraph (1) shall be brought in the district court of the United States for the district in which the alleged violation occurred or in which the defendant resides or in which the defendant's principal place of business is located. Any action brought under paragraph (2) shall be brought in the district court for the District of Columbia, or the United States district court for the judicial district in which the plaintiff is domiciled. The district courts shall have jurisdiction over suits brought under this section, without regard to the amount in controversy or the citizenship of the parties. In any civil action under this subsection, process may be served on a defendant in any judicial district in which the defendant resides or may be found and subpoenas for witnesses may run into any judicial district.

(b) Limitation. — No civil action may be commenced —

(1) under subsection (a)(1) to restrain a violation of this Act or rule or order under this Act —

(A) before the expiration of sixty days after the plaintiff has given notice of such violation (i) to the Administrator, and (ii) to the person who is alleged to have committed such violation, or

(B) if the Administrator (or Attorney General on his behalf) has commenced and is diligently prosecuting a civil action in a court of the United States to require compliance with this Act or such rule, but if such action is commenced after the giving of notice, any person giving such notice may intervene as a matter of right in such action ; or

(2) under subsection (a)(2) before the expiration of 60 days after the plaintiff has given notice to the Administrator of the alleged failure of the Administrator to perform an act or duty which is the basis for such action or, in the case of an action under such subsection for the failure of the Ad-

ministrator to file an action under section 7, before the expiration of 10 days after such notification.

Notice under this subsection shall be given in such manner as the Administrator shall prescribe by rule.

(c) General. – (1) In any action under this section, the Administrator, if not a party, may intervene as a matter of right.

(2) The court, in issuing any final order in any action brought pursuant to subsection (a), may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(3) Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of this Act or any rule under this Act or to seek any other relief.

(d) Consolidation. – When two or more civil actions brought under subsection (a) involving the same defendant or plaintiffs and the same issues or violations are pending in two or more judicial districts, such pending actions, upon

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application of such defendant or plaintiff to such actions which is made to a court in its discretion so decides, be consolidated for trial by order (issued after giving all parties reasonable notice and opportunity to be heard) of such court and tried in –

(1) any district which is selected by such defendant or plaintiff and in which one of such actions is pending.

(2) a district which is agreed upon by stipulation between all the parties to such actions and in which one of such actions is pending, or

(3) a district which is selected by the court and in which one of such actions is pending.

The court issuing such an order shall give prompt notification of the order to the other courts in which the civil actions consolidated under the order are pending.

citizens' petitions

Sec. 21. (a) **General.** – Any person may petition the Administrator to issue a rule or order, or to take other action under this Act, the purpose of which is to protect against an unreasonable risk of injury to health or the environment.

(b) **Procedures.** – (1) Such petition shall be filed in the principal office of the Administrator and shall set forth the facts which it is claimed establish that such rule, order or other action is necessary.

(2) The Administrator may hold a public hearing or may conduct such investigation or proceeding as the Administrator deems appropriate in order to determine whether or not such petition should be granted.

(3) Within 90 days after filing of a petition described in paragraph (1), the Administrator shall either grant or deny the petition. If the Administrator grants such petition, the Administrator shall promptly commence an appropriate proceeding to comply with such petition. If the Administrator denies such petition, the Administrator shall publish in the Federal Register the Administrator's reasons for such denial.

(4) (A) If the Administrator denies a petition filed under this section (or if the Administrator fails to grant or deny such petition within the 90-day period), the petitioner may commence a civil action in a United States district court to compel the Administrator to initiate the action requested. Any such action shall be filed within 60 days after the Administrator's denial of the petition or, if the Administrator fails to grant or deny the petition within 90 days after filing the petition, within 60 days after the expiration of the 90-day period.

(B) If the petitioner can demonstrate to the satisfaction of the court, by a preponderance of the evidence in a de novo proceeding before such court, that the action requested in the petition conforms to the applicable requirements of this Act, the court shall order the Administrator to initiate the action requested by the petitioner.

(C) The court in issuing any final order in any action brought pursuant to subparagraph (A), may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(5) The remedies under this section shall be in addition to, and not in lieu of, other remedies provided by law.

NATIONAL DEFENSE WAIT:R

Sec. 22. The Administrator shall waive compliance with any provision of this Act upon request of the Secretary of Defense and upon a determination by the President that the requested waiver is necessary in the interest of national defense. The Administrator shall maintain a written record of the basis upon which such waiver was granted and make such record available for in camera examination when relevant in a judicial proceeding under this Act. Upon the issuance of such a waiver, the Administrator shall publish in the Federal Register a notice that the waiver was granted for national defense purposes, unless, upon the request of the Secretary of Defense, the Administrator determines to omit such publication because the publication itself would be contrary to the interests of national defense, in which event the Administrator shall submit notice thereof to the Armed Services Committees of the Senate and the House of Representatives.

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EMPLOYEE PROTECTION

Sec. 23. (a) General. - No employer may discharge any employee or otherwise discriminate against any employee with respect to the employee's compensation, terms, conditions, or privileges of employment because the employee (or any person acting pursuant to a request of the employee) has -

(1) commenced, caused to be commenced, or is about to commence or cause to be commenced a proceeding under this Act;

(2) testified or is about to testify in any such proceeding; or

(3) assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes of this Act.

(b) Remedy. - (1) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person in violation of subsection (a) of this section may, within 30 days after such alleged violation occurs, file (or have any person file on the employee's behalf) a complaint with the Secretary of Labor (hereinafter in this section referred to as the "Secretary") alleging such discharge or discrimination. Upon receipt of such a complaint, the Secretary shall notify the person named in the complaint of the filing of the complaint.

(2) (A) Upon receipt of a complaint filed under paragraph (1), the Secretary shall conduct an investigation of the violation alleged in the complaint. Within 30 days of the receipt of such complaint, the Secretary shall complete such

investigation and shall notify in writing the complainant (and any person acting on behalf of the complainant) and the person alleged to have committed such violation of the results of the investigation conducted pursuant to this paragraph. Within 90 days of the receipt of such complaint the Secretary shall, unless the proceeding on the complaint is terminated by the Secretary on the basis of a settlement entered into by the Secretary and the person alleged to have committed such violation, issue an order either providing the relief prescribed by subparagraph (B) or denying the complaint. An order of the Secretary shall be made on the record after notice and opportunity for agency hearing. The Secretary may not enter into a settlement terminating a proceeding on a complaint without the participation and consent of the complainant.

(B) If in response to a complaint filed under paragraph (1) the Secretary determines that a violation of subsection (a) of this section has occurred, the Secretary shall order (i) the person who committed such violation to take affirmative action to abate the violation, (ii) such person to reinstate the complainant to the complainant's former position together with the compensation (including back pay), terms, conditions, and privileges of the complainant's employment, (iii) compensatory damages, and (iv) where appropriate, exemplary damages. If such an order is issued, the Secretary, at the request of the complainant shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorney's fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

(c) REVIEW. - (1) Any person adversely affected or aggrieved by an order issued under subsection (b) may obtain review of the order in the United States Court of Appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred. The petition for review must be filed within 60 days from the issuance of the Secretary's order. Review shall conform to chapter 7 of title 5 of the United States Code.

(2) An order of the Secretary, with respect to which review could have been obtained under paragraph (1), shall not be subject to judicial review in any criminal or other civil proceeding.

(d) Enforcement. - (1) Whenever a person has failed to comply with an order issued under subsection (b)(2), the Secretary shall file a civil action in the United States district court for the district in which the violation was found to occur to enforce such order. In actions brought under this subsection, the district courts shall have jurisdiction to grant all appropriate relief, including injunctive relief and compensatory and exemplary damages. Civil actions brought under this subsection shall be heard and decided expeditiously.

(2) Any nondiscretionary duty imposed by this section is enforceable in a mandamus proceeding brought under section 1361 of title 28, United States Code.

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(e) Exclusion. – Subsection (a) of this section shall not apply with respect to any employee who, acting without direction from the employee's employer (or any agent of the employer), deliberately causes a violation of any requirement of this Act.

(f) Employment Effects. – (1) The Administrator shall conduct continuing evaluations of the potential loss or shifts of employment which may result from the issuance of any rule or order under this Act, including, where appropriate, investigating threatened plant closures or reductions in employment allegedly resulting from such rule or order.

(2) Any employee who is discharged or whose employment is otherwise interrupted, or is threatened with discharge or such interruption, or otherwise discriminated against by any person because of the results of any rule or order issued under this Act, or a representative of such employee, may request the Administrator to conduct a full investigation of the matter. The Administrator shall thereupon investigate the matter and, at the request of any interested party, shall hold a public hearing on not less than 5 days notice, and shall at such hearings require the parties, including the employer involved, to present information relating to the actual or potential effect of such rule or order on employment and on any alleged discharge, interruption of employment, or other discrimination and the detailed reasons or justification therefor. Any such hearing shall be of record and shall be conducted in accordance with section 554 of title 5, United States Code.

(3) Upon receiving the report of any such investigation, the Administrator shall make findings of fact as to the effect of such rule or order on employment and the alleged discharge, interruption of employment, or discrimination and shall make such recommendations as he deems appropriate. Such report, findings, and recommendations shall be available to the public.

(4) Nothing in this subsection shall be construed to require the Administrator to modify or withdraw any rule or order issued under this Act.

STUDIES

Sec. 24. (a) Indemnification. – The General Accounting Office shall conduct a study of all Federal laws administered by the Administrator for the purpose of determining whether and under what conditions, if any, indemnification should be accorded any person as a result of any action taken by the Administrator under any such law. The study shall –

(1) include an estimate of the probable cost of any indemnification programs which may be recommended ;

(2) include an examination of all viable means of financing the cost of any recommended indemnification ; and

(3) be completed and submitted to Congress not less than 2 years from the date of enactment of this Act.

(b) Classification. Storage, and Retrieval. – The Council on Environmental Quality, in consultation with the Administrator, the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate Federal departments or agencies, shall coordinate a study of the feasibility of establishing (1) a standard classification system for chemical substances and related substances, and (2) a standard means for storing and for obtaining rapid access to information respecting such substances. A report on such study shall be completed and submitted to Congress not later than 18 months after the date of the enactment of this Act.

state demonstration programs

Sec. 25. (a) Establishment of Program. – The Administrator is authorized to assist no more than three states in establishing demonstration programs by such States to protect against unreasonable risks to health or the environment associated with chemical substances and mixtures. Such programs shall –

(A) identify and inventory chemical substances and mixtures within such State, including their manufacture, processing, distribution, use, and disposal ;

(B) monitor the extent to which such chemical substances or mixtures are present in the environment of such State and the human exposure to such substances or mixtures within such State;

(C) establish a program to (i) prevent or eliminate unreasonable risks

to health or the environment presented by chemical substances or mixtures, (ii) integrate the control of chemical substances and mixtures under this

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section with other programs or environmental and public health protection within such State so as to appropriately minimize the overall pollution of the environment within such State; and (iii) identify the appropriate governmental institutions and processes necessary to implement a program

for the prevention of unreasonable risks to health or the environment presented by chemical substances and mixtures :

(D) analyze and evaluate the results of such programs through annual reports to the Administrator ; and

(E) complement and in no way reduce Federal efforts under this Act in such State.

{[D]) Rkports. - The Administrator shall submit a report to the appropriate committees of Congress not later than July 1 of each calendar year. Such report shall include (1) a description of progress with respect to programs authorized under this section and any suggestions for improvement in such program, (2) recommendations as to the manner by which programs within the States for the prevention of unreasonable risk to health or the environment presented by chemical substances may feasibly be implemented, and (3) the extent to which the Administrator has disseminated information regarding programs authorized under this section to other interested States and other persons.

(c) Authorization for Appropriations. - For the purposes of providing assistance under this section, there are hereby authorized to be appropriated not to exceed \$2,000,000 for the fiscal year ending September 30, 1977 ; \$2,000,000 for the fiscal year ending September 30, 1978, and \$2,000,000 for the fiscal year ending on September 30, 1979. Any funds appropriated under the authority of this subsection shall remain available until expended. Funds available under this section shall not be available for programs which would duplicate any authority or requirements of the Administrator under this Act, including sections 4, 5, 6, and 9(c). Funds available under the authority of this section shall support not more than 75 percent of the costs of any such program described under subsection (a) engaged in by the State.

(d) Priorities. - Assistance afforded under this section shall be available (subject to the requirements of subsection (a)) to those States which can establish a priority need for such assistance, as determined by the rules of the Administrator. In establishing such rules, the Administrator shall consider the existence of serious health effects associated with chemical substances within such State including cancer, birth defects, and gene mutations; the extent to which chemical substances and mixtures are manufactured, processed, distributed in commerce, used and disposed of within such State ; and the extent of exposure of human beings and the environment to chemical substances and mixtures within such State. The Administrator shall approve all such programs and establish a mechanism for monitoring such programs.

(e) Discretion. - Nothing contained in this section shall affect any provision of section 18 of this Act.

administration of act

Sec. 26. (a) Cooperation of Federal Agencies. – Upon request by the Administrator, each Federal department and agency is authorized –

(1) to make its services, personnel, and facilities available (with or without reimbursement) to the Administrator to assist the Administrator in the administration of this Act ; and

(2) to furnish to the Administrator such information, data, estimates, and statistics, and to allow the Administrator access to all information in its possession as the Administrator may reasonably determine to be necessary for the administration of this Act.

(b) Fees. – The Administrator may, by rule, require the payment of a reasonable fee from any person required to submit data under section 4 or 5 of this Act to defray the costs of administering this Act. Such rules shall not provide for any fee in excess of \$2,500. In setting such a fee, the Administrator shall take into account the ability to pay of the person required to submit the data and the cost to the Administrator of reviewing such data. Such rules may provide for sharing such a fee in any case in which the expenses of testing are shared under section 4 or 5 of this Act.

(c) Action With Respect to Categories. – (1) Any action which may be taken by the Administrator under any provision of this Act with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the Administrator takes action under a provision of this Act

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with respect to a category of chemical substances or mixtures, any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to all chemical substances or mixtures in such category.

(2) For purposes of paragraph (1) :

(A) The term "category of chemical substances" means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

(B) The term "category of mixtures" means a group of mixtures the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act.

(d) Statement of Purpose and Justification. - Any proposed or final rule or order issued under this Act shall be accompanied by a statement of purpose and justification. Such a statement shall be considered part of the "record of the proceedings" for purposes of judicial review under section 19(a).

(e) Assistant Administrator. - The President, by and with the advice and consent of the Senate, shall appoint an Assistant Administrator for Toxic Substances of the Environmental Protection Agency. Such Assistant Administrator shall be a qualified individual who is, by reason of background and experience, especially qualified to direct a program concerning the effects of chemicals on human health and the environment. Such Assistant Administrator shall be responsible for the collection of data, the preparation of studies, and the making of recommendations to the Administrator for regulatory and other actions to carry out the purposes, and to facilitate the administration of this Act.

authorization for appropriations

Sec. 27. (a) In General. - There is authorized to be appropriated to the Administrator, for purposes of carrying out this Act, \$11,000,000 for the fiscal year ending June 30, 1976, \$2,600,000 for the period beginning July 1 1976 and ending September 30, 1976, and \$10,100,000 for the fiscal year ending September 30, 1977. No part of the funds so authorized to be appropriated shall be used to construct any research laboratories.

(b) Budget Requests. - Whenever the Administrator directly or indirectly submits in connection with this Act, any budget requests, supplemental budget estimates, legislative recommendations, prepared testimony for congressional hearings, or comments on legislation to the President or to the Office of Management and Budget, or persons acting on their behalf, the Administrator shall concurrently transmit a copy thereof to the Congress. No officer or agency of the United States shall have any authority to require the Administrator to submit budget requests or estimates, legislative recommendations, prepared testimony for congressional hearings, or comments on legislation relating to this Act to any officer or agency of the United States for approval, comments, or review, prior to the submission of such requests, estimates, recommendations, testimony, or comments to the Congress.

annual report

Sec. 28. The Administrator shall prepare and submit to the President and

the Congress on or before January 1 of each year a comprehensive report on the administration of this Act during the preceding fiscal year. Such report shall include -

(1) a list of the testing required under section 4 during the year for which the report is made and an estimate of the costs incurred during such year by the persons required to perform such tests ;

(2) the number of notices received during such year under section 5, the number of such notices received during such year under such section for chemical substances and mixtures subject to a section 4 rule, and a summary of any action taken during such year under section 5(e) ;

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(3) a list of rules issued during such year under section 6 ;

(4) a list, with a brief statement of the issues, of completed or pending judicial or enforcement actions under this Act during such year ;

(5) a summary of major problems encountered in the administration of this Act ; and

(6) such recommendations for additional legislation as the Administrator deems necessary to carry out the purposes of this Act.

Mr. Hartke subsequently said : Mr. President, in view of the large vote by which the toxic substances bill was passed, I would like to point out this matter has now been pending as a matter of request from the administration since February of 1970, and we have worked very closely with some members of the House of Representatives, and I would hope that the House would give urgent consideration to coming forward now with legislation which will not be stalemated as it has been in the past.

There is not need for us to delay any longer the protection which could be afforded to millions of Americans simply by the utilization of the scientific method of telling the people what they need to know. I think it is high time that we eliminate the scare tactics which frequently are put forward about some item which may be dangerous to the health or environment and, at the same time, prove at a later date that it is not.

On the other hand, there are thousands and thousands of items

which, at this moment, still are going undetected and unknown by millions of Americans and it is high time we recognized that they are entitled not alone to the right to know but the right to have the Administrator of the Environmental Protection Agency to move effectively and immediately to do what he can to provide better health and a cleaner environment for Americans.

Mr. Talmadge. Mr. President, if the distinguished Senator from California and the distinguished Senator from Kansas will give me their attention, there are two questions I desire to propound on this bill.

I ask the distinguished floor manager of the bill : A^lat effect would this legislation have upon the small bulk blend fertilizer operator who, in response to a farmer's request, changes the fertilizer mix ratio and perhaps add a pesticide?

Mr. TuxxEY. It would have no effect if this mixture is« classified as a pesticide under the pesticide law.

Mr. Talmadge. Does the Senator from Kansas share that view?

^Ir. Pearson. I share that view.

Mr. Talmadge. One further inquiry: \\Tiat sort of individual recordkeeping and notification requirements would be made of this small fertilizer operator?

Mr. TuxxEY. Xone, if the mixture is classified as a pesticide under the i^esticide law.

Mr. Pearsox. The answer is in the negative, no.

Mr. Talmadge. Does the Senator from Kansas share that view?

Mr. Pearson. Yes.

Mr. Talmadge. I thank the Senators.

CHAPTER III

H.R. 14032 TOGETHER WITH EEPOR T AND DEBATE

Note. - H.R. 14032 was the last of several versions of the Toxic Substances

Control Act introduced in the House ; early versions on which hearings were held included H.R. 7229, H.R. 7548, and H.R. 7664. and a later version reported by the Subcommittee on Consumer Protection and Finance was H.R. 10318.

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Union Calendar No. 694

~ H. R. 14032

[Report No. 94-1341]

IN THE HOUSE OF REPRESENTATIVES

May 26, 1976

Mr. ECKHARDT (for himself, Mr. Broyhill, Mr. Murphy of New York, Mr. Van Deerlin, Mr. Moss, Mr. Rooney, Mr. Scheuer, Mr. Carney, Mr. MOFFETT, Mr. RiNAUX), and Mr. Lent) introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

July 14, 1976

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To regulate commerce and protect health and the environment by requiring testing and necessary restrictions on certain chemical substances and mixtures, and for other purposes.

1 Be it enacted by the Senate and House of Representa-

2 tives of the United States of America in Congress assembled.

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SHORT TITLE

Section 1. This Act may be cited as the "Toxic Substances Control Act"

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Sec. 1. Short title.

Sec. 2. Findings, policy, and intent.

Sec. 3. Definitions.

Sec. 4. Testing of chemical substances and mixtures.

Sec. 5. Manufacturing and processing notices.

Sec. 6. Regulation of hazardous chemical substances and mixtures.

Sec. 7. Imminent hazards.

Sec. 8. Reporting and retention of information.

Sec. 9. Relationship to other Federal laws.

Sec. 10. Research, collection, dissemination, and utilization of data.

Sec. 11. Inspections.

• Line type deleted.

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Sec. 12. Exports.

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Sec. 20. Citizens' civil actions.

Sec. 21. Citizens' petitions.

Sec. 22. National defense waiver.

Sec. 23. Employee protection.

Sec. 24. Employment effects.

Sec. 25. Studies.

Sec. 26. Administration of Act.

Sec. 27. Development and evaluation of test methods.

Sec. 28. Authorization for appropriations.

Sec. 29. Annual report.

Sec. 30. Effective date.

1 FINDINGS, POLICY, AND INTENT

2 Sec. 2. (a) Findings.— The Congress finds that[^]

3 (1) humans and the environment are being exposed

4 to a large number of chemical substances and mixtures

5 each year;

6 (2) among the many chemical substances and mix-
tures constantly being developed and produced are some

[^] whose manufacture, processing, distribution in commerce,

^ use, or disposal may cause or significantly contribute to
1^ an unreasonable risk to health or the environment; and
1^ (3) the effective regulation of interstate commerce

in such chemical substances and mixtures also necessitates
the regulation of intrastate commerce in such chemical
substances and mixtures.

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1 (b) Policy. - It is the policy of the United States that-

2 (1) hazardous and potentially hazardous chemical

3 substances and mixtures should be adequately tested with

4 respect to their effect on health and the environment and

5 that such testing should be the responsibility of those

6 who manufacture and those who process such chemical

7 substances and mixtures;

8 (2) adequate authority should exist to regulate

9 chemical substances and mixtures which cause or signifi-

10 cantly contribute to an unreasonable risk to health or the

11 environment, and to take action with respect to chemical

12 substances and mixtures which are imminent hazards;

1^ and

14 (3) authority over chemical substances and, mix-

15 tures should be exercised in such a manner as not un-

1^ duly to impede, or to create unnecessary economic bar-

1'^ rriers to, technological innovation while fulfilling the

10 primary purpose of this Act to assure that such innova-

1^ tion and commerce in such chemical substances and

20 mixtures do not cause or significantly contribute to an

21 unreasonable risk to health or the environment.

22 (c) Intent of Congress. – It is the intent of Congress
23 that the Administrator shall carry out this Act in a reason-
24 able and prudent manner, and that the Administrator shall

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1 consider the environmental, economic, and social impact of
2 any action the Administrator proposes to take under this Act.

3 DEFINITIONS

4 Sec. 3. As used in this Act:

5 (1) The term "Administrator" means the Administrator
6 of the Environmental Protection Agency.

7 (2) (A) Except as provided in subparagraph (B), the

8 term "chemical substance" means –

9 (i) any organic or inorganic substance of a par-

10 ticular molecular identity including a combination of

11 such substances occurring (I) in whole or in part as a

12 result of a chemical reaction, or (II) in nature, or

13 (ii) any element or uncombined radical.

14 (B) Such term does not include –

15 (i) any mixture,

16 (ii) any pesticide (as defined in the Federal In-
secticide, Fungicide, and Rodenticide Act) when manu-

17 factured, processed, or distributed in commerce for use

19 as a pesticide,
20 (Hi) tobacco or any tobacco product,
21 (iv) any source material, special nuclear material,
22 or byproduct material (as such terms are defined in the
23 Atomic Energy Act of 1954 and regulations issued
24 under such Act) ,

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1 (v) any article the sale of which is subject to the
2 tax imposed by section 4181 of the Internal Revenue
3 Code of 1954 (determined without regard to any ex-
4 emptions from such tax provided by section 4182 or 4221
5 or any other provision of such Code) , and
6 (vi) any food, food additive, drug, cosmetic, or
7 device (as such term^s are defined in section 201 of the
8 Federal Food, Drug, and Cosmetic Act) when manu-
9 factured, processed, or distributed in commerce for use
10 as a food, food additive, drug, cosmetic, or device.
11 The term "food" as used in clause (vi) of this subparagraph
12 includes poultry and poultry products (as defined in sections
13 4(e) and 4(f) of the Poultry Products Inspection Act),
14 meat and meat food products (as defined in section 1(i) of

15 the Federal Meat Inspection Act), and eggs and egg prod-
16 ucts (as defined in section 4 of the Egg Products Inspection
17 Act).

18 (3) The term "commerce" means trade, traffic, or trans-
19 portation (A) between a place in a State and any place out-
20 side of such State, or (B) which affects trade, traffic, or
21 transportation described in clause (A).

22 (4) The term "distribute in commerce" or "distribu-
23 tion in commerce" when used to describe an action taken
24 with respect to a chemical substance or mixture or article
25 containing a substance or mixture means to sell or the sale

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1 of, the substance, mixture, or article in commerce; to in-
2 troduce or deliver for introduction into commerce, or the
3 introducing or delivery for introduction into commerce of,
4 the substance, mixture, or article; or to hold, or the holding
5 of, the substance, mixture, or article after its introduction
6 into commerce,

7 (5) The term environment^{^^} includes water, air, and
8 land and the interrelationship which exist among and be-
9 tween water, air, and land and all living things.

10 (6) The term "health and safety study" means any

11 study of any effect of a chemical substance or mixture on
' 2 health or the environment, including epidemiological studies,
13 studies of occupational exposure to a chemical substance or

mixture, toxicological, clinical, and ecological studies of a
chemical substance or mixture, and any test performed pur-
suant to this Act.

(7) The term "manufacture" means to import, produce,

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or manufacture.

(8) The term "mixture" means any combination of two
or more chemical substances if the combination does not
occur in nature and is not, in whole or in part, the result of
a chemical reaction; except that such term does include a
combination which occurs, in whole or in part, as a result of

^ a chemical reaction if each of the chemical substances com-

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1 prising the combination is not a new chemical substance and

2 if the combination could have been manufactured for commer-

3 cial purposes without a chemical reaction at the time the

4 chemical substances comprising the combination were com-

5 bined.

6 (9) The term "new chemical substance" means any

7 chemical substance not included in the chemical substance

8 list compiled and published under section 8(b).

9 (10) The term "process" means the preparation of a
10 chemical substance or mixture for distribution in commerce -

11 (A) in the same form or physical state, or in a
12 different form or physical state from that, in which it
13 was received by the person making such preparation, or

14 (B) as part of an article containing the chemical
15 substance or mixture,

16 (11) The term "processor" means any person who
17 processes a chemical substance or mixture.

18 (12) The term "standards for the development of test
19 data" means a prescription of -

20

(A) the-

21

23

22

(i) health and environmental effects, and

(ii) information relating to toxicity, persistence,
- and other characteristics which affect health and the

24

environment,

25

for which test data for a chemical substance or mixture

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1 are to be developed and any analysis that is to be per-

2 formed on such data, and

3 (B) to the extent necessary to assure that such data

4 are reliable and adequate, the manner in which such

5 data are to be developed, the specification of any test

6 protocol or methodology to be employed in the develop-

7 ment of such data, and such other requirements as are

8 necessary to provide such assurance.

9 (13) The term "State" means any of the several States,

10 the District of Columbia, the Commonwealth of Puerto Rico,

11 the Virgin Islands, Guam, the Canal Zone, American

12 Samoa, or the Trust Territory of the Pacific Islands.

13 (14) The term "United States", when used in the
14 geographic sense, means all the States.

15 TESTING OF CHEMICAL SUBSTANCES AND MIXTURES

16 Sec. 4. (a) Testing Requirements. – If the Ad-

17 ministrator finds that –

18 (1)(A)(i) the manufacture, distribution in com-
19 merce, processing, use, or disposal of a chemical sub-
20 stance or mixture or any combination of such actions
21 may cause or significantly contribute to an unreasonable
22 burden: to health or the environment,

23 (ii) there are insufficient data and experience upon
24 which the effects of such manufacture, distribution in
25 commerce, processing, use, or disposal or combination of

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1 such actions on health or the environment can reason-
2 ably be determined or predicted, and
3 (Hi) testing of such substance or mixture with
4 respect to such effects is necessary to develop such data;
5 or

6 (B)(i) a chemical substance or mixture is or will

7 he produced in substantial quantities, and it enters or
8 may reasonably be anticipated to enter the environment
9 in substantial quantities or there is or may be signifi-
10 cant or substantial human exposure to such substance or
11 mixture,

12 (ii) there are insufficient data and experience upon
13 which the effects of the manufacture, distribution in
14 commerce, processing, use, or disposal of such substance
1[^] or mixture or any combination of such actions on health
16 or the environment can reasonably be determined or
1'[^] predicted, and

18 (Hi) testing of such substance or mixture with re-
19 spect to such effects is necessary to develop such data;
20 and

21 (2) in the case of a mixture, the effects which the
22 mixture's manufacture, distribution in commerce, proc-
2[^] easing, use, or disposal or any combination of such ac-
24 tions may have on health or the environment may not be
2[^] reasonably and more efficiently determined or predicted

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1 by testing the chemical substances which comprise the
2 mixture;
3 the Administrator shall by rule require that testing be con-
4 ducted on such substance or mixture to develop data with

5 respect to the health and environmental effects for which
6 there is an insufficiency of data and experience and which
7 are relevant to a determination that the manufacture, distri-
8 bution in commerce, processing, use, or disposal of such
9 substance or mixture or any combination of such actions does
10 or does not cause or significantly contribute to an unreason-
11 able risk to health or the environment.

12 (b)(1) Testing Requirement Rule.— A rule under
13 subsection (a) requiring the testing of a chemical substance or
14 mixture shall include –

15 (A) identification of the substance or mixture for
16 which testing is required,

17 (B) standards for the development of test data for
18 such substance or mixture, and

19 (C) a specification of the period (which period may
20 not be unreasonable) within which the persons required
21 to conduct the testing shall submit to the Administrator
22 data developed in accordance with the standards referred
23 to in subparagraph (B).

24 In determining the standards and period to be included, pur-
25 suant to subparagraphs (B) and (C), in a rule under sub-

1 section (a), the Administrator shall consider the relative
2 costs of the various test protocols and methodologies which
3 may be required under the rule and the reasonably foreseeable
4 availability of facilities and personnel for performing testing
5 under the rule. Such a rule may require the submission of
6 preliminary data during the period prescribed under sub-
7 paragraph (C) .

8 (2) (A) The health and environmental effects for which
9 standards for the development of test data may be pre-
10 scribed include carcinogenesis, mutagenesis, terato genesis,
11 behavioral disorders, cumulative or synergistic effects, and
12 any other effect which may cause or significantly contribute
13 to an unreasonable risk to health or the environment, and
14 the characteristics of chemical substances and, mixtures for
which such standards may be prescribed include persistence,
15 acute toxicity, subacute toxicity, chronic toxicity, and any
16 other characteristic which may cause or significantly con-
17 tribute to such a risk. The methodologies that may be pre-
18 scribed in such standards include epidemiology, serial, or
19 hierarchical tests; in vitro tests; and whole animal tests.
20 Before prescribing epidemiology tests in such standards, the
21 Administrator shall consult with the Director of the National
22 Institute for Occupational Safety and Health.

24 (B) From time to time, but not less than once each
25 twelve months, the Administrator shall review the adequacy

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1 of the standards for development of data prescribed in rules
2 under subsection (a) and shall, if necessary, institute pro-
3 ceedings to make appropriate revisions of such standards.

4 (3) (A) A rule under subsection (a) respecting a chem-
5 ical substance or mixture shall require the persons described
6 in subparagraph (B) to conduct tests and submit data on
7 such substance or mixture, except that the Administrator may
8 permit two or more of such persons to designate one such
9 person or a qualified third party to conduct such tests and
10 submit such data on behalf of the persons making the
H designation.

12 (B) The following persons shall be required to conduct
tests and submit data on a chemical substance or mixture sub-
14 ject to a rule under subsection (a) :

15 (i) Each person who manufactures or intends to
16 manufacture such substance or mixture if the Adminis-
17 trafor makes a finding described in subsection (a)(1)

18 (A)(ii) or (a) (1) (B) (ii) with respect to the manu-
19 facture of such substance or mixture.

20 (ii) Each person who processes or intends to process
21 such substance or mixture if the Administrator makes a
22 finding described in subsection (a) (1) (A) (ii) or (a)
23 (1)(B)(ii) with respect to the processing of such

2^ substance or mixture.

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1 (Hi) Each person who manufactures or processes or
2 intends to manufacture or process such substance or mix-
3 ture for diMrihution in commerce if with respect to the
4 distribution in commerce of such substance or mixture
5 the Administrator makes a finding described in siibsec-
6 tion (a)(1)(A)(ii) or (a) (1) (B) (ii) .

7 (iv) Each person who manufactures or processes oi'
8 intends to manufacture or process such substance or mix-
9 ture if with respect to the disposal of such substance or
10 mixture the Administrator makes a finding described
11 in subsection (a) (1) (A) (ii) or (a) (1) (B) (ii) .

12 (v) Each person who manufactures or processes or
13 intends to manufacture or process such chemical sub-
14 stance or mixture for a use with respect to which the
15 Administrator makes a finding described in subsection
16 (a) (1) (A) (ii) or (a) (1)(B) (ii).

17 ('^) A rule under subsection (a) requiring the testing of

18 a chemical substance or mixture shall expire at the end of the

19 reimbursement period (as defined in subsection (c) (3) (B))
20 applicable to test data for such substance or mixture, unless
21 the Administrator repeals the rule before such date.
22 (5) Rules issued under subsection (a) (and any amend-
23 ment thereto or repeal thereof) shall be promulgated pur-
24 suant to section 553 of title 5, United States Code, except

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J that in promulgating, amending, or repealing any such rule
2 (A) the Administrator shall give interested persons an op-
3 portunity for the oral presentation of data, views, or argu-
4 ments, in addition to an opportunity to make written sub-
5 missions; and (B) a transcript shall be made of any oral
6 presentation. The Administrator may not promulgate a rule
7 under subsection (a) respecting a substance or mixture unless
8 the Administrator makes and publishes with the rule the find-
9 ings described in paragraph (1) (A) or (1) (B) of such
10 subsection and, in the case of a rule respecting a mixture,
11 the finding described in paragraph (2) of such subsection.
12 (c) Exemption- (1) Any person required by a rule
13 under subsection (a) to conduct tests and submit data on a
14 chemical substance or mixture may apply to the Adminis-
15 trator (in such form and manner as the Administrator shall
16 prescribe) for an exemption from such requirement.
17 (2) If, upon receipt of an application under paragraph
18 (1), the Administrator determines that -

19 (A) the chemical substance or mixture (including
20 any contaminant present in such substance or mixture)
21 with respect to which such application was submitted
22 is equivalent to a chemical substance or mixture for
23 which data has been submitted to the Administrator in
24 accordance with a rule under subsection (a) or for

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1 which data is being developed pursuant to such a rule,

2 and

3 (B) submission of data by the applicant on such

4 substance or mixture would be duplicative of data which

5 has been submitted to the Administrator in accordance

6 with such rule or which is being developed pursuant to

7 such rule,

8 the Administrator shall exempt, in accordance with para-

9 graph (3) or (4), the applicant from conducting tests and

10 submitting data on such substance or mixture.

11 (3) (A) If the exemption of any person from the re-

12 quirement to conduct tests and submit test data on a chemical

13 substance or mixture is granted on the basis of the existence

14 of previously submitted test data and if such exemption is

15 granted during the reimbursement period for such test data
16 (as prescribed by subparagraph (B)), then (unless such
17 person and the persons referred to in clauses (i) and (ii)
18 agree on the amount and method of reimbursement) the Ad-
19 ministrator shall order the person granted the exemption to
20 provide fair and equitable reimbursement (in an amount
21 determined under rules of the Administrator) -
22 (i) to the person who previously submitted such test
23 data, for a portion of the costs incurred by such person
in complying with the requirement to submit such data,

^ and

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1 (ii) to any other person who has been required
2 under this subparagraph to contribute with respect to
3 such costs, for a portion of the amount such person was
4 required to contribute.

5 In promulgating rules for the determination of fair and
6 equitable reimbursement to the persons described in clauses
7 (i) and (ii) for costs incurred with respect to a chemical
8 substance or mixture, the Administrator shall consider all
9 relevant factors, including the effect on the competitive

10 position of the person required to provide reimbursement in
11 relation to the persons to be reimbursed and the share of the
12 market for such substance or mixture of the person re-
13 quired to provide reimbursement in relation to the share of
14 such market of the persons to be reimbursed. An order under
15 this subparagraph shall, for purposes of judicial review, be
16 considered final agency action .

17 (B) For purposes of subparagraph (A), the reimburse-
18 ment period for any test data for a chemical substance or
19 mixture is a period -

20 (i) beginning on the date such data was submitted
21 in accordance with a rule promulgated under subsection

22 (a), and

23 (ii) ending -

24 (I) five years after the date referred to in

25 clause (i), or

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1 (II) at the expiration of a period which begins

2 on the date referred to in clause (i) and is equal to

3 the period which the Administrator determines was

4 necessary to develop such data,

5 whichever is later.

6 (4) (A) If the exemption of any person from the require-

7 ment to conduct tests and submit test data on a chemical

8 substance or mixture is granted on the basis of the fact that

9 test data is being developed by one or more persons pursuant

10 to a rule promulgated under subsection (a), then (unless such

11 person and the persons referred to in clauses (i) and (ii)

12 agree on the amount and method of reimbursement) the Ad-

13 ministrator shall order the person granted the exemption to
provide fair and equitable reimbursement (in an amount
determined under rules by the Administrator) -

(i) to each such person who is developing such test

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data, for a portion of the costs incurred by each stick

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person in complying with such rule, and

(a) to any other person who has been required

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under this subparagraph to contribute with respect to

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the costs of complying with such rule, for a portion of

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the amount such person was required to contribute.

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In promulgating rules for the determination of fair and

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equitable reimbursement to the persons described in clauses

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1 (i) and (ii) for costs incurred with respect to a chemical

2 substance or mixture, the Administrator shall consider the

3 factors described in the second sentence of paragraph (3)

4 (A). An order under this subparagraph shall, for purposes

5 of judicial review, be considered final agency action.

6 (B) If an exemption is granted on the basis of the fact

7 that one or more persons are developing test data pursuant to

8 a rule promulgated under subsection (a) and if after such

9 exemption is granted the Administrator determines that no

10 such person has complied with such rule, the Administrator

11 shall (i) after providing written notice to the person who

12 holds such exemption and an opportunity for a hearing, by

13 order terminate such exemption, and (ii) notify in writing

such person of the requirements of the rule with respect to
which such exemption was granted.

(d) Notice. - Upon the receipt of any test data pur-

suant to a rule under subsection (a), the Administrator shall, subject to section 14, promptly publish a notice of the receipt of such data in the Federal Register. Each such notice shall (1) identify the chemical substance or mixture for which data have been received; (2) list the uses or intended uses of such substance or mixture and the information required by the applicable standards for the development of test data; and (3) describe the nature of the test data de-

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1 veloped. Except as otherwise provided in section 14, such
2 data shall be made available by the Administrator for ex-
3 amination by any person.

4 (e) Priority List.— (1) (A) There is established a
5 committee to make recommendations to the Administrator
6 respecting the chemical substances and mixtures to which the
7 Administrator should give priority consideration for the
8 promulgation of a rule under subsection (a). In making such
9 a recommendation with respect to any chemical substance or
10 mixture, the committee shall consider all relevant factors,
11 including —

12 (i) the quantities in which the substance or mix-
13 ture is or will be manufactured,

14 (ii) the quantities in which the substance or mixture
15 enters the environment,

16 (Hi) the number of persons who will be exposed to
17 the substance or mixture in their places of employment

18 and the duration of such exposure,

19 (iv) the extent of human exposure to the substance

20 or mixture,

21 (v) the extent to which the substance or mixture is

22 closely related to a chemical substance or mixture which

23 is known to cause or significantly contribute to an un-

24 reasonable risk to health or the environment.

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1 (vi) the existence of data concerning the effects of

2 the substance or mixture on health or the environment,

3 (vii) the extent to which testing of the substance

4 or mixture may result in the development of data upon

5 which the effects of the substance or mixture on health

6 or the environment can reasonably be determined or

7 predicted, and

8 (viii) the reasonably foreseeable availability of facil-

9 ities and personnel for performing testing on the sub-

10 stance or mixture.

11 The recommendations of the committee shall be in the form

12 of a list of chemical substances and mixtures which shall
13 be listed, either by individual substance or mixture or by
groups of substances or mixtures, in the order in which
the committee determines the Administrator should take
action under subsection (a) with respect to the substances
and mixtures.

(B) Not later than twelve months after the effective
1^ date of this Act, the committee shall transmit to the
Administrator the list required by subparagraph (A) to-
'^^ gether with the reasons for the committee's inclusion of each
chemical substance or mixture on the lists. At least every six
months after the transmission to the Administrator of the
list pursuant to the preceding sentence, the committee shall

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make such revisions in the list as it determines to be neces-
2 sary and shall transmit them to the Administrator together
3 with the committee's reasons for th- ^'evisions. The Adminis-
4 trator shall make available to the public the list transmitted
5 by the committee, any revision by the committee in such list
6 (including the date on which such revision was transmitted
7 to the Administrator), and the reasons of the committee for
g inclusion of a chemical substance or mixture on the list and
9 for any revision in the list. The Administrator shall provide
10 reasonable opportunity to any interested person to file with
11 the Administrator written comments on the committee's list
12 or any revision of the committee of such list and shall make
13 such comments available to the public.

14 (C) The Administrator may promulgate a rule under
15 subsection (a) with respect to a chemical substance or mix-
16 ture which is not contained on a list published under this
17 subsection.

18 (2) (A) The committee established by paragraph (1)
19 (A) shall consist of eight members as follows:

20 (i) One member (or designee of the member) ap-
21 pointed from the Environmental Protection Agency by
22 the Administrator.

23 (ii) One member (or designee of the member)
24 appointed by the Secretary of Labor from officers of
25 the Department of Labor engaged in the Secretary's

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1 activities under the Occupational Safety and Health
2 Act of 1970.

3 (Hi) One member (or designee of the member)
4 appointed from the Council on Environmental Quality
5 by the Chairman of the Council.

6 (iv) One member (or designee of the member)
7 appointed from, the National Institute for Occupational
8 Safety and Health by the Director of the Institute.

9 (v) One member (or the designee of the member)

10 appointed from the National Institute of Environmental

11 Health Sciences by the Director of the Institute.

12 (vi) One member (or designee of the member)
appointed from the National Cancer Institute by the
Director of the Institute.

(vii) One member (or designee of the member)
appointed from the National Science Foundation by
the Director of the Foundation.

(viii) One member (or designee of the member)
appointed from the Department of Commerce by the
Secretary of Commerce.

A member may designate an individual to serve on the
member's behalf only with the approval of the applicable
appointing authority and only if the individual is from the
entity from which the member was appointed. A vacancy in

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1 the committee shall be filled in the same manner in which

2 the original appointment was made.

3 (B)(i) The term of office of a member of the committee
4 is four years, except that of the members first appointed,
5 four members shall have initial terms of two years. Any
6 member appointed to fill a vacancy occurring prior to the
7 expiration of the term for which the members predecessor
8 was appointed shall be appointed only for the remainder of
9 such term. If any member of the committee leaves the office
10 or entity from which the member was appointed, such mem-
11 ber may not continue as a member of the committee, and, for
12 purposes of the preceding sentence, the member's position
13 shall be considered as being vacant. A member may serve
14 after the expiration of the member's term of office until a
15 successor has taken office.

16 (a) Initial appointments to the committee shall be made
17 not later than the sixtieth day after the effective date of this
18 Act. Not later than the ninetieth day after such date the
19 members of the committee shall hold a meeting for the selec-
20 tion of a chairman from among their number and to deter-
21 mine, by lot, the four members who shall have initial terms
22 of two years.

23 (C) The Administrator shall provide the committee
24 such administrative support services as may be necessary for
25 the committee to carry out its function under this subsection.

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1 MANUFACTURING AND PROCESSING NOTICES

2 Sec, 5. (a) Notification for Manufacture of

3 New Chemical Substances -On and after the date on

4 which the Administrator first publishes under section 8(h)

5 a list of chemical substances manufactured or processed in

6 the United States, no person may manufacture a new

7 chemical substance unless (except as provided in subsection

8 (i) (relating to exemptions)) such person -

9 (1) has, at least ninety days before such manu-

10 facture, submitted to the Administrator, in accordance

11 with subsection (f) (relating to notice content), a notice

12 of such person's intention to manufacture such sub-

13 stance, and

(2) has complied with any applicable requirement

1^ of subsection (d) (relating to submission of test data).

1^ (b) Notification for the Manufacture or Proc-

^^ ESSiNG OF a Chemical Substance for a Significant

1^ New Use. - (1) No person may manufacture or process a

1^ chemical substance for a use which the Administrator has

20 determined, in accordance with paragraph (2), is a signifi-

21 cant new use of such substance unless (except as provided

22 in subsection (i)) such person -

23 (A) has, at least ninety days before such manu-
24^ facture or processing, submitted to the Administrator, in
25 accordance with subsection (f), a notice of such person's

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1 intention to manufacture or process such substance for

2 such use, and

3 (B) has complied with any applicable requirement

4 of subsection (d).

5 (2) A determination by the Administrator that a new

6 use of a chemical substance is a significant new use with

7 respect to which notification is required under paragraph

8 (1) or subsection (c)(1)(B) shall be made by a rule

9 promulgated after a consideration of all relevant factors,

10 including -

11 (A) the projected volume of manufacturing and

12 processing of such substance for such use,

13 (B) the extent to which such use changes the type

14 or form of exposure of humans or the environment to

15^ such substance, and

16^ (C) the extent to which such use increases the mag-

nitude and duration of exposure of humans or the en-

17^ vironment to such substance.

1^ The last sentence of section 19(c)(1) shall not apply to
20 judicial review of any rule promulgated under this para-
graph.

22 (c) Notification for the Manufacture or Proc-

23 ESSING OF Listed Chemical Substances.- (1) (A)

24 No person may manufacture a chemical substance -

25 (i) which is listed under paragraph (2), and

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1 (ii) which was a new chemical substance at the

2 time of publication of the earliest proposed rule under

3 paragraph (2) listing such substance,

4 unless (except as provided in subsection (i)) such person

5 ha^, at least ninety days before such manufacture, submitted

6 to the Administrator, in accordance with subsection (f), a

7 notice of such persons intention to manufacture such sub-

8 stance and has complied with the requirement of subsection

9 (d).

10 (B) No person may manufacture or process a chemical

11 substance, listed under paragraph (2), for a use which the

12 Administrator has determined, in accordance with subsection

13 (b)(2), is a significant new use of such substancp unless

14 (except as provided in subsection (i)) such person -

1^ (i) has, at least ninety days before such manufac-
1^ ture or processing, submitted to the Administrator, in
a^ cordance with subsection (f), a notice of such per-
1^ son's intention to manufacture or process such substance

19 for such use, and

20 (a) has complied with the requirement of subsection

21 (d).

22 (2)(A)(i) Within twelve months after the effective date

23 of this Act, the Administrator shall, by rule, compile, and

24 from time to time thereafter revise, a list of chemical sub-
2^ stances the manufacture, processing, distribution in com-

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1 merce, use, or disposal of which, or any combination of such
2 actions respecting which, the Administrator finds causes or
3 significantly contributes to or may cause or significantly con-
4 tribute to an unreasonable risk to health or the environment.

5 (ii) In making a finding under clause (i) that the
6 manufacture, processing, distribution in commerce, use, or
7 disposal of a chemical substance or any combination of such
8 actions causes or significantly contributes to or may cause or
9 significantly contribute to an unreasonable risk to health or
10 the environment, the Administrator shall consider all rele-

11 vant factors, including –

12 (I) the effects of the chemical substance on health

13 and the magnitude of human exposure to it; and

14 (II) the effects of the chemical substance on the

15 environment and the magnitude of environmental ex-

16 posure to it.

17 (B) The Administrator shall, in prescribing a rule under

18 subparagraph (A) which lists any chemical substance,

19 identify those uses, if any, which the Administrator deter-

20 mines, in accordance with subsection (b)(2), would consti-

21 tute a significant new use of such substance. The last sen-

22 tence of section 19(c)(1) shall not apply to judicial review

23 of any provision of a rule under subparagraph (A) which

24 provision is prescribed pursuant to this subparagraph.

25 (C) Any rule under subparagraph (A), and any

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1 amendment or repeal of such a rule, shall be promulgated

2 pursuant to the procedures specified in section 558 of title 5,

3 United States Code, except that (i) the Administrator shall

4 give interested persons an opportunity for the oral presenta-

5 tion of data, views, or arguments, in addition to an oppor-

6 tunity to make written submissions, and (ii) a transcript
7 shall be kept of any oral presentation. The Administrator
8 may not promulgate under subparagraph (A) a rule listing
9 a chemical substance unless the Administrator makes and
10 publishes with the rule the finding described in such sub-
11 paragraph.

12 (d) Requirement Respecting Submission of Test

13 Data.--(1)(A) If--

14 (i) a person is required by subsection (a), (b), or
15 (c) to submit a notice to the Administrator before be-
16 ginning the manufacture or processing of a chemical
substance, and

17 (ii) such person is required to submit test data for
18 such substance pursuant to a rule promulgated under
19 section 4 before the submission of such notice or such
20 person has been granted an exemption under section 4
21 (c) from the requirement of such rule,

22 such person may not, before the expiration of the period pre-

23 scribed by subparagraph (B), manufacture such substance
if the person is subject to subsection (a) or (c)(1)(A) or

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1 manufacture of process such substance for a significant new

2 use if the person is subject to subsection (b) or (c) (1) (B) .

3 (B) The period referred to in subparagraph (A) is -

4 (i) in the case of a person required to submit test

5 data pursuant to a rule promulgated under section 4 (a)

6 a period of ninety days which begins on the date on

7 which such person submits to the Administrator such

8 data in accordance with such rule, and

9 (a) in the case of a person who under section 4(c)

10 is exempt from a requirement to submit test data pursu-

1.1 ant to a rule promulgated under section 4(a), a period of

2 ninety days which begins on the date of the submission in

13 accordance with such rule of the test data the submission

14 or the development of which was the basis for the

15 exemption.

16 (2) (A) If-

17 (i) a person is required by subsection (c) to sub-

18 mit a notice to the Administrator before beginning the

19 manufacture or processing of a chemical substance, and

20 (a) (I) a rule promulgated under section 4 before

21 the submission of such notice requiring the submission of

22 test data for such substance does not require such person

23 to submit such data, or

24 (II) the Administrator has not promulgated such a

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1 rule for such substance before the submission of such
2 notice,
3 such person may not, before the expiration of the ninety-day
4 period which begins on the date such person submits to the
5 Administrator data prescribed by subparagraph (B), manu-
6 facture such substance if such person is subject to subsection
7 (c)(1)(A) or manufacture or process such substance for a
8 significant new use if such person is subject to subsection
9 (c)(1)(B).

10 (B) Data submitted pursuant to subparagraph (A)
11 shall be data which the person submitting the data believes
12 show that -

13 (i) in the case of a substance for which notice is
14 required under subsection (c) (1) (A), the manufacture,
15 processing, distribution in commerce, use, and disposal
16 of the chemical substance or any combination of such
17 actions would not cause or significantly contribute to an
18 unreasonable risk to health or the environment, or
19 (ii) in the case of a chemical substance for which
20 notice is required under subsection (c) (1) (B) , the in-
21 tended significant new use of the chemical substance

22 would not cause or significantly contribute to an unrea-
23 sonable risk to health or the environment.

24 (3) Data submitted under paragraph (1) or (2) shall

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1 be made available, subject to section 14, for examination
2 by interested persons.

3 (e) Extension of Notice Period.— The Administrator

4 may for good cause extend for one additional period of

5 not to exceed ninety days the period, prescribed by subsec-

6 tion (a), (b), (c), or (d), before ivhich the manufacturing or

7 processing of a chemical substance subject to such subsection

8 may begin. Subject to section 14, such an extension and the

9 reasons therefor shall be published in the Federal Register

10 and shall constitute a final agency action subject to judicial

11 review.

12 (f) Content of Notice; Publication in the

13 Federal Register. — (1) The notice required by sub-

14 sections (a), (b), and (c) respecting a chemical substance

15 shall include —

16 (A) the name of the chemical substance;

1*7 (B) the chemical identity and molecular structure

18 of the substance, insofar as such are reasonably ascer-
19 tainable;

20 (C) the proposed categories of use of such sub-
21 stance, insofar as such are reasonably ascertainable;

22 (D) a reasonable estimate of the amount of the sub-
23 stance to be manufactured or processed and, insofar as
24 reasonably ascertainable, a reasonable estimate of the

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1 amount of the substance to be manufactured or proc-
2 essed for each proposed category of use of the substance;

3 (E) a description of the byproducts, if any, result-
4 ing from the manufacture, processing, use, or disposal of
5 the substance, insofar as such are reasonably ascertain-
6 able; and

7 (F) any test data in the possession or control of
8 the person giving such notice which are related to the
9 effect on health or the environment of any manufac-
10 ture, processing, distribution in commerce, use, or dis-
11 posal of the substance or any article containing such
12 substance,

13 Such a notice shall be made available, subject to section 14,
for examination by interested persons.

(2) Subject to section 14, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a), (b), or (c) or data under subsection (d) the Administrator shall
1^ publish in the Federal Register a notice which -

20 (A) identifies the chemical substance for which

21 notice or data has been received;

22 (B) lists the uses or intended uses of such sub-

23 stance; and

(C) in the case of the receipt of data under sub-

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1 section (d), describes the nature of the tests performed

2 on such substance and any data which was developed

3 pursuant to subsection (d) or a rule under section 4.

4 Notice under this paragraph respecting a chemical substance

5 shall identify the chemical substance by generic class unless
5 the Administrator determines that more specific identification

7 is required in the public interest.

8 (g) Regulation Pending Development of In-

9 formation .-(1) (A) The district courts of the United

10 States shall, upon application of the Administrator made

11 through attorneys of the Environmental Protection Agency,

12 have jurisdiction to enjoin in accordance tuith subparagraph

13 (B), the manufacture, processing, or distribution in com-
1[^] merce of a chemical substance subject to a notification require-
1[^] ment of subsection (a), (b), or (c) if the court find.[^] that -

(i) information available to the Administrator is
insufficient to permit a reasoned evaluation of the effects
on health or the environment of the manufacture, process-
1[^] ing, distribution in commerce, use, or disposal of such

20 chemical substance or any combination of such actions,

21 and

22 (a) in the absence of such information, the manu-
2[^] facture, processing, distribution in commerce, use, or dis-
2[^] ■ posal of such substance or any combination of such actions

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1 may cause or significantly contribute to an unreasonable
2 risk to health or the environment.

3 (B) An injunction issued under subparagraph (A)

4 with respect to a chemical substance subject to a notification

5 requirement under subsection (b) or (c)(1)(B) respecting

6 a significant new use of such substance shall apply only to

7 the manufacture, processing, or distribution in commerce,

8 as the case may be, of the substance for such use.

9 (C) An injunction issued under subparagraph (A)

10 with respect to a chemical substance shall expire -

11 (i) upon the expiration of the five-day period be-

12 ginning on the day after the issuance of the injunction,
^^ if the Administrator does not within such period publish

the notice required by paragraph (2), or

(ii) if the Administrator publishes such notice with-

in such period, upon the completion or termination of

the proceeding begun by publication of such notice.

(2) (A) Within five days after the issuance of an in-
junction under paragraph (1) ivith respect to a chemical
substance, the Administrator shall publish, in accordance
with section 553(b) of title 5, United States Code, a general
notice of proposed rulemaking to begin proceedings for the
promulgation of a rule to apply to such substance one or
^ more of the requirements described in section 6 (a) as is

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1 necessary to adequately protect against the risk to health or

2 the environment found by the court under paragraph (1)

3 (A)(U).

4 (B) Upon publication of such a notice the Administrator

5 shall, as expeditiously as possible, provide reasonable oppor-

6 tunity for a hearing (in accordance with paragraphs (2)

7 and (3) of section 6(c)) on such proposed rule, and either

8 adopt such rule (as proposed or with modifications) or by

9 notice published in the Federal Register terminate the pro-

10 ceeding for the promulgation of the rule. If such a hearing
11 is requested, the Administrator shall commence the hearing
12 within fifteen days from the date such request is made unless
13 the Administrator and each person making the request agree
1^ upon a later date for the hearing to begin, and after the
1^ hearing is concluded the Administrator shall, within thirty
days of the conclusion of the hearing, either adopt such rule
■'^^ (as proposed or with modifications) or terminate the proceed-
ing (as prescribed in the preceding sentence).

(3) After a rule promulgated under paragraph (2) has
taken effect any person may petition the Administrator to
^■^ initiate a proceeding to amend or repeal such rule. Within
thirty days of the receipt of such a petition, the Adminis-
trator shall by order either grant or deny the petition. If the
^ Administrator grants such petition, the Administrator shall
promptly initiate a proceeding for the amendment or repeal,

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1 as the case may be, of such rule. Such a proceeding shall be
2 conducted in accordance with paragraphs (2) and (3) of
3 section 6(c).

4 (h) Petition for Standards for the Develop-
5 MENT of Test Data. – A person intending to manufacture
6 or process a chemical substance for which notice is required
7 under subsection (a), (b), or (c) and who is not required

8 under a rule under section 4 to conduct tests and submit data
9 on such substance may petition the Administrator to pre-
10 scribe standards for the development of test data for such
11 substance. The Administrator shall either grant or deny
12 any such petition within sixty days of its receipt. If the
13 petition is granted ^ the Administrator shall prescribe such
standards for such substance within seventy-five days of the
1^ date the petition is granted. If the petition is denied, the
1^ Administrator shall publish in the Federal Register the
reasons for such denial.
1^ (i) Exemption. - (1) The Administrator may, upon
1^ application (made in such form and manner as the Ad-
20 ministrator may prescribe) exempt any person from the re-
21 quirement of subsection (a), (b), (c), or (d) or of any
22 combination of such subsections to enable such person to
2^ manufacture or process a chemical substance for test market-
ing purposes -
25 (A) upon a showing by such person satisfactory

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"1^ to the Administrator that the manufacture, processing,
2 distribution in commerce, use, and disposal of such sub-
3 stance for such purposes would not cause or significantly

4 contribute to any unreasonable risk to health or the envi-
5 ronment, and

6 (B) under such restrictions as the Administrator
7 considers appropriate.

8 Within forty-five days of the receipt of an application under
9 this paragraph the Administrator shall either approve
10 deny such application.

11 (2) (A) The Administrator may upon application
12 (made in such form and manner as the Administrator may
13 prescribe) exempt any person from the requirement of sub-

14 section (d)(2) to submit data for a chemical substance.
15 Upon receipt of an application under the preceding sen-
16 tence the Administrator determines that -

(i) the chemical substance (including any contami-
nant present in such substance) with respect to which
19 such application was submitted is equivalent to a chemi-
20 cal substance for which data has been submitted to the
21 Administrator in accordance with subsection (d)(2),
22 and

23 (a) submission of data by the applicant on such
24 substance would be duplicative of data which has been

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1 submitted to the Administrator in accordance with such

2 subsection,

3 the Administrator shall exempt the applicant from submit-
4 ting such data on such substance. No exemption granted
5 under this subparagraph with respect to the submission of
6 data for a chemical substance may take effect before the
7 beginning of the reimbursement period applicable to such
8 data.

9 (B) If the Administrator, under subparagraph (A),
10 exempts any person from submitting under subsection (d)
11 (2) data for a chemical substance because of the existence of
12 previously submitted data and if such exemption is granted
13 during the reimbursement period for such data, then (unless
such person and the persons referred to in clauses (i) and
(ii) agree on the amount and method of reimbursement)
the Administrator shall order the person granted the exemp-
tion to provide fair and equitable reimbursement (in on
amount determined under rides of the Administrator) -

(i) to the person who previously submitted the
29 data on which the exemption icas based, for a portion of
2-^ the costs incurred by such person in complying with the
22 requirement under subsection (d)(2) to submit such
2^ data, and

2^ (ii) to any other person who has been required

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1 under this subparagraph to contribute with respect to

2 such costs, for a portion of the amount such person was
3 required to contribute.

4 In promulgating rules for the determination of fair and
5 equitable reimbursement to the persons described in clauses
6 Q (i) and (ii) for costs incurred with respect to a chemical
7 substance, the Administrator shall consider all relevant fac-
8 tors, including the effect on the competitive position of the
9 person required to provide reimbursement in relation to the
10 persons to be reimbursed and the share of the market for
11 such substance of the person required to provide reimburse-
12 ment in relation to the share of such market of the persons to
13 be reimbursed. An order under this subparagraph shall be
14 considered final agency action, for purposes of judicial
15 review.

16 (C) For purposes of this paragraph, the reimbursement
17 period for any previously submitted data for a chemical sub-
18 stance is a period -

19 ' (i) beginning on the date of the termination of the
20 prohibition, imposed under this section, on the manufac-
21 ture or processing of such substance by the person who
22 submitted such data to the Administrator, and
23 (ii) ending -

24 (I) five years after the date referred to in

25 clause (i), or

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1 (II) at the expiration of a period which begins

2 on the date referred to in clause (i) and is equal

3 to the period which the Administrator determines

4 wa[^] necessary to develop such data,

5 whichever is later,

6 (3) The requirements of subsections (a), (b), (c), and

7 (d) do not apply with respect to the manufacturing or

8 processing of any chemical substance which is manufactured

9 or processed, or proposed to be manufactured or processed,

10 only in small quantities (as defined by the Administrator by

11 rule) solely for –

12 (A) scientific experimentation or analysis, or

13 (B) chemical research or analysis on such sub-

14 stance or another substance, including such research or

15 analysis for the development of a product,

16 if all persons engaged in such experimentation, research, or

17 analysis for a manufacturer or processor are notified (in such

18 form and manner as the Administrator may prescribe) of

19 any risk to health which the manufacturer or processor has

20 reason to believe may be associated with such chemical

21 substance.

22 (4) (A) The requirements of subsections (a) and (c)

23 (1) (A) do not apply with respect to the manufacturing or

24 processing of any chemical substance which is the same as a

25 listed chemical substance.

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1 (B) For purposes of subparagraph (A), a chemical

2 substance shall not be considered as different from a listed

3 chemical substance solely because –

4 (i) the proportion of the inert chemical substances

5 which are present in the listed chemical substance is dif-

6 ferent from the proportion of such substances present in

7 the chemical substance being compared to the listed

8 chemical substance; or

9 (a) an inert listed chemical substance has been

10 added to or deleted from the chemical substance being

11 compared.

12 (C) For purposes of this paragraph –

13 (i) the term "inert chemical substance" means a

14 chemical substance which when combined with other

1^ chemical substances to produce another chemical sub-

1^ stance does not react chemically with such other chemical substances; and

(a) the term "listed chemical substance" means a

1^ chemical substance included in the list compiled and

2^ published under section 8(b).

21 (5) The Administrator may, upon application, by

22 rule exempt the manufacturer of any new chemical sub-
25 stance from all or part of the requirements of this section if
2^ the Administrator determines that such chemical substance
2^ will not cause or significantly contribute to an unreasonable

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1 risk to health or the environment. A rule under this para-
2 graph (and any substantive amendment to, or repeal of, such
3 a rule) shall be promulgated in accordance with paragraphs
4 (2) and (3) of section 6(c).

5 (j) Definition. - For purposes of this section, the
6 terms ^'manufacture" and " process' ' mean to manufacture
7 or to process for commercial purposes.

8 REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES

9 AND MIXTURES

10 Sec. 6. (a) Scope of Regulation.- If the Adminis-

11 trator finds that there is a reasonable basis to conclude that

12 the manufacture, processing, distribution in commerce, use,
13 or disposal of a chemical substance or mixture or any com-
14 bination of such actions causes or significantly contributes to
15 or will cause or significantly contribute to an unreasonable
1^ risk to health or the environment, the Administrator shall by
1'^ rule apply to such substance or mixture one or more of the

following requirements as is necessary to adequately protect
1^ against such risk:

20 (1) ^ requirement prohibiting the manufacturing,
processing, or distribution in commerce of such substance
22 or mixture or limiting the amount of such substance or
mixture which may be manufactured, processed, or dis-
24 tributed in commerce.

(2) A requirement -

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1 (A) prohibiting the manufacture, processing
2 or distribution in commerce of such substance or
3 mixture for (i) a particular use or (ii) a particular
4 use in a concentration in excess of a level specified
5 by the Administrator in the rule imposing the re-
6 quirement, or
7 (B) limiting the amount of such substance or
8 mixture which may be manufactured, processed,

9 or distributed in commerce for (i) a particular use
10 or (ii) a particular use in a concentration in excess
11 of a level specified by the Administrator in the rule
12 imposing the requirement.

13 (3) A requirement that such substance or mixture
14 or any article containing such substance or mixture be
15 marked with or accompanied by clear and adequate
16 warnings and instructions with respect to its use or dis-
17 disposal or with respect to both. The form and content of
18 such warnings and instructions shall be prescribed by
19 the Administrator.

20 (4) A requirement that manufacturers and proc-
21 essors of such substance or mixture make and retain
22 records of the processes used to manufacture or process
23 such substance or mixture.

24 (5) (A) A requirement regulating the manner or
25 method of disposal of such substance or mixture or

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1 article containing such substance or mixture by its
2 manufacturer or processor or any other person who
3 uses it for commercial purposes.

4 (B) A requirement under subparagraph (A) may
5 not require any person to take any action which would
6 be in violation of any law of a State or political subdivi-
7 sion, and shall require each person subject to it to notify
8 each State and political subdivision in which a required
9 disposal may occur of such requirement.

10 (6) If the rule imposes on a chemical substance
11 or mixture a requirement described in paragraph (1)
12 or (2), a requirement directing the manufacturer, proc-
13 essor, or distributor in commerce of such substance or
mixture or article containing such substance or mixture
or directing any combination of such persons (A) to
to give notice of such risk to processors or distributors
^^ in commerce of such substance, mixture, or article, or
to both, and, to the extent reasonably ascertainable, to
1^ any other person in possession of or exposed to such
20 substance, mixture, or article; (B) to give public notice
21 of such risk; or (C) to give both such notices.
22 A requirement imposed under this subsection shall be the
23 least burdensome requirement necessary to adequately pro-
24 tect against the risk with respect to which the requirement

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1 was imposed and may be limited in application to specified

2 geographic areas,

3 (b) Protection Against Adulteration or Con-

4 TAMINATION OF SUBSTANCES AND MIXTURES.- If the

5 Administrator has good cause to believe that a particular

6 manufacturer or processor is manufacturing or processing a

7 chemical substance or mixture in a manner which unintentionally

8 causes the chemical substance or mixture to cause

9 or significantly contribute to or to be likely to cause or sig-

10 nificantly contribute to an unreasonable risk to health or the

11 environment -

12 (1) the Administrator may by order require such

13 manufacturer or processor to submit a description of

14 the relevant quality control procedures followed in the

15 manufacturing or processing of such chemical substance

16 or mixture; and

17 (2) if the Administrator determines after the issuance

18 of an order described in paragraph (1) -

19 (A) that such quality control procedures are

20 inadequate to prevent the chemical substance or mixture

21 from causing or significantly contributing to

22 such risk, the Administrator may order the manu-

23 facturer or processor to revise such quality control

24 procedures to the extent necessary to remedy such

25 inadequacy; or

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(B) that the use of such quality control procedures has resulted in the distribution in commerce of chemical substances or mixtures which cause or significantly contribute to an unreasonable risk to health or the environment, the Administrator may order the manufacturer or processor to (i) give notice of such risk to processors or distributors in commerce of any such substance or mixture, or to both, and, to the extent reasonably ascertainable, to any other person in possession of or exposed to any

11 such substance, (ii) to give public notice of such

12 risk, and (iii) to provide such replacement or re-

13 purchase of any such substance or mixture as is

14 necessary to adequately protect health or the en-

15 • vironment.

16 A determination under subparagraph (A) or (B) of para-

17 graph (2) shall be made on the record after opportunity for

18 hearing in accordance with section 554 of title 5, United

19 States Code. The manufacturer or processor subject to a

20 requirement to replace or repurchase a chemical substance

21 or mixture may decide whether to replace or repurchase the

22 substance or mixture and shall take either such action in the

23 manner prescribed by the Administrator.

24 (c) Promulgation of Subsection (a) Rules.—

25 (1) In promulgating any rule under subsection (a) with

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^ respect to a chemical substance or mixture, the Administrator shall consider all relevant factors and make findings with respect to —

^ (A) the effects of such substance or mixture on

health and the magnitude of human exposure to such
_ substance or mixture,

^ (B) the effects of such substance or mixture on the

g environment and the magnitude of environmental expo-
^ sure to such substance or mixture,

(C) the benefits of such substance or mixture for
various uses and the availability of other substances or

j2 mixtures for such uses, and

(D) the reasonably ascertainable economic conse-
24 quences of such rule taking into account the impact on
j5 small business.

If the Administrator determines that a risk to health or the
17 environment could be eliminated or reduced to a sufficient
Ig extent by actions taken under another Federal law (or

19 laws) administered in whole or in part by the Administra-

20 the Administrator may not promulgate a rule under

21 subsection (a) to protect against such risk unless the Admin-

22 istrator makes a finding that it is in the public interest

23 to protect against such risk under such rule taking into con-

24 sideration all aspects of the risk, the authorities under this

25 Act and such other law (or laws) to enforce actions taken

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1 under this Act or such law (or laws) to protect against such

2 risk, a comparison of the estimated costs of complying with

3 actions taken under this Act and under such law (or laws),

4 and the relative efficiency of actions under this Act and

5 under such law (or laws). In the judicial review of a rule

6 under subsection (a) the last sentence of section 19(c)(1)

7 shall not apply with respect to the determinations and find-

8 ings required to be made by this paragraph.

9 (2) (A) Rules under subsection (a) shall be promul-

10 gated pursuant to section 558 of title 5 of the United States

11 Code; except that in promulgating any such rule (i) the

12 Administrator shall give interested persons an opportunity

1^ for the oral presentation of data, views, or arguments, in

1^ addition to an opportunity to make written submissions; (ii)

1^ a transcript shall be kept of any oral presentation; and (Hi)

during any such oral presentation, the Administrator shall

^^ include an opportunity for cross-examination as provided

in subparagraph (B). The Administrator may not promul-

1^ gate a rule under subsection (a) respecting a chemical sub-

20 stance or mixture unless the Administrator makes and pub-

21 lishes with the rule the finding described in such subsection.

22 (B) An interested person is entitled, if the Administrator determines that it is necessary to resolve disputed issues

24 of material fact, to conduct or have conducted by the Administrator such cross-examination of persons as the Administrator

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1 istrator determines (i) to be appropriate in view of any
2 need for expedition, the nature of the issues involved, and
3 the number of participants and the nature of their interests,
4 and (ii) to be required for a full and true disclosure with
5 respect to such issues.

6 (C)(i) If the Administrator determines that a group
7 of persons, each of whom would but for this subparagraph
8 be entitled to conduct (or have conducted) cross-examination,
9 has the same or similar interests in a proceeding, the
10 Administrator may (I) conduct cross-examination on behalf
11 of such group, or (II) require such group to designate a
12 single representative of such interests for purposes of conducting
13 cross-examination in such proceeding and such representative shall, except as provided in clause (ii), conduct such cross-examination. If such group cannot agree upon a single representative for such purposes, the Administrator

may limit the representation of such interests for such

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purposes.

(ii) When any person who is a member of a group with respect to which the Administrator has made a determination under clause (i) is unable to agree upon group repre-

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sentation with the other members of the group, then such

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person shall not be denied under the authority of such clause

^ the opportunity to conduct (or have conducted) cross-exami-
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nation as to issues affecting the person's particular interests

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1 if (I) the person satisfies the Administrator that the person

2 has made a reasonable and good faith effort to reach agree-

3 ment upon group representation with the other members of

4 the group and (II) the Administrator determines that there

5 are substantial and relevant issues which are not adequately

6 presented by the group representative.

7 (D) The Administrator may issue procedural rules

8 for the conduct of any oral presentation (including cross-
9 examination) under this paragraph and may impose such
10 reasonable time limits on each persons oral presentations
11 authorized by this paragraph as may be appropriate in view
12 of any need for expeditioUj the nature of the issues involvedy
13 and the number of participants and the nature of their
interests.

(E) In the judicial review of a ride under subsection
(a) the last sentence of section 19(c)(1) shall not apply to
^^ any determination of the Administrator under this paragraph.
^@ (3) (A) The Administrator may, pursuant to rules pre-
1^ scribed by it, provide compensation for reasonable attorneys^
2^ fees, expert witness fees, and other costs of partimpating in a
rulemaking proceeding for the promulgation of a rule under
subsection (a) to any person who represents an interest
which will substantially contribute to a fair determination of
^ the issues to be resolved in the proceeding taking into account
the number and complexity of such issues and whether rep-

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1 resentation of such interest will contribute to widespread
2 public participation in the proceeding and representation
3 of a fair balance of interests for the resolution of such issues
4 if-
5 (i) the economic interest of such person is small in
6 comparison to the costs of effective participation in the
7 proceeding by such person^ or

8 (ii) such person demonstrates to the satisfaction of
9 the Administrator that such person does not have suffi-
10 dent resources adequately to participate in the proceed-
11 ing in the absence of compensation under this subpara-
12 graph.

13 In determining whether compensation should be provided
to a person under this subparagraph and the amount of such
compensation, the Administrator shall take into account the

14

financial burden which will be incurred by such person in

15

participating in the rulemaking proceeding.

(B) The aggregate amount of compensation paid under
this paragraph in any fiscal year to all persons who, in rule-
making proceedings in which they receive compensation, are

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persons who either -

(i) would be regulated by the proposed rule, or

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(ii) represent persons who would be so regulated,

^ may not exceed 25 per centum of the aggregate amount

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paid as compensation under this paragraph to all persons

2 in such fiscal year.

3 (4) Paragraphs (1), (2), and (3) of this subsection

4 apply to the promulgation of a rule repealing, or making

5 a substantive amendment to, a rule promulgated under sub-

6 section (a).

7 (d) Effective Date.—(1) The Administrator shall

8 specify in any rule under subsection (a) the date on which it

9 shall take effect, which date shall be as soon as feasible.

10 (2) (A) The Administrator may declare a proposed

11 rule under subsection (a) to be effective upon its publication

12 in the Federal Register and until the effective date of final

13 action taken, in accordance with subparagraph (B), respect-
ing such rule if —

(i) the Administrator determines that —

(I) the manufacture, processing, distribution

11

in commerce, use, or disposal of the chemical sub-
stance or mixture subject to such proposed rule or
any combination of such activities is likely to result
in an unreasonable risk of serious or widespread
harm to health or the environment before such effec-

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tive date; and

(II) making such proposed rule so effective

^ is necessary to protect the public interest; and

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2 (a) in the case of a proposed rule to prohibit the
2 manufacture, processing, or distribution of a chemical
3 substance or mixture because of the risk determined un-
4 der clause (i) (I), a court has in an action under section
5 7 granted relief with respect to such risk associated with
6 such substance or mixture.

7 (B) If the Administrator makes a proposed rule effec-
8 tive upon its publication in the Federal Register, the Ad-
9 ministrator shall, as expeditiously as possible, give interested
10 persons prompt notice of such action, provide reasonable
11 opportunity, in accordance with paragraphs (2) and (3)
12 of subsection (c), for a hearing on such rule, and either
13 affirm such rule (as proposed or with modifications) or re-
14 voke it; and if such a hearing is requested, the Administrator
15 shall commence the hearing within five days from the date
16 such request is made unless the Administrator and the person
17 making the request agree upon a later date for the hearing
18 to begin, and after the hearing is concluded the Administrator
19 shall, within ten days of the conclusion of the hearing, either
20 affirm such rule (as proposed or with modifications) or re-
21 voke it.

22 IMMINENT HAZARDS

23 Sec. 7. (a) Actions Authorized and Required.—

24 (1) The Administrator may file an action in a district court

25 of the United States —

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1 (A) for seizure of an imminently hazardous chemi-

2 cal substance or mixture or any article containing such

3 a substance or mixture,

4 (B) for relief (as authorized by subsection (b))

5 against any person who manufactures, processes, or

6 distributes in commerce an imminently hazardous chemi-

7 cal substance or mixture or any article containing such

8 a substance or mixture, or

9 (C) for both such seizure and relief.

10 An action may be filed under this paragraph notwithstand-

11 ing the existence of a rule under section 4, 5, or 6, and not-

12 withstanding the pendency of any administrative or judicial

1^ proceeding under any provision of this Act.

1*^ (2) If the Administrator has not made a rule under

1^ section 6(a) immediately effective (as authorized by sub-

1^ section 6(d) (2) (A) (i)) with respect to an imminently haz-

1'^ arduous chemical substance or mixture, the Administrator

shall file in a district court of the United States with respect

1^ to such substance or mixture or article containing such sub-

stance or mixture an action described in subparagraph (A),

(B), or (C) or paragraph (1) .

(b) Jurisdiction of Court.— (1) The district court

of the United States in which an action under subsection (a)
^ is broug}it shall have jurisdiction to grant such temporary
or permanent relief as may be necessary to protect health

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1 or the environment from the unreasonable risk associated
2 with the chemical substance^ mixture, or article involved in
3 such action.

4 (2) In the case of an action under subsection (a)

5 brought against a person who manufactures, processes, or

6 distributes in commerce a chemical substance or mixture or

7 an article containing a chemical substance or mixture, the

8 relief authorized by paragraph (1) may include the issuance

9 of a mandatory order requiring (A) in the case of purchasers

10 of such substance, mixture, or article known to the defendant,

11 notification to such purchasers of the risk associated with it;

12 (B) public notice of such risk; (C) recall; (D) the re-

13 placement or repurchase of such substance, mixture, or

14 article; or (E) any combination of the actions described

15 in the preceding clauses.

16 (3) In the case of an action under subsection (a) against

17 a chemical substance, mixture, or article, such substance,
18 mixture, or article may be proceeded against by process of
19 libel for its seizure and condemnation. Proceedings in such
20 an action shall conform as nearly as possible to proceedings
21 in rem in admiralty.

22 (c) Venue and Consolidation.— (1) (A) An action
23 under subsection (a) against a person who manufactures,
24 processes, or distributes a chemical substance or mixture or
25 an article containing a chemical substance or mixture may be

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1 brought in the United States District Court for the District
2 of Columbia or for any judicial district in which any of the
3 defendants is founds resides[^] or transacts business; and
4 process in such an action may be served on a defendant in
5 any other district in which such defendant resides or may
6 be found. An action under subsection (a) against a chemical
7 substancCy mixture[^] or article may be brought in any United
8 States district court within the jurisdiction of which the sub-
9 stance, mixture, or article is found.

10 (B) In determining the judicial district in which an
11 action may be brought under subsection (a) in instances in
12 which such action may be brought in more than one judicial
13 district, the Administrator shall take into account the [^]con-

14 venience of the parties.

15 (C) Subpenas requiring attendance of witnesses in an

16 action brought under subsection (a) may run into any judi-
17 cial district.

18 (2) Whenever proceedings under subsection (a) in-

19 volving identical chemical substances, mixtures, or articles

20 are pending in courts in two or more judicial districts, they

21 shall be consolidated for trial by order of any such court

22 upon application reasonably made by any party in interest,

23 upon notice to all parties in interest.

24 (d) Action Under Section 6.- Where appropriate,

25 concurrently with the filing of an action under subsection (a)

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1 or as soon thereafter as may be practicable, the Administrator

2 shall initiate a proceeding for the promulgation of a rule

3 under section 6(a).

4 (c) Representation. - Notwithstanding any other

5 provision of law, in any action under subsection (a), the

6 Administrator may direct attorneys of the Environmental

7 Protection Agency to appear and represent the Administra-

8 tor in such an action.

9 (f) Definition. – For purposes of subsection (a), the
10 term "imminently hazardous chemical substance or mixture"
11 means a chemical substance or mixture which causes or
12 significantly contributes to an imminent and unreasonable
13 risk of serious or widespread harm to health or the environ-
14 ment. Such a risk to health or the environment shall be con-
15 sidered imminent if it is shown that the manufacture, proc-
16 essing, distribution in commerce, use, or disposal of the
17 chemical substance or mixture or any combination of such
18 actions is likely to result in such harm to health or the envi-
19 ronment before a final rule under section 6 can protect
20 against such risk.

21 REPORTING AND RETENTION OF INFORMATION

22 Sec. 8. (a) Reports. – (1) The Administrator shall
23 promulgate rules under which –
24 (A) each person (other than a small manufacturer
25 or processor) who manufactures or processes or proposes

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1 to manufacture or process a chemical substance (other
2 than a chemical substance described in subparagraph
3 ii)) shall maintain such records[^] and shall submit
4 to the Administrator such reports, as the Administrator
5 may reasonably require, and

6 (B) each person (other than a small manufacturer
7 or processor) who manufactures or processes or proposes
8 to manufacture or process –
9 (i) a mixture J or
(ii) a chemical substance in small quantities
•^^ (as defined by the Administrator by rule) solely for
^2 scientific experimentation or analysis or for chemical
1^ research or analysis on such substance or another
substance, including such research or analysis for
the development of a product,
shall maintain records and submit to the Administrator
^^ reports but only to the extent the Administrator deter-
mines the maintenance of records or submission of
reports, or both, is necessary for the effective enforcement
^ of this Act.

The Administrator may not require in a rule promulgated
under this paragraph the maintenance of records or the sub-
mission of reports with respect to changes in the proportions
^ of the components of a mixture unless the Administrator finds
^ that the maintenance of such records or the. submission of such

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1 reports^ or both, is necessary for the effective enforcement of
2 this Act. For purposes of the compilation of the list of chemi-
3 cal substances required under subsection (b), the Administra-
4 tor shall promulgate rules pursuant to this subsection not later
5 than one hundred and eighty days after the effective date of
6 this Act.

7 (2) The Administrator may require under paragraph •
8 (1) reporting with respect to the following:
9 (A) The common or trade name, the chemical
10 identity, and the molecular structure of each chemical
11 substance or mixture for which such a report is required,
12 insofar as known to the person making the report or
13 insofar as reasonably ascertainable.
14 (B) The categories or proposed categories of use
15 of each such substance or mixture, insofar as known to
16 the person making the report or insofar as reasonably
17 ascertainable.
18 (C) Reasonable estimates of the amount of each
19 substance and mixture to be manufactured or processed
20 and, insofar as known to the person making the report
21 or insofar as reasonably ascertainable, a reasonable esti-
22 mate of the amount of each such substance and mixture
23 to be manufactured or processed for each of its categories
24 or proposed categories of use.
25 (D) A description of the byproducts resulting from

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1 the manufacture[^] processing, use, or disposal of each such

2 substance or mixture, insofar as known to the person
3 making the report or insofar as reasonably ascertainable.

4 (E) All existing data concerning the adverse en-
5 vironmental and health effects of such substance or mix-
6 ture, insofar as known to the person making the report.

7 (F) Estimates of the number of persons who will
8 be exposed to such substance or mixture in their places
9 of employment and the duration of such exposure, inso-
10 far as known to the person making the report.

11 To the extent feasible the Administration shall not require
12 under paragraph (1) unnecessary or duplicate reporting.

13 (3)(A)(i) The Administrator may by rule require a
14 small manufacturer or processor of a chemical substance to
15 submit to the Administrator such information respecting the
16 chemical substance as the Administrator may require for
17 publication of the first list of chemical substances required
18 by subsection (b).

19 (ii) The Administrator may by rule require a small
20 manufacturer or processor of a chemical substance or mix-
21 ture -

22 (ij subject to a rule proposed or promulgated under
23 section 4, 5(c) , 5(g), or 6, or

24 (II) with respect to which relief has been granted
25 pursuant to a civil action brought under section 7,

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1 to maintain such records on such substance or mixture, and
2 to submit to the Administrator such reports on such sub-
3 stance or mixture, as the Administrator may reasonably
4 require. A rule under this clause requiring reporting may
5 require reporting with respect to the matters referred to
6 in paragraph (2) .

7 (B) The Administrator, after consultation with the Ad-
8 ministrator of the Small Business Administration, shall by
9 rule prescribe standards for determining the manufacturers
10 and processors which qualify as small manufacturers and
11 processors for purposes of this paragraph and paragraph
12 (1).

13 (b) Inventory. - (1) The Administrator shall com-
14 pile, keep current, and publish a list of each chemical sub-
15 . .

stance which is manufactured or processed in the United

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States. Such list shall at least include each chemical sub-

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stance which any person reports, under section 5 or sub-

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section (a) of this section, is manufactured or processed in

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the United States or was manufactured or processed in the

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United States within three years before the effective date of

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the rules promulgated pursuant to the last sentence of sub-

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section (a) (1) . In the case of a chemical substance for which

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a notice is submitted in accordance with section 5, such

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chemical substance shall be included in such list as of the

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1 earliest date (as determined by the Administrator) on which

2 such substance was manufactured or processed in the United

3 States. The Administrator shall first publish such a list not

4 later than one year after the effective date of this Act, The

5 Administrator shall not include in such list any chemical

6 substance which is manufactured or processed only in small

7 quantities (as defined by the Administrator by rule) solely

8 for scientific experimentation or analysis or for chemical

9 research or analysis on such substance or another substance,
10 including such research or analysis for the development of a
11 product.

12 (2) To the extent consistent with the purposes of this
13 Act, the Administrator may, in lieu of listing, pursuant to
paragraph (1), a chemical substance individually, list a
category of chemical substances in which such substance is
included.

(c) Records, -Any person who manufactures, proc-
esses, or distributes in commerce or proposes to manufacture,
process, or distribute in commerce any chemical substance or
mixture shall, as required by the Administrator by rule,
maintain records of adverse reactions to health or the envi-
ronment alleged to have been caused by the substance or
mixture. In such a rule the Administrator may require that -
^ (1) records of adverse reactions to the health of

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1 employees he retained for a period of not more than fifty
2 years from the date such reactions were first reported to
3 or known by the person maintaining such records^ and

4 (2) any other record be retained for a period of
5 not more than five years from the date the information
6 contained in the record was first reported to or known by
7 the person maintaining the record,

8 Records required to be maintained under this subsection may
9 include records of consumer allegations of personal injury

10 or harm to health, reports of occupational disease or injury,
11 and reports or complaints of injury to the environment
12 submitted to the manufacturer, processor, or distributor in
13 commerce by individuals or governmental agencies. Upon
14 request of an officer or employee duly designated by the Ad-
15 ministrator, each person who is required to maintain records
1^ under this subsection shall permit the inspection of such
1'^ records and shall submit copies of such records.

18 (d) Health and Safety Studies. – The Adminis-
19 trator shall promulgate rules under which the Administrator
20 may require any person who manufactures, processes, or dis-
21 tinguishes in commerce or who proposes to manufacture, proc-
22 ess, or distribute in commerce any chemical substance or mix-
23 ture (or with respect to paragraph (2), any person who
^ has possession of a study) to submit to the Administrator –

(1) lists of health and safety studies conducted or

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1 initiated by or for such person at any time or known
2 to such person; and
3 (2) copies of any such studies appearing on a list
4 submitted pursuant to paragraph (1) or (2), or other-
5 wise known by such person,

6 (e) Notice to Administrator of Unreasonable

7 Risks, - Any person who manufactures, processes, or dis-
8 tributes in commerce a chemical substance or mixture and
9 who obtains information which reasonably supports the con-
10 elusion that such substance or mixture causes or significantly
11 contributes to a substantial risk to health or the environment
12 shall immediately inform the Administrator of such infor-
13 mation unless such person has actual knowledge that the
14 Administrator has been adequately informed of such in-
15 formation,

(f) Definitions. - For purposes of this section, the
16 terms "manufacture" and "process" mean manufacture or
17 process for commercial purposes,

18 RELATIONSHIP TO OTHER FEDERAL LAWS

19 Sec, 9, (a) Laws Not Administered by the Ad-

20 MINISTRATOR. - (1) If the Administrator has reason to be-
21 lieve that the manufacture, processing, distribution in com-
22 merce, use, or disposal of a chemical substance or mixture or
23 any combination of such actions causes or significantly con-
24 tributes to or is likely to cause or significantly contribute to

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1 an unreasonable risk to health or the environment and deter-
2 mines that such risk may be prevented or reduced to a suffi-
3 cient extent by action taken under a Federal law not adminis-
4 tered by the Administrator, the Administrator shall submit to

5 the agency which administers such law a report which de-
6 scribes such risk and includes in such description a specifica-
7 tion of the activity or combination of activities which the
8 Administrator has reason to believe so causes or contributes
9 to such risk. Such report shall also request such agency -

10 (A)(i) to determine if the risk described in such
11 report may be prevented or reduced to a sufficient extent
12 by action taken under such law, and
13 (ii) if the agency determines that such risk may be
14 so prevented or reduced, to issue an order declaring
15 whether or not the activity or combination of activities
16 specified in the description of such risk causes or signifi-
17 cancy contributes to such risk; and
18 (B) to report such determination and order to the
19 Administrator,

20 Any report of the Administrator shall include a detailed
21 statement of the information on which it is based and shall
22 be published in the Federal Register. The agency receiving
23 a request under such a report shall make the requested de-
24 termination, issue the requested order, and make the re-
25 quested report within such time as the Administrator specifies

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1 in the request, but such time specified may not be less than
2 ninety days from the date the request was made. The report
3 of an agency in response to a request of the Administrator
4 shall be accompanied by a detailed statement of the findings
5 and conclusions of the agency respecting the order and de-
6 termination requested to be made and shall be published in
7 the Federal Register,

8 (2) If the Administrator makes a report under para-
9 graph (1) with respect to a chemical substance or mixture
10 and the agency to which such report was made either -
11 (A) issues an order declaring that the activity or
12 combination of activities specified in the description of the
13 risk described in the report does not cause or significantly
14 contribute to the risk described in the report, or
15 (B) initiates, within ninety days of the publication
16 in the Federal Register of the report of the agency under
17 paragraph (1) in response to the Administrator's report,
18 action under the law (or laws) administered by such

19 agency to protect against such risk,

20 the Administrator may not take any action under section 6

21 or 7 with respect to such risk.

22 (S) If the Administrator has initiated action under sec-

23 Hon 6 or 7 with respect to a risk associated with a chemical

24 substance or mixture which was the subject of a report made

25 to an agency under paragraph (1), such agency shall before

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1 taking action under the law (or laws) administered by it to

2 protect against such risk consult with the Administrator for

3 the purpose of avoiding duplication of Federal action against

4 such risk.

5 (h) Laws Administered by the Administrator,-

6 The Administrator shall coordinate actions taken under this

7 Act with actions taken under other Federal laws administered

8 in whole or in part by the Administrator. If a risk to health

9 or the environment associated with a chemical substance or

10 mixture could be eliminated or reduced to a sufficient extent

11 by actions taken under the authorities contained in such other

12 Federal laws, the Administrator shall use such authorities to

13 protect against such risk unless the Administrator determines

14 that it is in the public interest to protect against such risk by
15 actions taken under this Act. This subsection shall not be
16 construed to relieve the Administrator of any requirement
17 imposed on the Administrator by such other Federal laws.

18 (c) Occupational Safety and Health.— In exer-
19 dsing any authority under this Act, the Administrator shall
20 noty for purposes of section 4(b)(1) of the Occupational
21 Safety and Health Act of 1970, be deemed to be exercising
22 statutory authority to prescribe or enforce standards or regu-
23 lations affecting occupational safety and health.

24 (d) Coordination. — In administering this Act, the
25 Administrator shall consult and coordinate with the Secre-

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1 tary of Health, Education, and Welfare and the heads of
2 any other appropriate Federal executive department or
3 agency, any relevant independent regulatory agency, and
4 any other appropriate instrumentality of the Federal Gov-
5 ernment for the purpose of achieving the maximum enforce-
6 ment of this Act while imposing the least burdens of dupli-
7 cative requirements on those subject to the Act and for other
8 purposes. The Administrator shall report annually to the
9 Congress on actions taken to coordinate with such other Fed-

10 eral departments, agencies, or instrumentalities, and on
11 actions taken to coordinate the authority under this Act with
12 the authority granted under other Acts referred to in sub-
13 section (b).

14 RESEARCH, COLLECTION, DISSEMINATION, AND
15 UTILIZATION OF DATA

16 Sec. 10. (a) Authority. – The Administrator shall, in
17 consultation and cooperation with the Secretary of Health,
18 Education, and Welfare and with other heads of appropriate
19 departments and agencies, conduct such research and moni-
20 toring as is necessary to carry out the purposes of this Act.
21 The Administrator may enter into contracts and may make
22 grants for such research and monitoring. Contracts may be
23 entered into under this subsection without regard to sections
24 3648 and 8709 of the Revised Statutes (31 U.S.C. 529, 41
25 U.S.C.5).

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1 (b) Data Systems.– (1) The Administrator shall
2 establish, administer, and be responsible for the continuing
3 activities of an interagency committee which will design,
4 establish, and coordinate an efficient and effective system,

5 within the Environmental Protection Agency, for the collec-
6 tion, dissemination to other Federal departments and agen-
7 cies, and use of data submitted to the Administrator under this
8 Act.

9 (2) (A) The Administrator shall, in consultation with
10 the Secretary of Health, Education, and Welfare and other
11 heads of appropriate departments and agencies design, estab-
12 lish, and coordinate an efficient and effective system for the
13 retrieval of toxicological and other scientific data which could
be useful to the Administrator in carrying out the purposes
of this Act. Systematized retrieval shall be developed for use
by all Federal and other departments and agencies with re-
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sponsibilities in the area of regulation or study of chemical

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substances and mixtures and their effect on health or the
environment.

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(B) The Administrator, in consultation with the Secre-

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tary of Health, Education, and Welfare, is authorized to

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make grants and enter into contracts for the development of

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a data retrieval system described in subparagraph (A). Con-

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tracts may be entered into under this subparagraph without

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regard to sections 3648 and 3709 of the Revised Statutes
(31 U.S.C. 529, 41 U.S.C. 5).

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1 INSPECTIONS

2 Sec. 11. (a) In General. – For purposes of enforce-

3 ment of this Act the Administrator, or any representative of

4 the Administrator, duly designated by the Administrator, may

5 inspect any establishment, facility, or other premises in which

6 chemical substances or mixtures are manufactured, processed,

7 stored, or held before or after their distribution in commerce

8 and any conveyance being used to transport chemical sub-

9 stances or mixtures in connection with distribution in com-

10 merce. Such an inspection may only be made upon presenting

11 appropriate credentials and a written notice to the owner,

12 operator, or agent in charge of the premises or conveyance

1[^] to be inspected. A separate notice shall be given for each such

1[^] inspection, but a notice shall not be required for each entry

1[^] made during the period covered by the inspection. Each

such inspection shall be commenced and completed with rea-
sonable promptness and shall be conducted at reasonable times,
within reasonable limits, and in a reasonable manner.

1[^] (b) Scope. – (1) Except as provided in paragraph (2) ,

20 an inspection under subsection (a) shall extend to all things
21 within the premises or conveyance inspected (including rec-
22 ords, files, papers, processes, controls, and facilities) bearing
on whether the requirements of this Act applicable to the
^ chemical substances or mixtures within such premises or con-
veyance have been complied with.

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1 (2) No inspection under subsection (a) shall extend to -
2 (A) financial data,
3 (B) sales data other than shipment data,
4 (C) pricing data,
5 (D) personnel data, or
6 (E) research data (other than research data re-
7 quired by this Act) ,
8 unless the nature and extent of such data are described with
9 reasonable specificity in the written notice required by sub-
10 section (a) for such inspection.

11 EXPORTS

12 Sec, 12. (a) General. - (1) Except as provided in
13 paragraph (2) and subsection (b), this Act (other than
14 section 8) shall not apply to any chemical substance, mix-
15 ture, or an article containing a chemical substance or mix-
16 ture if-

■'^^ (A) it can be shown that such substance, mixture,
or article is being manufactured, processed, sold, or held
1^ for sale, for export from the United States, unless such
20 substance, mixture, or article was, in fact, manufactured,
21 processed, or distributed in commerce, for use in the
United States, and

(B) such substance, mixture, or article when dis-
^ tributed in commerce, or any container in which it is en-
^ closed when so distributed, bears a stamp or label stating

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1 that such substance, mixture^ or article is intended for
2 export.

3 (2) Paragraph (1) shall not apply to any chemical sub-
4 stance, mixture, or article if the Administrator finds that the
5 substance, mixture, or article will cause or significantly con-
6 tribute to an unreasonable risk to health within the United
7 States or to the environment of the United States. The
8 Administrator may require, under section 4, testing of a
9 chemical substance or mixture exempted from this Act by
1^ paragraph (1) to determine whether or not such substance
11 or mixture causes or significantly contributes to an unreason-
12 able risk to health within the United States or to the environ-
1^ ment of the United States.

(b) Notice. – (1) If any person exports or intends

to export to a foreign country a chemical substance or mixture for which the submission of data is required under section 4 or 5(d), such person shall notify the Administrator of such exportation or intent to export and the Administrator shall 1[^] furnish to the government of such country notice of the avail- 2[^] ability of the data submitted to the Administrator under such section for such substance or mixture.

' (2) If any person exports or intends to export to a foreign country a chemical substance or mixture for which a rule [^] hm been proposed or promulgated under section 5 or 6, or with respect to which an action is pending, or relief has been

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1 granted under section 7, such person shall notify the Ad-
2 ministrator of such exportation or intent to export and the
3 Administrator shall furnish to the government of such country
4 notice of such rule, action, or relief.

5 ENTRY INTO CUSTOMS TERRITORY OF THE UNITED

6 STATES

7 Sec. 13. (a) In General.— (1) The Secretary of the
8 Treasury shall refuse entry into the customs territory of the
9 U nited States (as defined in general headnote 2 to the Tariff
10 Schedules of the United States) of any chemical substance,
11 mixture, or article containing a chemical substance or mix-
12 ture offered for entry if –
13 (A) it fails to comply with any rule in effect under
14 this Act, or

15 (B) it is offered for entry in violation of section 5,
16 a rule or order under section 5 or 6, or an order issued
17 in an action brought under section 5 or 7.

18 (2) If a chemical substance, mixture, or article is
19 refused entry under paragraph (1), the Secretary of the
20 Treasury shall notify the consignee of such entry refusal,
21 shall not release it to the consignee, and shall cause its
22 disposal or, storage (under such rules as the Secre-
23 tary of the Treasury may prescribe) if it has not been ex-
24 ported by the consignee within ninety days from the date of
25 receipt of notice of such refusal, except that the Secre-

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1 tary of the Treasury may, pending a review by the Admin-
2 istrator of the entry refusal, release to the consignee such
3 substance, mixture, or article on execution of bond for the
4 amount of the full invoice of such substance, mixture, or
5 article (as such value is set forth in the customs entry) ,
6 together with the duty thereon. On failure to return such
7 substance, mixture, or article for any cause to the custody
8 of the Secretary of the Treasury when demanded, such
9 consignee shall be liable to the United States for liquidated
10 damages equal to the full amount of such bond. All charges

11 for storage, cartage, and labor on substances, mixtures, or
12 articles which are refused entry or release under this sec-
13 tion shall be paid by the owner or consignee, and in de-
14 fault of such payment shall constitute a lien against any
15 future entry made by such owner or consignee.

16 (b) Rules. – The Secretary of the Treasury, after
17 consultation with the Administrator, shall issue rules for
18 the enforcement of subsection (a) of this section.

19 DISCLOSURE OF DATA

20 Sec. 14. (a) In General. – Except as provided by
21 subsection (b), any information reported to, or otherwise
22 obtained by, the Administrator (or any representative of
23 the Administrator) under this Act, which is exempt from
24 disclosure pursuant to subsection (a) of section 552 of
25 title 5, United States Code, by reason of subsection (b)

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1 (4) of such section, shall not be disclosed by the Admin-
2 istrator or by any officer or employee of the United States,
3 except that such information may be disclosed –
4 (1) to officers and employees of the United States –
5 (A) in connection with their official duties un-

6 der laws for the protection of health or the environ-
7 ment, or
8 (B) for specific law enforcement purposes;
9 (2) to contractors with the United States and
10 employees of such contractors if in the opinion of the
11 Administrator such disclosure is necessary for the satis-
12 factory performance by the contractor of a contract
1^ with the United States entered into on or after the
effective date of this Act for the performance of work
in connection with this Act; or

(3) when relevant in any proceeding under this

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Act, except that disclosure in such a proceeding shall

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be made in such manner as to preserve confidentiality

(b) Data From Health and Safety Studies.—

(1) Subsection (a) does not prohibit the disclosure of —

(A) any health and safety study submitted under
this Act with respect to —

(i) any chemical substance or mixture which

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1 on the date the study is to be disclosed has been

2 offered for commercial distribution, or

3 (ii) any chemical substance or mixture for
4 which testing is required under section 4 or for
5 which notification is required under section 5, and

6 (B) any data reported to, or otherwise obtained
^ by the Administrator from a health and safety study
8 which relates to a chemical substance or mixture de-
^ scribed in clause (i) or (ii) of subparagraph (A).

This paragraph does not authorize the release of data which
discloses processes used in the manufacturing or processing
●^^ of a chemical substance or mixture or, in the case of a mix-
ture, the release of data disclosing the portion of the mixture
comprised by any of the chemical substances in the mixture.

(2) If a request is made to the Administrator under sub-
section (a) of section 552 of title 5, United States Code, for

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information which is described in the first sentence of para-

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graph (1) and which is not information described in the
second sentence of such paragraph, the Administrator may
not deny such request on the basis of subsection (b)(3) or

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(b)(4) of such section.

(c) Designation of Confidential Data; Dis-

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putes. - (1) In submitting data under this Act, a person

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may (A) designate the data which the person believes is
entitled to confidential treatment under subsection (a), and

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1 (B) submit such designated data separately from other data
2 submitted under this Act.

3 (2) If the Administrator proposes to release for inspec-
4 tion data which has been designated under paragraph (1)
5 (A), the Administrator shall notify, in writing and by certi-
6 fied mail, the person who submitted such data of the intent
7 to release such data. If the release of such data is to be made
8 pursuant to a request made under section 552 (a) of title 5,
9 United States Code, such notice shall be given immediately
10 upon approval of such request by the Administrator. The
11 Administrator may not release such data until the expira-
12 tion of thirty days after the person submitting such data has
13 received the notice required by this paragraph.

14 (d) Criminal Penalty for Wrongful Disclo-
1^ SURE. - (1) Any officer or employee of the United States
1^ or former officer or employee of the United States, who by
-^-'^ virtue of such employment or official position has obtained
1^ possession of, or has access to, material the disclosure of which
19 prohibited by subsection (a), and who knowing that dis-
closure of such material is prohibited by such subsection, will-
^1 fully discloses the material in any manner to any person not
^ entitled to receive it, shall be guilty of a misdemeanor and
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fined not more than \$5,000 or imprisoned for not more than

^ one year, or both. Section 1905 of title 18, United States

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1 Code, does not apply with respect to the publishing, divulging,
2 disclosure, or making known of, or making available, infor-
3 mation reported or otherwise obtained under this Act.

4 (2) For the purposes of paragraph (1), any contractor
5 with the United States who is furnished information as
6 authorized by subsection (a)(2), and any employee of any
7 such contractor, shall be considered to be an employee of the
8 United States.

9 (e) Access by Congress. – Notwithstanding any
10 limitation contained in this section or any other provision of
11 law, all information reported to or otherwise obtained by the
12 Administrator (or any representative of the Administrator)
13 under this Act shall be made available, upon written request
14 of any duly authorized committee of the Congress, to such
15 committee.

16 PROHIBITED ACTS

17 Sec. 15. It shall be unlawful for any person to –

18 (1) fail or refuse to comply with (A) any rule or
19 order promulgated or issued under section 4, (B) any
20 requirement prescribed by section 5, or (C) any rule

21 order promulgated under section 5 or 6;

22 (2) use for commercial purposes a chemical sub-
^ stance or mixture which such person knew or had reason
24 to know was manufactured, processed, or distributed in

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1 commerce in violation of section 5, a rule or order
2 under section 5 or 6, or an order issued in an action
3 brought under section 5 or 7;
4 (3) fail or refuse to (A) establish or maintain rec-
5 ords, (B) submit reports, notices, or other information,
6 or (C) permit access to or copying of records^ as re-
7 quired by this Act or a rule thereunder; or
8 (4) fail or refuse to permit entry or inspection as
9 required by section 11 .

10 PENALTIES

11 Sec. 16. (a) Civil. - (1) Any person who violates
12 a provision of section 15 of this Act shall be liable to the
13 United States for a civil penalty in an amount not to exceed
^' \$25,000 for each such violation. Each day such a violation
continues shall for purposes of this subsection constitute a
separate violation of section 15.

(2) (A) A civil penalty for a violation of section 15
shall be assessed by the Administrator by an order made on
the record after opportunity (provided in accordance with
this subparagraph) for a hearing in accordance with sec-

tion 554 of title 5, United States Code. Before issuing such

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an order, the Administrator shall give written notice to the

Administrator s proposal to issue such order and provide

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1 such person an opportunity to request, within fifteen days of

2 the date the notice is received by such person, such a

3 hearing on the order.

4 (B) In determining the amount of a civil penalty, the

5 Administrator shall take into account the nature, drcum-

6 stances, extent, and gravity of the violation or violations

'7 and, with respect to the violator, ability to pay, effect on

8 ability to continue to do business, any history of prior such

9 violations, the degree of culpability, and such other matters

1^ as justice may require.

(C) The Administrator may, in the Administrator s

-^^ discretion, compromise, modify, or remit, with or without

1^ conditions, any civil penalty which may be imposed under

this subsection. The amount of such penalty, when finally

determined, or the amount agreed upon in compromise, may

be deducted from any sums owing by the United States to

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the person charged.

(3) Any person who requested in accordance with paragraph (2) (A) a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in ^ which such person resides or transacts business. Such a

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1 petition may only be filed within the thirty-day period be-
2 ginning on the date the order making such assessment was
3 issued.

4 ('^) If any person fails to pay an assessment of a civil
5 penalty after it has become a final order and does not file
6 a petition for judicial review of the order in accordance
7 with paragraph (3) or after a court in an action brought
8 under paragraph (3) has entered final judgment in favor
9 of the Administrator, the Attorney General shall recover the
10 amount assessed (plus interest at currently prevailing rates
11 from such date) in an action brought in any appropriate
12 district court of the United States. In such an action, the
13 validity, amount, and appropriateness of such penalty shall
14 not be subject to review.

15 (b) Criminal. - Any person who knowingly or will-
16 fully violates any provision of section 15 shall, in addition

17 to or in lieu of a civil penalty which may be imposed under
18 subsection (a) of this section for such violation, be subject,
19 upon conviction, to a fine of not more than \$25,000 for each
20 day of violation, or to imprisonment for not more than one
21 year, or both.

22 (c) Notice, Repurchase, or Replacement,- If in
23 a proceeding for the issuance of an order under paragraph
24 (1) to assess a civil penalty against a person the Adminis-
25 trator determines that such person manufactured, processed,

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1 or distributed in commerce a chemical substance or mixture
2 in violation of a requirement applicable to such substance or
3 mixture under paragraph (1) or (2) of section 6(a) or
4 otherwise determines by order made on the record after op-
5 portunity for agency hearing that a person has so violated
6 such a requirement, the Administrator may, in such order,
7 require such person (1) to give notice of the risk associated
8 with the chemical substance or mixture subject to such require-
9 ment to processors or distributors in commerce of such sub-
10 stance or mixture, or to both, and, to the extent reasonably

11 ascertainable, to any other person in possession of or exposed
12 to such substance or mixture; (2) to give public notice of
13 such risk; (3) to either replace or repurchase such substance
or mixture, as determined by the person (or persons) to
whom the requirement is directed, in the manner prescribed
by the Administrator; or (4) to take any combination of the
actions described in the preceding clauses.

SPECIFIC ENFORCEMENT AND SEIZURE

1^ Sec, 17. (a) Specific Enforcement.- (1) The
district courts of the United States shall have jurisdiction
over civil actions to -
^ (A) restrain any violation of section 15,
(B) restrain any person from manufacturing or
^ processing a chemical substance before the expiration

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1 of the 'period before which such manufacturing or proc-
2 essing is prohibited under section 5,
3 (C) restrain any person from taking any action
4 prohibited by section 5 or by a rule or order under sec-
5 tion 5 or 6, or
6 (D) compel the taking of any action required by
7 or under this Act .
8 (2) A civil action described in paragraph (1) may be
9 brought -

10 (A) in the case of a civil action described in sub-
11 paragraph (A) of such paragraph, in the United States
12 district court for the judicial district wherein any act,
13 omission, or transaction constituting a violation of sec-
tion 15 occurred or wherein the defendant is found or

15

transacts business, or

16

(B) in the case of any other civil action described

17

in such paragraph, in the United States district court

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for the judicial district wherein the defendant is found
or transacts business.

may be found. Subpenas requiring attendance of witnesses
in any such action may run into any judicial district.

(b) Seizure, - Any chemical substance or mixture

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1 which was manufactured, processed, or distributed in com-
2 merce in violation of this Act or any rule or order promul-
3 gated under this Act or any article containing such a sub-
4 stance or mixture shall be liable to be proceeded against, by

5 process of libel for the seizure and condemnation of such sub-
6 stance, mixture, or article, in any district court of the United
7 States within the jurisdiction of which such substance, mix-
8 ture, or article is found. Such proceedings shall conform as
9 nearly as possible to proceedings in rem in admiralty.

10 PREEMPTION

11 Sec. 18. (a) Effect on State Law.—(1) Except
12 as provided in paragraph (2), nothing in this Act shall
13 affect the authority of any State or political subdivision of
14 a State to establish or continue in effect regulation of any
15 chemical substance, mixture, or article containing a chemi-

16

cal substance or mixture.

IT

(2) Except as provided in subsection (b) —

(A) if the Administrator requires by a rule pro-
mulgated under section 4 the testing of a chemical sub-
stance or mixture, no State or political subdivision may,
after the effective date of such rule, establish or con-
tinue in effect a requirement for the testing of such
substance or mixture for purposes similar to those for
^ which testing is required under such rule; and

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1 (B) if the Administrator prescribes a rule or
2 order under section 5 or 6 of this Act (other than

3 a rule imposing a requirement described in subsection
4 (a)(5) of section 6) which is applicable to a chemical
5 substance or mixture, and which is designed to protect
6 against a risk to health or the environment associated
7 with such substance or mixture, no State or political
8 subdivision of a State may, after the effective date of
9 such requirement, establish or continue in effect a re-
10 quirement applicable to such substance or mixture, or
11 an article containing such substance or mixture, and
12 designed to protect against such risk unless such require-
13 ment is identical to the requirement prescribed by the
14 Administrator or unless such requirement is adopted
15 under the authority of the Clean Air Act or any other
16 Federal law.

17 (b) Exemption. - Upon application of a State or
18 political subdivision of a State the Administrator may by
19 rule exempt from subsection (a)(2), under such conditions
20 as may be prescribed in such rule, a requirement of such
21 State or political subdivision designed to protect against a
22 risk to health or the environment associated with a chemical
23 substance, mixture, or article containing a chemical substance
24 or mixture if -

25 (±) compliance with the requirement would not

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1 cause the manufacturing, processing, distribution in com-

2 merce, or use of the substance, mixture, or article to be in
3 violation of the applicable requirement under this Act
4 described in subsection (a) (2), and
5 (2) the State or political subdivision requirement
6 (A) provides a significantly higher degree of protec-
7 tion from such risk than the requirement under this Act
8 described in subsection (a)(2) and (B) does not,
9 through difficulties in marketing, distribution, or other
10 factors, unduly burden interstate commerce.

11 JUDICIAL REVIEW

12 Sec. 19. (a) In General.— Not later than sixty days
13 following the promulgation of a rule under section 4, 5, or
14 6(a) of this Act, any person may file a petition for judicial
15 review of such rule with the United States Court of Appeals
16 for the District of Columbia Circuit or for the circuit in
17 which such person resides or in which such person's principal
18 place of business is located. Copies of the petition shall
19 be forthwith transmitted by the clerk of such court to the
20 Administrator and to the Attorney General. The Adminis-
21 trator shall transmit to the Attorney General, who shall
22 file in the court, the record of the proceedings on which
23 the Administrator based such rule as provided in section
24 2112 of title 28, United States Code. For purposes of this
section, the term "record" means such rule; any transcript

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1 required of any oral presentation; any written submission
2 of interested parties; and any other information which the
3 Administrator considers to be relevant to such rule and
4 with respect to which the Administrator, on or before the
5 date of the promulgation of such rule, published a notice in
6 the Federal Register identifying such information.

7 (b) Additional Data. - If the petitioner applies to
8 the court for leave to adduce additional data, views, or
9 arguments, and shows to the satisfaction of the court that
10 such additional data, views, or arguments are material and
11 that there are reasonable grounds for the petitioner's failure
12 to adduce such data, views, or arguments in the proceeding
1[^] before the Administrator, the court may order the Adminis-

trator to provide additional opportunity for oral presentation
of data, views, or arguments and for written submissions.
The Administrator may modify findings or determinations
upon which the rule subject to review by such court was
based, or make new findings or determinations by reason of
the additional data, views, or arguments so taken and shall
2[^] file such modified or new findings or determinations, and the
'^{^^} Administrator's recommendation, if any, for the modifica-
tion or setting aside of such rule, with the return of such
additional data, views, or arguments.

[^] (c) Authority and Review Standard,- (1)

Upon the filing of a petition under subsection (a), the court

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1 shall have jurisdiction (A) to review the rule involved, in
2 accordance with chapter 7 of title 5, United States Code, and
3 (B) to grant appropriate relief, including interim relief, as
4 provided in such chapter. Any rule promulgated by the Ad-
5 ministrator under section 4, 5, or 6 of this Act and reviewed
6 under this section shall be affirmed, unless the determination
7 or findings required to be made by the Administrator under
8 the applicable section are not supported by substantial evi-
9 dence on the record taken as a whole.

10 (2) The judgment of the court affirming or setting aside,
11 in whole or in part, any rule reviewed in accordance with
12 this section shall be final, subject to review by the Supreme
1[^] Court of the United States upon certiorari or certification, as
1[^] provided in section 1254 of title 28, United States Code.
1[^] (8) The judgment of the court in an action brought

pursuant to subsection (a) may include an award of costs

1[^] of suit and reasonable fees for attorneys and expert witnesses
if the court determines that such an award is appropriate,

19 The Supreme Court of the United States in its decision on a
20 review of a judgment in such an action may provide for the
21 award of costs of suit and reasonable fees for attorneys if the
22 court determines that su^h an award is appropriate.

23 (d) Other Remedies, - The remedies provided in this
24 section- shall be in addition to and not in lieu of any other
25 remedies provided by law, .

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1 citizens' civil actions

2 Sec. 20. (a) In General.— Except as provided in

3 subsection (b), any person may commence a civil action –

4 (1) against any person (including (A) the United

5 States, and (B) any other governmental instrumentality

6 or agency to the extent permitted by the eleventh

7 amendment to the Constitution) who is alleged to be

8 in violation of this Act or any rule prescribed under

9 section 4, 5, or 6(a) to restrain such violation, or

10 (2) against the Administrator to compel the Ad-

11 ministrator to perform any act or duty under this Act

12 which is not discretionary.

13 Any civil action under paragraph (1) shall be brought in the

14 United States district court for the district in which the
alleged violation occurred or in which the defendant resides

15 or in which the defendant's principal place of business is lo-

16 cated. Any action brought under paragraph (2) shall be
brought in the United States District Court for the District of

17 Columbia, or the United States district court for the judicial

18 district in which the plaintiff is domiciled. The district courts

19 shall have jurisdiction over suits brought under this section,

22 without regard to the amount in controversy or the citizen-
23 ship of the parties. In any civil action under this subsection
24 process may be served on a defendant in any judicial district

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1 in which the defendant resides or may be found and subpoenas
2 for witnesses may run into any judicial district.

3 (b) Limitation,- No civil action may be com-
4 menced -

5 (1) under subsection (a)(1) to restrain a viola-
6 tion of this Act or rule under this Act -

7 (A) before the expiration of sixty days after
8 the plaintiff has given notice of such violation (i) to
9 the Administrator, and (ii) to the person who is
10 alleged to have committed such violation, or

11 (B) if the Administrator (or the Attorney
12 General on behalf of the Administrator) has com-
1^ menced and is diligently prosecuting a civil action

in a court of the United States to require compli-
ance with this Act or such rule, but if such action
is commenced after the giving of notice, any person
giving such notice may intervene as a matter of

-to

right in such action; or

(2) under subsection (a)(2) before the expiration of sixty days after the plaintiff has given notice to the Administrator of the alleged failure of the Administrator to perform an act or duty which is the basis for such action or, in the case of an action under such subsection ^ for the failure of the Administrator to file an action

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1 under section 7, before the expiration of ten days after
2 such notification.

3 Notice under this subsection shall be given in such manner
4 as the Administrator shall prescribe by rule.

5 (c) General. - (1) In any action under this section,
6 the Administrator, if not a party, may intervene as a matter
7 of right.

8 (2) The court, in issuing any final order in any action
9 brought pursuant to subsection (a), may award costs of suit
10 and reasonable fees for attorneys and expert witnesses if the
11 court determines that such an award is appropriate. Any
12 court, in issuing its decision in an action brought to review
13 such an order, may award costs of suit and reasonable fees
for attorneys if the court determines that such an award is
appropriate.

(3) Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of this Act or any rule under this Act or to seek any other relief.

(d) Consolidation. – When two or more civil actions brought under subsection (a) involving the same defendant and the same issues or violations are pending in two or more judicial districts, such pending actions, upon application of such defendants to such actions which is made to a

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1 court in which any such action is brought, may, if such
2 court in its discretion so decides, be consolidated for trial
3 by order (issued after giving all parties reasonable notice
4 and opportunity to be heard) of such court and tried in –
5 (1) any district which is selected by such defend-
6 ant and in which one of such actions is pending,
7 (2) a district which is agreed upon by stipulation
8 between all the parties to such actions and in which one
9 of such actions is pending, or
10 (3) a district which is selected by the court and
11 in which one of such actions is pending.
12 The court issuing such an order shall give prompt notification
13 of the order to the other courts in which the civil actions con-
14 solidated under the order are pending.
15 citizens' petitions

16 Sec. 21. (a) In General. – Any person may petition

1'^ the Administrator to initiate a proceeding for the issuance,
18 amendment, or repeal of a rule under section 4, 5(c), or
19 6(a).

20 (b) Procedures. - (1) Such petition shall be filed in
21 the principal office of the Administrator and shall set forth
22 the facts which it is claimed establish that it is necessary to
23 issue, amend, or repeal a rule under section 4, 5(c), or 6(a).
24 (2) The Administrator may hold a public hearing or

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1 may conduct such investigation or proceeding as the Admin-
2 istrator deems appropriate in order to determine whether or
3 not such petition should be granted.

4 (3) Within ninety days after filing of a petition de-
5 scribed in paragraph (1), the Administrator shall either
6 grant or deny the petition. If the Administrator grants such
7 petition, the Administrator shall promptly commence an ap-
8 propriate proceeding in accordance with section 4, 5(c), or
9 6(a). If the Administrator denies such petition, the Adminis-
10 trator shall publish in the Federal Register the Administra-
11 tors reasons for such denial.

12 (4) (A) If the Administrator denies a petition filed

13 under this section (or if the Administrator fails to grant or
14 deny such petition within the ninety-day period) the peti-
15 tioner may commence a civil action in a United States dis-
16 trict court to compel the Administrator to initiate a rule-
17 making proceeding to take the action requested. Any such
18 action shall be filed within sixty days after the Administra-
19 tors denial of the petition or, if the Administrator fails to
20 grant or deny the petition within ninety days after filing
21 the petition, within sixty days after the expiration of the
22 ninety-day period.

23 (B) If in an action under subparagraph (A) respect-
24 ing a petition to initiate a proceeding to issue a rule under
25 section 4, 5(c), or 6(a) the petitioner demonstrates to the

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1 satisfaction of the court, by a preponderance of the evidence
2 in a de novo proceeding before the court, that -
3 (i) in the case of a petition to initiate a proceeding
4 for the issuance of a rule under section 4, that the manu-
5 facture, distribution in commerce, processing, use, or dis-
6 posal of the chemical substance or mixture to be subject
7 to such rule may cause or significantly contribute to an

8 unreasonable risk to health or the environment,

9 (a) in the case of a petition to initiate a proceeding

10 for the issuance of a rule under section 5(c), that the

11 manufacture, processing, distribution in commerce, use,

12 or disposal of a chemical substance petitioned to be in-

13 eluded in a list compiled under such rule causes or sig-

14 nificantly contributes to or may cause or significantly

15 contribute to an unreasonable risk to health or the en-

16 vironment, or

17 (Hi) in the case of a petition for the issuance of a

18 rule under section 6(a), that there is a reasonable basis

19 to conclude that the manufacture, processing, distribution

20 in commerce, use, or disposal of a chemical substance

21 or mixture to be subject to such rule causes or signifi-

22 cantly contributes to or will cause or significantly con-

23 tribute to an unreasonable risk to health or the en-

24 vironment,

25 the court shall order the Administrator to initiate the action

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1 requested by the petitioner unless the court finds, after con-

2 sidering the extent of the risk to health or the environment

3 alleged by the petitioner in relation to the extent of risks to
4 health or the environment with respect to which the Admin-
5 istrator is taking action under this Act, the resources avail-
6 able to the Administrator to take the action requested by the
7 petitioner, and other relevant factors, the failure of the
8 Administrator to initiate such action was not unreasonable.

9 (C) The court in issuing any final order in any action
10 brought pursuant to subparagraph (A) may award costs of
11 suit and reasonable fees for attorneys and expert witnesses
12 if the court determines that such an award is appropriate.

13 Any court, in issuing its decision in an action brought to
14 review such an order, may award costs of suit and reason-
15 able fees for attorneys if the court determines that such an
16 award is appropriate.

(5) The remedies under this section shall be in addi-
17 tion to, and not in lieu of, other remedies provided by law.

18 NATIONAL DEFENSE WAIVER

19 Sec. 22. The Administrator shall waive compliance
20 with any provision of this Act upon a request and determi-
21 nation by the President that the requested waiver is neces-
22 sary in the interest of national defense. The Administrator
23 shall maintain a written record of the basis upon which such
24 waiver was granted and make such record available for in

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1 camera examination when relevant in a judicial proceeding
2 under this Act. Upon the issuance of such a waiver, the Ad-
3 ministrator shall publish in the Federal Register a notice
4 that the waiver was granted for national defense purposes,
5 unless, upon the request of the President, the Administrator
6 determines to omit such publication because the publication
7 itself would be contrary to the interests of national defense,
^ in which event the Administrator shall submit notice thereof
^ to the Armed Services Committees of the Senate and the
House of Representatives.

EMPLOYEE PROTECTION

Sec. 23. (a) In General. – No employer may dis-
charge any employee or otherwise discriminate against any
employee with respect to the employee's compensation, terms,
conditions, or privileges of employment because the employee
(or any person acting pursuant to a request of the employee)
has –

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(1) commenced, caused to be commenced, or is
about to commence or cause to be commenced a pro-

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ceeding under this Act;

(2) testified or is about to testify in any such pro-
ceeding; or

23

(3) assisted or participated or is about to assist or

^ participate in any manner in such a proceeding or in any

25

other action to carry out the purposes of this Act.

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1 (b) Remedy, - (1) Any employee who believes that
2 the employee has been discharged or otherwise discrimi-
3 nated against by any person in violation of subsection (a)
4 of this section may, within thirty days after such alleged
5 violation occurs, file (or have any person file on the em-
6 ployee's behalf) a complaint twith the Secretary of Labor
'7 (hereinafter in this section referred to as the '^Secretary')
8 alleging such discharge or discrimination. Upon receipt of
9 such a complaint, the Secretary shall notify the person named
10 in the complaint of the filing of the complaint.

(2)(^) Upon receipt of a complaint filed under para-
12 graph (1), the Secretaiy shall conduct an investigation of the
1^ violation alleged in the complaint. Within thirty days of the
receipt of such complaint, the Secretary shall complete such
inevstigation and shall notify in writing the complainant
(and any person acting on behalf of the complainant) and

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the person alleged to have committed such violation of the

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results of the investigation conducted pursuant to this para-
graph. Within ninety days of the receipt of such complaint the
Secretary shall, unless the proceeding on the complaint is

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terminated by the Secretary on the basis of a settlement

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entered into by the Secretary and the person alleged to have
23 .

committed such violation, issue an order either providing

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the relief prescribed by subparagraph (B) or denying the
^ complaint. An order of the Secretary shall be made on the

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1 record after notice and opportunity for agency hearing. The

2 Secretary may not enter into a settlement terminating a

3 proceeding on a complaint without the participation and

4 consent of the complainant.

5 (B) If in response to a complaint filed under paragraph

6 (1) the Secretary determines that a violation of subsection

7 (a) of this section has occurred, the Secretary shall order (i)

8 the person who committed such violation to take affirmative

9 action to abate the violation, (ii) such person to reinstate

10 the complainant to the complainant^ s former position to-
11 gether with the compensation (including back pay), terms,

12 conditions, and privileges of the complainant's employment,

13 (Hi) compensatory damages, and (iv) where apprs>priate,

14 exemplary damages. If such an order is issued, the Secre-

1^ tary, at the request of the complainant, shall assess against

16 the person against whom the order is issued a sum equal to

1'^ the aggregate amount of all costs and expenses (including

18 attorney's fees) reasonably incurred, as determined by the
19 Secretary, by the complainant for, or in connection with, the
20 bringing of the complaint upon which the order was issued.

21 (c) Review. – (1) Any person adversely affected or
22 aggrieved by an order issued under subsection (b) may
23 obtain review of the order in the United States Court of
24 Appeals for the circuit in which the violation, with respect
25 to which the order- was issued, allegedly occurred. The peti-

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1 Hon for review must be filed within sixty days from the issu-
2 ance of the Secretary's order. Review shall conform to chap-
3 ter 7 of title 5 of the United States Code.

4 (2) An order of the Secretary, with respect to which
5 review could have been obtained under paragraph (1), shall
6 not be subject to judicial review in any criminal or other
7 civil proceeding.

8 (d) Enforcement.– (1) Whenever a person has
9 failed to comply with an order issued under subsection (b)
10 (2), the Secretary shall file a civil action in the United
11 States district court for the district in which the violation
12 was found to occur to enforce such order. In actions brought

13 under this subsection, the district courts shall have jurisdic-
14 tion to grant all appropriate relief, including injunctive relief
15 and compensatory and exemplary damages. Civil actions
16 brought under this subsection shall be heard and decided
expeditiously.

17 (2) Any nondiscretionary duty imposed by this section
18 is enforceable in mandamus proceeding brought under section
19 1361 of title 28, United States Code.

20 (e) Exclusion. – Subsection (a) of this section shall
21 not apply with respect to any employee who, acting with-
22 out direction from the employee's employer (or any agent of
23 the employer), deliberately causes a violation of any require-
24 ment of this Act.

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1 EMPLOYMENT EFFECTS

2 Sec. 24. (a) In General.– The Administrator shall
3 evaluate on a continuing basis the potential effects on em-
4 ployment (including reductions in employment or loss of
5 employment from threatened plant closures) of –
6 (1) the issuance of a rule or order under section 4,
7 5, or 6, or

8 (2) a requirement of section 5.

9 (b)(1) Investigations. – Any employee (or any
representative of an employee) may request the Adminis-

11 trator to make an investigation of –

12 (A) a discharge or layoff or threatened discharge or

13 layoff of the employee, or «^

14 (B) adverse or threatened adverse effects on the

15 employee's employment,

16 allegedly resulting from a rule or order under section 4, 5,

17 or 6 or a requirement of section 5. Any such request shall be

18 made in writing, shall set forth with reasonable particularity

19 the grounds for the request, and shall be signed by the

20 employee, or representative of such employee, making the

21 request.

22 (2) (A) Upon receipt of a request made in accordance

23 with paragraph (1) the Administrator shall (i) conduct the

24 investigation requested, and (ii) if requested by any inter-

25 ested person, hold public hearings on any matter involved

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1 in the investigation unless the Administrator determines that

2 there are no reasonable grounds for holding such hearings.

3 If the Administrator makes such a determination respecting

4 a request for a hearing, the Administrator shall notify in
5 writing the person requesting the hearing of the determination
6 and the reasons therefor.

7 (B) If public hearings are to be held on any matter
8 involved in an investigation conducted under this subsection –
9 (i) at least five days' notice shall be provided the
10 person making the request for the investigation and any
11 person identified in such request^

12 (ii) a transcript shall be made of the hearings, and

13 (Hi) each employee who made or for whom was
made a request for such hearings and the employer of
such employee shall be required to present information
respecting the applicable matter referred to in paragraph
(1)(A) or (1)(B) together with the basis for such
information.

(3) Upon completion of an investigation under para-
graph (2), the Administrator shall make findings of fact,
shall make such recommendations as the Administrator deems

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appropriate, and shall make available to the public such find-

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ings and recommendations.

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(4) In connection with any investigation or public hear-
ing conducted under this subsection, the Administrator may

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1 issue subpoenas for the attendance and testimony of witnesses
2 and the production of relevant papers, books, and documents,
3 and the Administrator may administer oaths. Witnesses
4 summoned shall be paid the same fees and mileage that are
5 paid witnesses in the courts of the United States. In case
6 of contumacy or refusal to obey a subpoena served upon any
7 person under this paragraph, the United States district
8 court for any district in which such person is found or
9 resides or transacts business, upon application by the United
10 States and after notice to such person, shall have jurisdic-
11 tion to issue an order requiring such person to appear and
12 give testimony before the Administrator to appear and pro-
13 duce papers, books, and documents before the Administrator,
14 or both, and any failure to obey such order of the court may
15 be punished by such court as a contempt thereof.

16 STUDIES

17 Sec. 25. (a) Indemnification Study. - The Admin-
18 istrator shall conduct a study of all Federal laws adminis-
19 tered by the Administrator for the purpose of determining
20 whether and under what conditions, if any, indemnification
21 should be accorded any person as a result of any action taken
22 by the Administrator under any such law. The study shall -
23 (1) include an estimate of the probable cost of any
24 indemnification programs which may be recommended;
25 (2) include an examination of all viable means of

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1 financing the cost of any recommended indemnification;

2 and

3 (3) be completed and submitted to Congress not

4 less than two years from the effective date of this Act.

5 The General Accounting Office shall review the adequacy of

6 the study submitted to Congress pursuant to paragraph (3)

7 and shall report the results of its review to the Congress

8 within six months of the date such study is submitted to

9 Congress.

1^ (b) Classification, Storage, and Retrieval

1^ Study, - The Council on Environmental Qv/dity, in consul-

^2 tation with the Administrator, the Secretary of Health, Edu-

cation, and Welfare, the Secretary of Commerce, and the

■^^ heads of other appropriate Federal departments or agen-

cies, shall coordinate a study of the feasibility of establishing

(1) a standard classification system for chemical substances

■^^ and related substances, and (2) a standard means for

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storing and for obtaining rapid access to information re-
specting such substances. A report on such study shall be
completed and submitted to Congress not later than eighteen
months after the effective date of this Act.

administration of act

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Sec, 26, (a) Cooperation of Federal Agencies,-
^ Upon request by the Administrator, each Federal department and agency is authorized -

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1 (1) to make its services, personnel, and facilities
2 available (with or without reimbursement) to the Administrator to assist the Administrator in the administration of this Act; and

5 (2) to furnish to the Administrator such information,

6 data, estimates, and statistics, and to allow the Administrator access to all information in its possession
'7 as the Administrator may reasonably determine to be
^ necessary for the administration of this Act.

1^ (b) Fees. - The Administrator may, by rule, require
^1 the payment of a reasonable fee from any person required to submit data under section 4 or 5 of this Act to defray the cost of administering this Act. Such rules shall not provide for any fee in excess of \$2,500. In setting such a fee, the Administrator shall take into account the ability to pay of the person required to submit the data and the cost to the Administrator of reviewing such data. Such rules may provide for sharing such a fee in any case in which the expenses of testing are shared under section 4 or 5 of this Act.

2^ (c) Action With Respect to Categories.- (1)
Any action authorized or required to be taken by the Administrator under any provision of this Act with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the

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1 Administrator takes action under a provision of this Act with
2 respect to a category of chemical substances or mixtures, any
3 reference in this Act to a chemical substance or mixture
4 (insofar as it relates to such action) shall be deemed to be
5 a reference to each chemical substance or mixture in such
6 category,

7 (2) For purposes of paragraph (1) :

8 (A) The term "category of chemical substances"
9 means a group of chemical substances the members of
10 which are similar in molecular structure, in physical,
11 chemical, or biological properties, in use, or in mode of
12 entrance into the human body or into the environment,
13 or the members of which are in some other way suitable
14 for classification as such for purposes of this Act, except
15 that such term does not mean a group of chemical sub-
16 stances which are grouped together solely on the basis
17 of their being new chemical substances.

18 (B) The term "category of mixtures" means a
19 group of mixtures the members of which are similar in
20 molecular structure, in physical, chemical, or biological

21 properties, in use, or in mode of entrance into the human
22 body or into the environment, or the members of which
23 are in some other way suitable for classification as such
24 for purposes of this Act.

25 (d) Assistance Office.— The Administrator shall

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1 establish in the Environmental Protection Agency an identi-
2 fiable office to provide technical and other nonfinancial assist-
3 ance to manufacturers and processors of chemical substances
4 and mixtures respecting the requirements of this Act appli-
5 cable to such manufacturers and processors, the policy of the
6 Agency respecting the application of such requirements to
7 such manufacturers and processors, and the means and
8 methods by which such manufacturers and processors may
9 comply with such requirements.

10 DEVELOPMENT AND EVALUATION OF TEST METHODS

11 Sec. 27. (a) The Secretary of Health, Education, and
12 Welfare, in consultation with the Administrator and acting
13 through the Assistant Secretary for Health, may conduct, and
make grants to public and nonprofit private entities and enter
into contracts with public and private entities for, projects for
-in

the development and evaluation of inexpensive and efficient methods (1) for determining and evaluating the health and environmental effects of chemical substances and mixtures, and their toxicity, persistence, and other characteristics which affect health and the environment, and (2) which may be used for the development of test data to meet the requirements of rules promulgated under section 4. The Administrator shall consider such methods in prescribing under section 4 and-

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ards for the development of test data.

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1 (b) No grant may be made or contract entered into
2 under subsection (a) unless an application therefor has
3 been submitted to and approved by the Secretary. Such an
4 application shall be submitted in such form and manner and
5 contain such information as the Secretary may require. The
6 Secretary may apply such conditions to grants and contracts
under subsection (a) as the Secretary determines are neces-
8 sary to carry out the purposes of such subsection. Contracts
9 may be entered into under such subsection without regard to
10 sections 3648 and 3709 of the Revised Statutes (31 U.S.C.
11 529; 41 U.S.C. 5),

1^ (c)(1) The Secretary shall prepare and submit to the

1^ President and the Congress on or before January 1 of each
1- year a report of the number of grants made and contracts

entered into under this section and the results of such grants and contracts.

(2) The Secretary shall periodically publish in the Federal Register reports describing the progress and results

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of any contract

AUTHORIZATION FOR APPROPRIATIONS

of any contract entered into or grant made under this section.

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Sec. 28. There are authorized to be appropriated to

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the Administrator for purposes of carrying out this Act (other than section 27 thereof) \$11,100,000 for the fiscal year ending September 30, 1978, \$10,100,000 for the fiscal year ending September 30, 1979, and \$11,100,000 for the

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1 fiscal year ending September 30 1980. No part of the funds

2 appropriated under this section may be used to construct any

3 research laboratories.

4 ANNUAL REPORT

5 Sec. 29. The Administrator shall prepare and submit to
6 the President and the Congress on or before January 1,
7 1979, and on or before January 1 of each succeeding year
8 a comprehensive report on the administration of this Act
9 during the preceding fiscal year. Such report shall include -
10 (1) a list of the testing required under section 4
11 during the year for which the report is made and an
12 estimate of the costs incurred during such year by the
1^ persons required to perform such tests;

(2) the number of notices received during such year
under section 5, the number of such notices received dur-
■^^ ing such year under such section for chemical substances
subject to a section 4 rule, and a summary of any action
■^^ taken during such year under section 5(g);
1^ (3) a list of rules issued during such year under
2^ section 6;
21 (4) a list,- with a brief statement of the issues, of
completed or pending judicial actions under this Act
no
during such year;
2^ (5) a summary of major problems encountered in
the administration of this Act; and

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1 (6) such recommendations for additional legislation

2 as the Administrator deems necessary to carry out the

3 purposes of this Act.

4 EFFECTIVE DATE

5 Sec. 30. This Act shall take effect October 1, 1977.

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, TOXIC SUBSTANCES CONTROL ACT

REPORT

BY THE

COMMITTEE ON INTERSTATE AND

FOREIGN COMMERCE

together with

SUPPLEMENTAL AND MINORITY VIEWS

(Including cost estimate of the Congressional Budget Office)

[To accompany H.R. 14032]

July 14, 1976.— Committed to the Committee of the Whole House
on the State of the Union and ordered to^be printed

U.S. GOVERNMENT PRINTING OFFICE
74-031 WASHINGTON : 1976

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(in)

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94th Congress) HOUSE OF REPRESENTATIVES j Report
2d Session f (No. 94-1341

TOXIC SUBSTANCES CONTROL ACT

July 14, 1976. - Ordered to be printed

Mr. Staggers, from the Committee on Interstate and Foreign
Commerce, submitted the following

REPORT

together with
SUPPLEMENTAL AND MINORITY VIEWS
(Including cost estimate of the Congressional Budget Office)
[To accompany H.R. 140² 1

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 14032) to regulate commerce and protect health and the environment by requiring testing and necessary restrictions on certain chemical substances and mixtures, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment strikes out all after the enacting clause of the bill and inserts a new text which appears in italic type in the reported bill.

Purpose of the Legislation

The Committee bill takes a major step forward in providing urgently needed authority to protect health and the environment from dangerous chemicals. It accomplishes this in a number of ways. For example, through its testing and premarket notification provisions, the bill provides for the evaluation of the hazard-causing potential of new chemicals before commercial production begins. Thus, in addition to the authority to take action against a chemically-caused harm after its occurrence, there will be authority to prevent such harm from occurring. Further, manufacturers and processors of potentially hazardous chemicals already on the market may be required to test them to determine their effects on health and the environment, and action can be taken against chemicals discovered to be unreasonably hazardous. In addi-

tion, the bill provides for the collection of information regarding commercially produced chemicals so that the total exposure to a chemi-

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cal and its total effect on health and the environment can be monitored and evaluated.

Brief Summary

Briefly, the bill will-

- Require manufacturers and processors of potentially harmful chemical substances and mixtures to test the substances or mixtures, as required by rules issued by the Administrator of the Environmental Protection Agency, so that their effect on health and the environment may be evaluated.
- Require manufacturers of new chemical substances and manufacturers and processors of existing chemical substances for significant new uses to notify the Administrator ninety days in advance of commercial production.
- Authorize delays or restrictions on the manufacture of a new chemical substance if there is inadequate information to evaluate the health or environmental effects of the substance and if in the absence of such information, the substance may cause or significantly contribute to an unreasonable risk to health or the environment.
- Authorize the Administrator to adopt rules to prohibit the manufacture, processing, or distribution of a chemical substance or mixture, to require labeling, or to regulate the manner of disposal of a chemical substance or mixture for which there is a reasonable basis to conclude that it causes or significantly 'contributes to an unreasonable risk to health or environment.
- Authorize the Administrator to obtain injunctive relief from a United States district court to protect the public and the environment from an imminently hazardous chemical substance or

mixture.

– Authorize the Administrator to require manufacturers and processors to submit reports and maintain records respecting their commercially produced chemical substances and mixtures, to maintain records respecting adverse health or environmental effects of such substances and mixtures, and to provide available health and safety data on them.

– Require manufacturers and processors of chemical substances and mixtures to immediately notify the Administrator of information indicating that one of their substances or mixtures causes or contributes to a substantial risk to health or environment.

– Permit administrative inspections to enforce the bill and authorize court actions for seizures of chemical substances and mixtures which have been manufactured or distributed in violation of the requirements of the bill or of rules and orders promulgated under it.

– Permit citizens to bring suits to obtain compliance with the bill.'

– Permit Federal district courts to order the Administrator to initiate rulemaking proceedings in response to citizen petitions.

– Set up procedural mechanisms to insure that all interested persons have an opportunity to participate in the agency rulemaking proceedings.

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– Provide protection for employees who cooperate in the enforcement of the bill.

– Provide for evaluation on a continuing basis of the effects on employment of actions taken under the bill.

Basis for the Legislation

Chemicals have become a pervasive and enduring part of our environment. They are in our air, our water, and our soil. They are used

in our manufacturing processes, and they are essential components for consumer and industrial goods. Production and use of chemicals have surged in the recent past. For example, in the past ten years, the production of synthetic organic chemicals has expanded by 233 percent,[^] and over 9,000 synthetic chemical compounds are each now in commercial use annually in amounts in excess of 1,000 pounds each.- In 1973, production of the top 50 chemicals alone totaled 410 billion pounds.[^] Society reaps enormous benefits from chemicals. However, it is generally accepted that as the number of chemicals in commercial use is greatly increased, the risk of producing chemicals that can cause grave and irreversible environmental damage or health problems is also increased.

This vast volume of chemicals have, for the most part, been released into the environment with little or no knowledge of their long-term health or environmental effects. As a result, chemicals currently in commercial and household use are now being found to cause or contribute to health or environmental hazards unknown at the time commercial use of the chemical began. For example, vinyl chloride was the 23rd most produced chemical when it was discovered to cause cancer, and the chemical has now been implicated as causing birth defects as well.* Asbestos, widely used in items ranging from talcum powder to brake linings to wallboard, is now known to cause cancer and other debilitating illnesses. However, such effects were not discovered until hundreds of workers had developed a rare form of lung cancer as a result of exposure to the substance.[^] Polychlorinated biphenyls (PCBs) had been used for forty years and approximately 390,000 tons had been released into the environment before they were recognized as an enduring environmental poison.*[^] Unfortunately, such recognition came too late to prevent contamination of such major water systems as the Great Lakes and the Hudson River.

As the preceding examples indicate, it is often many years after exposure to a harmful chemical before the effects of its harm become visible. By that time it may be too late to reverse those effects. As indicated, hundreds of people may have been exposed to a carcinogen or an entire river system may have been polluted.

The experience with chemicals over the past few years has contributed to a growing realization that many of the major health prob-

[^] Sixth Annual Report, Council on Environmental Policy, p. 23 (1975).
-Toxic Substances, Council on Environmental Quality, p. 3 (1975).

[^]Activities of Federal Agencies Concerning Selected High Volume Chemicals, U.S. Environmental Protection Agency. EPA-560-4-75-001, n. ii (1975K)

* Infante, Peter F.. "Oncofrenic and Mutagenic Risks in Communities with Polj'vinyl

Chloride Product Paciliries," 271 New York Academy of Science Annals, pp. 49-57 (1976).
Selicoff. I. J.. "Asbestos Criteria Document Highlights," American Society of Safety
■ ^'"/."^er.s Journal, p. 26 (March, 1974),

, " "Effects of Chronic Exposure to Low-Level Pollutants in the Environment," Congressional Research Service, p. 2 (1975).

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lems are caused by environmental factors. For example, approximately 60 to 90 per cent of all cancer is believed to be environmentally caused.^ The National Foundation for the March of Dimes estimates that about 20% of all birth defects as caused by environmental influences, including chemicals, on the unborn child, and another 60% of birth defects are believed to be due to a combination of environmental and hereditary factors.^

Because diseases caused by environmental factors such as chemicals are often not susceptible to direct medical cure, there is an urgent need to prevent such chemically caused harm. The Department of Health, Education, and Welfare's Forward Health Plan stresses such prevention, stating :

In recent years, it has become clear that only by preventing disease from occurring, rather than treating it late, can we hope to achieve any major improvement in the nation's health . . . [Heart disease, cancer, and stroke] are caused by factors (e.g., the environment and individual behavior) that are not susceptible to direct medical solution.

... It is therefore, a basic premise of the prevention strategy that much greater attention and resources must be directed at preventing the underlying causes of disease rather than at the disease itself - at controlling cigarette smoking, alcohol abuse, and exposures to toxic chemicals in the environment than at the diseases which they cause.^

Similarly, the environmental harm caused by chemicals, like health effects, may be irreversible, and prevention of such harm is also urgently needed.

Toxic Substances^ a 1971 report by the Council on Environmental

Quality, reviewed the problems presented by toxic chemicals and concluded that present authorities for protecting against hazardous chemicals are fragmented and inadequate. According to the report, authority is needed to require testing of chemicals to determine their health and environmental effects, to impose use and distribution restrictions on chemicals where necessary to protect the public health and environment, and to collect information on chemicals and establish a system for classifying and using such information.

The recommendations of the report provided the original basis for the toxic substances control legislation. However, subsequent events have dramatically illustrated the urgent need for the legislation. For example, a major epidemiological study by the National Cancer Institute indicates that industrial chemical use and activity have produced

1 "Sixth Annual Report," Council on Environmental Quality, p. 17 (1975). Chemicals are not, of course, the only environmental factors linked to cancer. Others include the large component of lung cancer attributable to cigarette smoking and natural agents such as solar radiation.

The costs to society from cancer are tremendous. The American Cancer Society estimates that 25 percent of the 213 million people now living in the United States will ultimately develop some form of cancer. "Cancer Facts and Figures." American Cancer Society, p. 3 (1975). Cancer killed an estimated 364,000 Americans in 1975. Ibid.

The economic costs of cancer are staggering. An estimated \$3 billion is spent annually for hospital care, physician fees, nurses, drugs and other treatment. If the direct and indirect costs (e.g., loss of productivity, earning power) are added, the annual costs of cancer lump to \$15 billion. Id. at 31.

2 "Effects of Chronic Exposure to Low-Level Pollutants In the Environment, p. 135.

» "Forward Plan for Health." fiscal years 1977-81, U.S. Department of Health, Education, and Welfare, Public Health Service, pp. 12, 13, 15, 16, 17 (June 1975).

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striking geographic concentrations of cancer deaths.[^] An unusually high rate of lung cancer among workers in a plant where bis chloro-

methyl ether (BCME) was produced as a by-product of a manufacturing process has led to the conclusion that BCME is a highly potent carcinogen. BCME may form spontaneously in ordinary humid air whenever formaldehyde and hydrochloric acid are present together. These two chemicals are widely used in processes such as the treatment of permanent press fabrics, in the manufacture of water repellants, and in the manufacture of ion exchange resins and dispersing agents. Further, tris 2, 3-dibromopropyl phosphate, a fire retardant widely used in such items as children's pajamas, has been shown to have mutagenic effects in microbial systems. And there are, unfortunately, numerous other examples of harm resulting from the industrial uses of chemicals.

Because of the lack of testing by manufacturers and processors of chemicals to determine their health and environmental effects, the general population and the environment now serve as the laboratory for discovering adverse health and environmental effects. Aside from the glaring inequities in relying on human experience to indicate when a chemical is harmful, such a method is also a grossly inefficient way to identify problems. For example, vinyl chloride and asbestos were relatively easy hazards to identify because exposure to these agents could be correlated with incidences of otherwise rare cancers in a uniquely defined group of workers. Other kinds of hazards, and other substances, cannot be expected to present such easily traceable cause and effect relationships. As a result exposure to an extremely harmful chemical may continue unabated because the harm it causes will never be linked to the chemical.

Fortunately our ability to screen and test substances for adverse effects and our capabilities for monitoring and predicting the health and environmental effects of chemicals are sufficiently well-developed that it is not necessary to choose between the alternatives of using the population as guinea pigs or doing without the benefits provided by the increasing use and development of chemical products. The validity of applying animal test results to man is now firmly based upon empirical evidence and thus such results provide an invaluable tool for predicting human health effects. Further, major methodological advances are occurring with respect to improving testing and monitoring methods for assessing the long-term effects of a chemical. For example, methods for detecting low levels of carcinogens in the environment have increased significantly in both accuracy and reliability, and it is now possible to detect concentrations of polynuclear compounds at 1 part of an individual compound per billion as opposed to the 1959 sensitivity standard of 100 parts per billion. Analytical methods have improved as well. Illustrative is the salmonella test developed by Dr. Bruce Ames of the University of California, Berkeley, which is now available for screening for cancer-causing properties of chemicals and which has considerably reduced both the costs and time

required for such screening. Although testing and monitoring may

^ Hearings on H.R. 7229. H.R. 7548. and H.R. 7664 before The Subcommittee on Consumer Protection and Finance of the House Committee on Interstate and Foreign Commerce, 94th Cong., 1st Sess., p. 132-138 (1975).

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not be able to provide certainty as to the long-term consequences resulting from exposure to a chemical, the restrictions from such testing and monitoring can provide a reasonable basis for regulatory action to protect against potential long-term adverse effects.

Present authorities for protecting against and regulating hazardous chemicals are fragmented and inadequate. Although there are a number of Federal laws which now provide some authority for regulation (e.g., the Clean Air Act, the Federal Water Pollution Control Act, the Occupational Safety and Health Act of 1970, and the Consumer Product Safety Act) conspicuous gaps exist in the protections provided by such laws. Most significant among the deficiencies are the following :

(1) In general, such laws provide regulatory authority which is not set in motion until after human or environmental exposure to a harmful chemical has occurred.

(2) The authorities provided to reduce or eliminate the harmful exposure to a chemical may not be adequate or may be cumbersome or inefficient.

(3) No authority exists for collection of data to determine the totality of human and environmental exposure to chemicals.

An example of the deficiency described in paragraph (1) is the fact that there is presently no authority to require manufacturers of potentially dangerous new chemicals to test the chemical to determine its health and environmental effects before marketing. Thus, although there is some authority to remove harmful chemicals from, the workplace, the home, etc., there is no authority which provides a means of assessing the safety of a chemical before exposure occurs. In addition, since present laws require regulatory agencies to bear the cost of testing to see if a chemical is safe, regulatory action often does not occur until adverse effects of a chemical become evident

in the population or in the environment.

The inadequacies in current authorities to deal with the recognized harm presented by poly chlorinated biphenyls (PCBs) illustrates the deficiencies in present law to deal with known harmful chemicals. Under the Federal Water Pollution Control Act, the Administrator of the Environmental Protection Agency has authority to control the discharge of PCBs into the waters. However, there is no means for regulating other avenues through which the environment is exposed to PCBs. For example, an estimated three-fourths of the amount of discarded PCB's have been disposed of in landfills. Under existing law there is no authority to deal with such disposal and even though water emissions may be restricted, environmental exposure through seepage from landfills will continue to occur.

Intelligent standards for regulating exposures to a chemical in the workplace, the home or elsewhere in the environment cannot be set unless the full extent of human or environmental exposure is considered. The importance of considering the cumulative impact of all sources of exposure and the synergistic effects resulting from exposure to a number of chemicals in regulatins: hazardous chemicals was pointed out by the National Academy of Sciences - National Academy of Engineers study which stated :

The concept of total body burden should be the significant indicator of exposure, rather than burden acquired in one or

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another part of the environment or from one or another toxic material. People who work in a factory in which dangerous substances are handled in high concentration may live in an adjacent area in which the same or other substances are dispersed, thus increasing overall exposure. More than one organ may be attacked because the offending substance is transported by two or more media. Synergistic effects among two or more substances, by which the combined effect is more than the sum of the separate effects should be considered.^

Yet a comprehensive data system indicating the totality of human or environmental exposure does not exist. As a result, present regula-

tions controlling workplace exposure, exposure in the home or elsewhere to a hazardous chemical may often be based on measurements indicating only one source of exposure, thereby resulting in less than full protection from the hazard.

In summary, the country faces serious risks of harm to the health of its people and to its environment from the substantial use which is made of chemicals, and Federal law is clearly inadequate to deal with such risks. A major element in our efforts to improve the nation's health and environment must be the enactment of protective legislation such as H.R. 14032. The overriding purpose of the bill is to provide protection of health and the environment through authorities which are designed to prevent harm.

Committee Consideration

A 1971 report by the Council on Environmental Quality highlighted the growing need for a comprehensive program of toxic substances control. Based upon the Council's recommendations, the Environmental Protection Agency submitted legislative proposals on behalf of the Administration to the 92d Congress. The Committee's Subcommittee on Commerce and Finance held hearings on the Administration bill, and a Senate-passed bill which made substantial amendments to the Administration bill. After executive session, the Subcommittee reported a clean bill which represented an accommodation between the Administration and Senate-passed bills. This bill with certain further amendments was reported by the full Committee and passed the House by a record vote of 240 to 61. Time did not permit a conference with the Senate to work out differences before the adjournment of the 92d Congress.

In the 93d Congress, the Subcommittee on Commerce and Finance held hearings on a new bill submitted by the Administration (H. K. 5087) and a bill introduced by the Subcommittee chairman, Mr. Moss, and others (H.R. 5356) which substantially followed the bill passed by the House in the 92d Congress. The Subcommittee reported H.R. 5356, with amendments. The bill with certain further amendments was reported by the full Committee and passed the House by a record vote of 324 to 73. However, the conference with the Senate was unable to work out differences in the bills in the time remaining.

ri?^^"' ^/'it^rlalp and Environment : A Report to the National Commission on Material
ancy , ^ational Academy of Sciences - National Academy of Engineers, p. 12 (March

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In the 94th Congress, the Subcommittee on Consumer Protection and Finance held hearings on June 16, July 9, 10, and 11, 1975, which focused on the bills H.R. 7229, H.R. 7548 and H.R. 7664, introduced by Mr. Eckhardt, Mr. Brodhead, and Mr. McCollister, respectively. After the hearings, Mr. Eckhardt introduced a new bill, H.R. 10318, which reflected comments received during the hearings. The Subcommittee reported H.R. 10318 on December 3, 1975. The full Committee began consideration of the legislation on May 26, 1976. The Committee agreed to substitute H.R. 14032, introduced by Mr. Eckhardt and Mr. Broyhill, for H.R. 10318. After three days of mark-up, this bill with certain amendments was reported by the full Committee by voice vote.

Cost of Legislation

In accordance with clause 7(a) of rule XIX of the Rules of the House of Representatives, the committee estimates that the following costs will be incurred in carrying out the functions under H.R. 14032 :

Fiscal year : Millions

1978 . \$11.1

1979 ,, 10.1

1980 11.1

The Environmental Protection Agency, which will administer the bill, has transmitted its projected resource requirements for purposes of the authorization of appropriations contained in H.R. 14032 :

Fiscal year : Millions

1978 \$12,625

1979 16.2

1980 17.35

1981 17.35

1982 17.35

Section-By- Section Analysis

section 1, short title

Section 1 of the bill provides that the bill when enacted may be cited as the "Toxic Substances Control Act".

SECTION 2, FINDINGS, POLICY, AND INTENT

Subsection (a) of section 2 contains Congressional findings that (1) humans and the environment are being exposed to a large number of chemical substances and mixtures each year; (2) some of these chemical substances and mixtures may cause or significantly contribute to an unreasonable risk to health or the environment; and (3) the effective regulation of such chemical substances and mixtures in interstate commerce necessitates the regulation of such substances and mixtures in intrastate commerce as well.

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The Committee has extended the reach of the regulatory authority of the bill to all chemical substances and mixtures whether in interstate commerce or not since the size and scope of the chemical industry makes it impossible to distinguish between those in interstate commerce and those which are not. Further, commerce in those which are arguably only in intrastate commerce may affect commerce in those which are in interstate commerce, and consequently there cannot be effective regulation of the latter without regulation of the former. Also regulation of only those in interstate commerce without regulation of the others could depress commerce and discriminate against those in interstate commerce and adversely burden, obstruct, and affect such commerce.

Subsection (b) provides that it is the policy of the United States that (1) hazardous and potentially hazardous chemical substances and mixtures should be adequately tested with respect to their effect on health and the environment; (2) such testing should be the responsibility of those who manufacture or process the chemical substances or mixtures ;

(3) adequate authority should exist to regulate chemical substances and mixtures which may cause or significantly contribute to an unreasonable risk to health or the environment, and to take action with respect to chemical substances and mixtures which are imminently hazardous; and (4) these authorities should be exercised so as not to unduly impede or create unnecessary economic barriers to technological innovation while assuring that such chemical substances and mixtures do not cause or significantly contribute to an unreasonable risk to health or the environment.

Subsection (c) of section 2 provides that it is the intent of Congress that the Administrator of the Environmental Protection Agency shall carry out the bill in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action proposed to be taken under the bill.

The Committee intends subsection (c) for the guidance of the Administrator in fulfilling the purposes of the bill. However, this statement of intent by the Committee as to the manner in which the Administrator is to exercise the authorities and fulfill the Administrator's responsibilities under the bill is not to be construed as a direction to the Administrator to make any statement of findings in addition to those required by specific provisions of the bill or to involve the Administrator in any cost-benefit justifications.

SECTION 3, DEFINITIONS

Section 3 defines the terms used in the bill. While most of the definitions are self-explanatory, a few are of particular importance and merit discussion.

The term "Administrator" means the Administrator of the Environmental Protection Agency.

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The bill grants the Administrator certain regulatory authority over "chemical substances" and "mixtures" of chemical substances. The term "chemical substance" is defined in this section to mean any organic or inorganic substance of a particular molecular identity, including a combination of such substances occurring in whole or in part as a result of a chemical reaction or in nature. The term also includes any

element or uncombined radical.

The Committee recognizes that basically everything in our environment is composed of chemical substances and therefore the definition of "chemical substances" is necessarily somewhat broad. However, because of the breadth of the definition, the Committee has carefully defined the authorities of the Administrator respecting such substances.

Certain categories are specifically exempted from the term "chemical substance" and thus are exempted from coverage under the bill. Pesticides (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; tobacco or tobacco products; source material, special nuclear material, and byproduct material (as defined in the Atomic Energy Act of 1954 and regulations issued under that Act) ; and articles which if sold would be subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (i.e., pistols, firearms, revolvers, shells and cartridges) .

Although the language of the bill is clear on its face as to the exemption for pistols, revolvers, firearms, shells, and cartridges, the Committee wishes to emphasize that it does not intend that the legislation be used as a vehicle for gun control. Consequently the Administrator has no authority to regulate ammunition as an unreasonable risk because it injures people when fired from a gun. However, the Committee does not exclude from regulation under the bill chemical components of ammunition which could be hazardous because of their chemical properties.

Also excluded from the definition of the term chemical substance and consequently from coverage under the bill are any food, food additive, drug, cosmetic, or device when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. As used in this exclusion, the terms "food", "food additive", "drug", "cosmetic", and "device" have the same meaning as is given them by section 201 of the Federal Food, Drug, and Cosmetic Act. The intent of the Committee in excluding these items is to exclude from coverage under the bill items which may be regulated under the Federal Food, Drug, and Cosmetic Act. By adopting the definitions given the items by that Act the Committee has made the exclusion of these items from the bill coextensive with the authority to regulate them under the Federal Food, Drug, and Cosmetic Act. Thus, if an item cannot be regulated as a food, food additive, drug, cosmetic, or deface under that Act because it does not come within the definitions in that Act, it is not the intent of the Committee to exclude it from coverage under the bill.

An amendment was offered during Committee consideration of the bill to add a provision which would add to the exclusion described above an exclusion of "any substance produced for research and devel^

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opment purposes and intended only for use in or on any such food, drug, cosmetic, or device". It was stated that the intent of the amendment was to make it clear that catalysts, intermediates, and precursors which are intended for use in the production of drugs in their final dosage forms or substances which are used in research and development of drugs and which do not necessarily become ingredients of the drugs in their final dosage forms would not be subject to regulation under the bill. The amendment was withdrawn with the understanding that the definition of the term "drug" in the Federal Food, Drug, and Cosmetic Act included the items described in the amendment, but that to the extent that any such item is not included in that definition and thus not subject to regulation under that Act, such item should be subject to regulation under the bill.

The definition of "drug" in the Federal Food, Drug, and Cosmetic Act includes "articles intended for use as a component" of substances included in the definition of "drug". As used in that Act, the term "component" does not mean only an item which may be identified as an ingredient of a drug in its final dosage form. Component includes any item used in the production of the drug. Thus, precursors, intermediates, and catalysts intended for use in the production of drugs in their final dosage form are "drugs" within the meaning of the Federal Food, Drug, and Cosmetic Act.

Further, the Federal Food, Drug, and Cosmetic Act clearly covers drugs during the "investigation" or research stage. Consequently, the definition of "drug" in that Act includes chemical substances used for drug research and development. The same is true of the definitions of food, food additives, and cosmetics.

Likewise, the definition of pesticide in the Federal Insecticide, Fungicide, and Rodenticide Act defines "pesticide" to include "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant." Thus the definition in that Act would include chemical

substances on which research is being performed with the intent that the substance be used for any of the purposes described in the definition of the term "pesticide". Such substances would be subject to regulation under that Act and, by virtue of the exemption for pesticides, are exempted from regulation under this bill.

The exclusion from the definition for any pesticide, food, food additive, drug, cosmetic, or device is conditioned upon its being manufactured or distributed in commerce for use as a pesticide, food, food additive, drug, cosmetic, or device. Such a condition is necessary because some chemical substances and mixtures which can be used as pesticides, foods, food additives, drugs, or cosmetics can also be used for other purposes. For example, aluminum subacetate is used as a burn treatment, but it is also used as a mordant in dyeing and for flame-proofing. Cuprous oxide is used as a pesticide, but it also is used as a flame-retardant.

Aluminum subacetate when used in dyeing or for flame-proofing could not be regulated under the Federal Food, Drug, and Cosmetic Act. nor could cuprous oxide when used as a flame-retardant be regulated under the Federal Insecticide, Fungicide, and Rodenticide Act.

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The Committee bill assures that the exemption will extend only insofar as the exempted substance or mixture is actually manufactured, processed, or distributed in commerce for use as a pesticide, food, food additive, drug, cosmetic, or device and thus is subject to regulation under the Federal Food, Drug, and Cosmetic Act or the Federal Insecticide, Fungicide, and Rodenticide Act.

Although the term chemical substance excludes mixtures of chemical substances, mixtures are not excluded from regulation under the bill. However, mixtures are regulated in a different manner than chemical substances – they are not subject to the manufacturing and processing notices for new chemical substances under section 5 and special findings are required before testing of them may be required or before they can be subject to rules under section 8(a) requiring recordkeeping and reporting for them. Consequently, it was necessary to establish chemical substances and mixtures as two separate identifiable terms.

The term "mixture" is defined to mean any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction. Certain combinations of chemical substances which do occur, in whole or in part, as a result of a chemical reaction are included within the term mixture and thereby excluded from the definition of chemical substance. If each of the chemical substances comprising the combination is not a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the substances comprising the combination were combined, then the combination will be a mixture rather than a chemical substance.

The inclusion of such reaction-produced combinations within the definition of mixture is necessary to prevent disparate treatment of identical combinations simply because of the number of steps used in the production of the combination. For example, a soap product may be manufactured by combining coconut oil soap, sodium tri-poly phosphate, sodium sulphate, and sodium bicarbonate. These four ingredients do not react chemically. Thus if a manufacturer combined the four ingredients, the resulting combination would clearly be considered a mixture. However, if another manufacturer simultaneously mixed two substances which react to form coconut oil soap, the first ingredient, together with the latter three ingredients, the resulting combination would have been produced in part by a chemical reaction. The two end products would be identical, and they should be subject to identical treatment under the bill. The Committee definition assures that they will be.

The term "environment" is broadly defined to include water, air, and land and the interrelationship which exists among and between water, air, land and all living things. Thus by providing for the protection of the environment, the bill includes protection for all living things within the environment.

The term "manufacture" means to import, produce, or manufacture. As a result, imported chemical substances and mixtures will be subject to regulation in the same manner as domestically produced chemical substances and mixtures are. In addition, importers of chemical

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substances and mixtures will have the same responsibilities and obligations as domestic manufacturers.

The bill does not attempt in the definition of the term "manufacture" to define exactly what activities are to be included in that term because the activities embraced by the term are generally well understood. However, it has come to the attention of the Committee that there are activities incidental to the end use or storage of certain substances or mixtures which under a literal reading of the definition would make a person engaging in them a manufacturer and thus subject to the provisions of the bill applying to manufacturers.

For example, there are certain substances or mixtures, such as adhesives, paints, inks, and drying oils, which during storage or upon end use, when exposed to environmental factors such as air, moisture, or sunlight, undergo a chemical reaction which produces a different substance or mixture. Similarly, plastic resins subjected to heat for purposes of molding undergo a thermal setting which produces a different substance. In such cases, the chemical reaction is merely incidental to the end use or storage of the original substance or mixture. The substance or mixture produced is not used as a chemical substance or mixture, per se. It is not the Committee's intent that a person, such as a painter, who is engaged in the end use or storage activity in which such a chemical reaction occurs is to be considered a manufacturer because of the reaction. Thus, such a person would not be subject to the notification requirements of section 5 even though a chemical substance resulting from the reaction is not included on the inventory compiled under section 8(b). Substances which occur incidentally to the storage or end use of such combinations should be considered as byproducts, and the responsibility for meeting the testing, notification, and other requirements with which manufacturers must comply would fall upon the manufacturer of the substance or mixture from which the byproduct is produced.

For example, there are certain combinations of substances, such as adhesives, paints, inks, and drying oils, which during storage or upon end use, when exposed to environmental factors such as air, moisture, or sunlight, undergo a chemical reaction which technically produces a different chemical substance. However, the chemical reaction is merely incidental to the storage or end use of the substances. The substance produced is not to be used as a chemical substance, per se.

It is the Committee's intent that a person who is engaged in a use or storage activity in which such a chemical reaction occurs is not to be subject to the notification requirements of section 5 even though the chemical substance resulting from such activity is not included on the inventory compiled under section 8(b). Substances which occur incidentally to the storage or use of such combinations

should be considered as byproducts and the responsibility for meeting the requirements of the bill respecting such byproducts is to be met by the manufacturer of the substance from which the byproduct is produced.

I During the hearings, a number of witnesses recommended that the [bill include a definition of unreasonable risk. Because the determination of unreasonable risk involves a consideration of probability, severity, and similar factors which cannot be defined in precise terms

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and is not a factual determination but rather requires the exercise of judgment on the part of the person making it, the Committee did not attempt a definition of such risk. In general, a determination that a risk associated with a chemical substance or mixture is unreasonable involves balancing the probability that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture, taking into account the availability of substitutes for the substance or mixture which do not require regulation, and other adverse effects which such proposed action may have on society.

The balancing process described above does not require a formal benefit-cost analysis under which a monetary value is assigned to the risks associated with a substance and to the cost to society of proposed regulatory action on the availability of such benefits. Because a monetary value often cannot be assigned to a benefit or cost, such an analysis would not be very useful.

As noted above, the Committee recognizes that risk is measured not solely by the probability of harm, but instead includes elements both of probability of harm and severity of harm and those elements may vary in relation to each other. Thus, the Administrator may properly find that health or the environment are exposed to an unreasonable risk by a lesser probability of a greater harm as well as by a greater probability of a lesser harm.

Although the standard for defining the regulatory authority of the Administrator throughout the bill is "unreasonable risk", the implementation of the standard will of necessity vary depending on the specific regulatory authority which the Administrator seeks to exer-

cise. For example, a testing rule under section 4 will ordinarily not result in depriving the public of the benefits of a substance or mixture subject to the rule. This is because such a rule does not prohibit the manufacture, processing, etc., of existing substances or of mixtures. At the most a testing rule may, through section 5(d), delay the Commercial availability of new substances and new uses of existing substances subject to the testing rule. Similarly, a requirement imposed under section 5(g) (regulation of new substances and significant new uses of substances pending the development of information) will only delay or restrict the availability of a substance subject to it until adequate health and safety data can be developed and evaluated.

However, this is to be contrasted with the effect of the imposition of a requirement under section 6 on a substance. Such a requirement may remove a substance from the market or impose lesser restrictions on its availability and such a requirement is not of limited duration. Thus, the effect on society may be far reaching. As a result regulatory effect will be of greater significance in a determination of unreasonable risk for purposes of section 6 than for a determination for purposes of section 4 or 5(g). Conversely, with respect to section 4 or 5(g), be-

A recent study by the National Academy of Sciences on regulating chemicals agrees. It states: "Highly formalized methods of benefit-cost analysis seldom can be used for making decisions about regulating chemicals in the environment. Thus the development of such methods should not have high priority." Decision Making for Regulating Chemicals in the Environment, Committee on Principles of Decision Making for Regulating Chemicals in the Environment, Environmental Studies Board, Commission on Natural Resources, National Research Council, National Academy of Sciences, xxv (July, 1975).

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cause the regulatory effect of action taken under either of those sections is less than that of action taken under section 6, the requirements for a determination of unreasonable risk for purposes of section 4 or 5 (g) are less demanding.

The Committee has limited the Administrator to taking action only against unreasonable risks because to do otherwise assumes that a risk-free society is attainable, an assumption that the Committee does not make.

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SECTION 4, TESTING OF CHEMICAL SUBSTANCES AND MIXTURES

Section 4 vests in the Administrator the authority necessary to accomplish one of the basic policy objectives of the bill: to require manufacturers and processors to bear the responsibility for adequately testing potentially dangerous chemical substances and mixtures to ascertain their health and environmental effects. The section may be made applicable to existing and new chemical substances and to mixtures.

When testing should be required

Sections 4(a) (1) (A) and 4(a) (1) (B) describe when the Administrator shall promulgate rules requiring manufacturers and processors to test a chemical substance or mixture. Both sections 4(a)(1)(A) and 4(a) (1) (B) require the Administrator to make certain findings, and absent those findings testing may not be required.

Section 4(a)(1)(A) states that if the Administrator finds that (1) the manufacture, distribution in commerce, processing, use or disposal of a chemical substance or mixture or any combination of such actions may cause or significantly contribute to an unreasonable risk to health or the environment, (2) there are insufficient data and experience to reasonably determine or predict the effects of such activity, and (3) testing of such substance or mixture is necessary to develop predictive data, and (4) in the case of a mixture, the effects may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture, then the Administrator shall by rule require testing of the substance or mixture.

The finding that a substance or mixture may cause or significantly contribute to an unreasonable risk is intended by the Committee to focus the Administrator's attention on those chemical substances and mixtures about which there is a basis for concern, but about which there is inadequate information to reasonably predict or determine the effects of the substance or mixture on health or the environment. For example, if one substance is structurally similar to a second chemical with known adverse health or environmental effects, the Administrator could reasonably conclude that the first chemical may cause or significantly contribute to an unreasonable risk. Or if there

is reliable preliminary data indicating that a substance may be dangerous, again it would be reasonable to conclude that such chemical may cause or significantly contribute to an unreasonable risk.

It should be noted that the bill does not require the Administrator to find that a substance or mixture does cause or significantly contribute to or will cause or significantly contribute to an unreasonable risk. Such a finding requirement would defeat the purpose of the section, for if the Administrator is able to make such a determination.

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regulatory action to protect against the risk, not additional testing, is called for. However, the term "may" as used in the phrase "may cause or significantly contribute to" does not permit the Administrator to make a finding respecting probability of a risk on the basis of mere conjecture or speculation, i.e., it may or may not cause a risk.

Section 4(a)(1)(B) sets forth the second set of conditions under which the Administrator is to require testing. If the Administrator finds that (1) a substance or mixture is or will be produced in substantial quantities and that it enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance or mixture, (2) there are insufficient data and experience upon which to determine or predict the effects of the manufacture, distribution in commerce, processing, use, or disposal of the substance or mixture, (3) testing is necessary to develop predictive data, and (4) in the case of a mixture, the effects may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture, then the Administrator shall by rule require testing of the substance or mixture.

The conditions specified in section 4(a)(1)(B) reflect the Committee's recognition that there are certain situations in which testing is desirable even though there is an absence of information indicating that the substance or mixture may be harmful.

In making the finding that there is or will be substantial production coupled with substantial environmental or human exposure to a substance or mixture, the Administrator is not limited to consideration of sheer volume of production or exposure at a specific point in time. The duration of the exposure, the level of or intensity of exposure at various periods of time, the number of people exposed, or the extent of environmental exposure are among the considerations which may be relevant in particular circumstances.

In both sections 4(a) (1) (A) and 4(a) (1) (B) a finding that there are insufficient data and experience upon which to determine or predict the effects of a substance or mixture is required. The Committee included this finding in each provision to eliminate unnecessary or duplicative testing! The Committee recognizes that experience with a chemical substance or mixture, as well as test data, may be useful in determining or predicting the effects of a substance or mixture. Experience may be particularly valuable in evaluating acute effects. However, the value of experience may be diminished with respect to effects of chronic exposure to a substance or mixture depending on the type of suspected harm and the length of experience with such substance or mixture.

The additional finding required with respect to a mixture (i.e., that the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture) is also intended to reduce unnecessary or duplicative testing. The assessment of safety of a mixture may well be based upon the toxicity of particular components, and tests of the entire mixture with its varying component ratios may be unnecessary or unrewarding. At the same time, the Committee recognizes that there may be instances in which

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a particular combination must be tested to reasonably evaluate the effects of the mixture. For instance, the effect of two chemicals, when combined, may be greater than the sum of the effects of the components taken independently. The Committee bill does not prohibit the Administrator from requiring testing of the mixture in such instances.

Contents of testing rule

Section 4(b) (1) requires a testing rule to identify the substance or mixture for which testing is required, include the standards for the development of test data, and specify the period of time within which the testing results shall be submitted to the Administrator. The period specified for conducting the testing and submitting results to the Administrator may not be unreasonable.

In determining the standards for the development of test data and the period for conducting the testing, the Administrator is to consider the relative costs of various test protocols and methodologies. The Committee recognizes that testing may, in some instances, involve considerable costs for a manufacturer or processor. To the extent consistent with the purpose of the bill and the public need for timely, thorough, and reliable data, the Administrator should attempt to minimize testing costs.

The Administrator is also to consider, in determining the standards and period for testing, the reasonably foreseeable availability of facilities and personnel for performing testing under the rule. Such consideration need not be limited to existing testing resources and personnel but might also include the anticipated increase in supply of such resources and personnel to meet increased demand. The testing rule may require the submission of preliminary data prior to the time the final data is to be submitted to the Administrator. As a result, the Administrator may check to insure that the testing data is being developed in a reliable and competent manner in compliance with the standard for the development of test data. Failure to comply with such standard would, of course, be a prohibited act under section 15.

Section 4(b) (2) (A) lists some of the health and environmental effects for which a standard for the development of test data may be prescribed. It also lists some of the testing methodologies which may be prescribed in the standard, including epidemiology, serial, or hierarchical tests, in vitro tests, and whole animal tests. The Committee considered and rejected an amendment which would have instructed the Administrator to give preference to tests which do not involve the use of animals if other tests provide an adequate and accurate means for ascertaining the effect of a chemical substance or mixture on health or the environment. The Committee determined not to so limit the Administrator's discretion since protection of human health demands that the Administrator not be denied the best, most reliable data possible. However the Committee does not intend that the Administrator needlessly require whole animal tests. The Administrator should consider alternative test methods. With the development of reliable non-animal tests for predicting the long-term effects of chem-

icals on health, the need for animal test data to determine if a substance or mixture causes or significantly contributes to an unreasonable risk will diminish.

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Before prescribing epidemiology tests, the Administrator is required to consult with the Director of the National Institute for Occupational Safety and Health. Such consultation will enable the Administrator to acquire the expertise and experience of the Director respecting epidemiology tests conducted under the Occupational Safety and Health Act of 1970.

Section 4(b) (2) (B) requires the Administrator to review the testing standards at least every twelve months. If necessary, the Administrator shall initiate rulemaking proceedings to make appropriate revisions of a testing standard.

Who is to conduct the testing

In general the manufacturers and processors of a chemical substance or mixture subject to a section 4 rule are responsible for the testing required by the rule. If two or more persons subject to the same testing requirement, the Administrator may permit them to designate one of their number or a qualified third party to conduct the tests and submit the test data on their behalf. However, such a designation does not relieve them of their underlying responsibility for compliance with the testing rule. Subsection (b) (3) specifies which manufacturers and processors are to do the testing. Under that subsection there must be a relationship between the activity of the manufacturer or processor and the finding made in connection with the issuance of the rule. Thus, for example, if the Administrator makes a finding respecting the manufacture of a substance, the persons engaged in such manufacturing must do the testing. Similarly, if the Administrator makes a finding respecting the use of a substance, the person responsible for manufacturing or processing the substance for that particular use would be responsible for testing.

A rule under subsection (a) requiring testing of a substance or mixture shall expire at the end of the reimbursement period applicable to the test data to be submitted pursuant to such rule. The reimbursement period is the period during which the person who submits test

data is entitled to be reimbursed by any person who receives an exemption from the testing requirement based on the data submitted by the first person.

Procedures for promulgating rules requiring testing

Section 4(b)(5) specifies the procedures by which the Administrator is to promulgate a rule under subsection (a). Such rules are to be promulgated in accordance with the informal rulemaking procedures of section 553 of title 5 of the United States Code. In addition to the procedures outlined in section 553, the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, as well as an opportunity to make written submissions. A transcript shall be made of any oral presentation. The Administrator may not promulgate a rule under subsection (a) unless the Administrator makes and publishes with the rule the findings described in paragraph (1) (A) or (1) (B) of subsection (a).

Exemptions from rules requiring testing

Subsection (c) specifies when the Administrator is to exempt a person from a requirement to conduct tests and submit test data on

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a chemical substance or mixture. To obtain an exemption, an applicant must demonstrate to the satisfaction of the Administrator that the chemical substance or mixture (including any contaminant in the substance or mixture) with respect to which the application is submitted is equivalent to the substance or mixture for which test data has already been submitted or for which test data is being developed, and that testing and submission of data by the applicant would be duplicative.

The person granted the exemption must, if the exemption is granted within the reimbursement period, provide fair and equitable reimbursement to the person upon whose testing the exemption is based and to any other person who has been required to contribute to the testing costs of such person. If the person granted the exemption and those who are to be reimbursed are unable to agree upon the amount and method of reimbursement, the Administrator may order the person granted the exemption to provide fair and equitable reimburse-

ment in any amount determined under rules of the Administrator. The Committee recognizes that burdens of testing could fall heaviest on small companies and, therefore, to alleviate such burdens the Administrator, in promulgating such rules, is directed to consider the effect on the competitive position of the various persons involved and their respective share of the market. The Committee recognizes that such rules will necessarily have to be somewhat general in scope, for the Administrator cannot be expected to anticipate all of the specific situations which may arise. An order requiring reimbursement is to be considered final agency action.

Public notice of receipt of test data

Subsection (d) requires the Administrator to promptly publish in the Federal Register a notice of receipt of any test data submitted pursuant to a rule under subsection (a). The notice, subject to the provisions of section 14 (relating to confidentiality) shall identify the substance or mixture for which data have been received, list the uses or intended uses of the substance or mixture and the information required under the section 4(a) rule, and describe the nature of the test data developed. Unless it is protected from disclosure by section 14, the data shall be made available by the Administrator for examination by any person.

Priorities for testing

Subsection (e) establishes an interagency committee to make recommendations to the Administrator regarding what chemical substances and mixtures should be considered priority candidates for the issuance of a testing rule under section 4(a). The committee is to be composed of representatives from the Environmental Protection Agency, the Occupational Safety and Health Administration, the Council on Environmental Quality, the National Institute for Occupational Safety and Health, the National Institute of Environmental Health Sciences, the National Cancer Institute, the National Science Foundation, and the Department of Commerce. During Committee deliberations, an amendment specifying that the representative from the Department of Commerce be selected from the National Oceanic and Atmospheric Agency was offered. Although the amendment was ultimately with-

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drawn, the Committee intends that the representative from the Department of Commerce be able to share with the interagency committee the particular expertise and knowledge found in XAAA respecting chemical substances and mixtures and their presence in, relationship to, and effects on the oceans and the atmosphere.

The interagency[^] committee is to submit its first list of recommendations to the Administrator within twelve months after the effective date of the bill. Any necessary revisions in the list are to be made at least every six months. The interagency committee's reasons for including a substance or mixture on the list are also to be submitted to the Administrator. The bill reported from Subcommittee required the interagency committee to publish its recommendations and supporting reasons in the Federal Register. The substitute adopted by the Committee deletes this requirement. Instead, the Committee bill places the burden on the Administrator for making the list and accompanying reasons available to the public. The Committee bill permits the Administrator to determine the best means for making the information available to the public. The Committee recognizes that individuals throughout the country may be interested in such information, and the Committee does not intend that access to the information be limited to persons who have physical access to the headquarters or a regional office of the Administrator.

The Committee bill also provides that the Administrator shall provide a reasonable opportunity to any interested person to file comments on the committee's recommendations. Such comments are also to be made available to the public

The Subcommittee bill required the Administrator to either initiate a rulemaking proceeding under subsection (a) to require testing of a chemical substance or mixture recommended by the interagency committee or to publish in the Federal Register the Administrator's reasons for not initiating such a proceeding. The substitute adopted by the Committee does not contain such a requirement. Although the Committee intends that the interagency committee's recommendations be given great weight by the Administrator, the Committee believes it would be counterproductive to require the Administrator to formally respond in the Federal Register to every chemical substance or mixture recommended for testing by the interagency committee on which the Administrator did not take action. The resources of the Administrator should be concentrated on preparing and promulgating testing requirements and taking other necessary regulatory action to protect the public from potentially dangerous chemical substances and mixtures.

SECnOX 5, MAXUFACTURING AXD PROCEv<&S(XG XOTICES

In General

Section 5 sets out the notification requirements with which manufacturers of new chemical substances and manufacturers and processors of existing chemicals for significant new uses must comply. In general, manufacturers of new^a chemical substances must give 90 days notice to the Administrator prior to such manufacture of the new chemical. Similarly, any person who intends to manufacture or process

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for commercial purposes an existing chemical for a use which the Administrator has determined, by rule, constitutes a significant new-use of the chemical must provide 90 days notice to the Administrator prior to such manufacture or processing.

Notice must include information respecting the substance, its chemical identity and molecular structure, proposed amount of production, uses, and test data respecting health and environmental effects. Such notice will give the Administrator an opportunity to review and evaluate information respecting the substance to determine if manufacture or processing should be restricted or delayed under the authorities in this section or other sections of the bill because the substance may be hazardous.

For example, in the case of a substance for which there is inadequate information to permit a reasoned evaluation of the health and environmental effects and which may, in the absence of such information, cause or significantly contribute to an unreasonable risk, the Administrator can in section 5(g), through court order and rulemaking, delay the manufacture or processing of the substance pending the development of such information. The provisions of section 5 reflect the Committee's recognition that the most desirable time to determine the health and environmental effects of a substance is before commercial production begins. Not only are human and environmental harm avoided or alleviated, but the costs of any regulatory action in terms of loss of jobs and capital investment are minimized.

Notification for Manufacture of New Chemical Substances

Subsection (a) provides that before a person may^a manufacture a new chemical substance, that is, a chemical substance which is not

included on the inventory published under section 8(b), the person must notify the Administrator at least 90 days before such manufacture unless the substance is exempt from the notification requirement by the provisions of subsection (i). If a rule requiring testing of the substance has been promulgated under section 4 before the submission of the notice and is applicable to such person, then the data required to be developed and submitted under the testing rule must be submitted to the Administrator at least ninety days before beginning such manufacture.

Chemical /Substances for a Significant New Use

Subsection (b) (1) provides that at least ninety days before beginning to manufacture or process a chemical substance for a use which the Administrator determines, by rule, is a significant new use of such substance, the manufacturer or processor must notify the Administrator unless the substance is exempted from the notification requirements by subsection (i). If before the submission of such notice, the manufacturer or processor is required by a testing rule in effect under section 4 to submit test data for such substance, then such person shall submit to the Administrator in accordance with such rule such data at least 90 days before beginning such manufacture or processing.

Subsection (b) (2) requires that a determination by the Administrator that a new use of an existing chemical substance is a significant new use for which notification is required shall be made by rule. In making such a determination, the Administrator is to consider all

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relevant factors, including the projected volume of manufacturing and processing of such substance for such use, the extent to which such use changes the type or form of exposure of humans or the environment to such substance, and the extent to which such use increases the magnitude and duration of exposure of humans or the environment to the substance.

The Committee has required that the determination that a new use constitutes a significant new use be made by rule in order to assure that such determination will not be made in an arbitrary manner.

By limiting the notification requirements for existing chemical sub-

stances to ones to be manufactured or processed for significant, new uses, the Committee intends to indicate that only when a new use of a substance may reasonably be expected to have health or environmental importance should it be subjected to the notification requirement. Ordinarily, where the projected volume of a new use is small, the Committee anticipates that the Administrator would not make a determination that such use constitutes a significant new use unless there is a significant change in the type or form of human or environmental exposure, a significant increase in the magnitude and duration of human or environmental exposure, or unless there are other factors indicating that any such use of the substance should be considered significant.

It has been suggested to the Committee that the Administrator could determine that any new use of a particular substance will be considered significant. The Committee does not intend that a new use be considered a significant new use solely on the basis that the use is new. However[^] because of the nature of a substance, it is possible that any new use of it will be significant. Thus a potentially dangerous substance which is manufactured for a particular use may, if manufactured for a different use present additional health or environmental problems and consenuently there should be notice of the intent to manufacture it for such different use.

Listed Chemical Substanees

Within twelve, months after the effective date of the bill, the Administrator shall, by rule, compile a list of chemical substances the manufacture, processing, distribution in commerce, use, or disposal of which (or any combination thereof) the Administrator finds causes or significantly contributes to or may cause or significantly contribute to an unreasonable risk. At the same time, the Administrator shall identify those uses of listed chemicals which the Administrator determines, in accordance with section 5(b)(2), are significant new uses. The Administrator shall revise the list from time to time.

Under subsection (c) before a person may -

(1) Manufacture a listed chemical substance which was a new chemical substance at the time of publication of the earliest proposed rule listing such substance, or

(2) Manufacture or process a listed chemical substance for a use determined by the Administrator to be a significant new use,

the person must notify the Administrator, unless the substance is exempted from the notification requirements by subsection (i). At

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least 90 days before such manufacture or processing, health and safety data respecting such substance must be submitted to the Administrator as provided in subsection (d).

A rule (and any amendment to or repeal of such rule) listing a chemical substance is to be promulgated pursuant to the informal rulemaking procedures prescribed by section 553 of title 5, United States Code, except that there is to be an opportunity for the oral presentation of data, views, or arguments. A transcript is to be kept of any such oral presentation.

Submission of Test Data

Subsection (d) describes the instances in which a person subject to a notification requirement respecting a chemical substance under subsection (a), (b), or (c) must submit test data to the Administrator before manufacture or processing of such substance can begin. It is important to note that the requirements of subsection (d) respecting submission of data are in addition to the notice requirements of subsection (a), (b), or (c). Compliance with subsection (d) does not waive compliance with the notice requirements.

Under subsection (d) (1) if a testing rule under section 4 respecting }i substance has been promulgated before submission of the notice required by subsection (a), (b), or (c), then a person who is required by such rule to submit test data for the substance may not manufacture or process such substance until ninety days after submission of the test data required by such rule.

Even though a person has been granted an exemption from the testing rule under section 4, such person is prohibited from manufacturing or processing such substance until ninety days after the submission of the test data.

It should be noted that if a testing rule under section 4 respecting a substance has not been promulgated prior to the submission of a notice required by section 5, the Administrator may promulgate a testing rule under section 4 for such substance. However, such a rule would not delay the manufacture or processing of the substance.

If a person is required by subsection (c) (listed chemical substances) to provide a notice respecting the manufacturing or processing of a chemical substance and is not required by subsection (d) (1) to submit test data to the Administrator, then subsection (d) (2) imposes certain test data submission requirements on such person. Under subsection (d) (2) such person must submit to the Administrator data respecting such substance which such person believes shows that -

(1) In the case of a new chemical substance, its manufacture, processing, distribution in commerce, use, and disposal (or any combination of such actions) will not cause or significantly contribute to an unreasonable risk to health or the environment, and

(2) In the case of a chemical substance for a significant new use, such use will not cause or significantly contribute to such a risk.

Such data must be submitted ninety days prior to the manufacture or processing of such substance.

Data submitted under subsection (d)(1) or (d)(2) is to be made available, subject to section 14, for examination by interested persons.

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Extension of Notice Period

The Administrator may for good cause extend the ninety-day periods prescribed by subsections (a), (b), (c), and (d) before which the manufacturing or processing of chemical substances subject to such subsections may begin. Subsection (e) provides that an extension may be made only once and only for a period of not to exceed ninety days. Notice of an extension together with the reasons for it shall be published in the Federal Register and shall constitute final agency action subject to judicial review.

Content of Notices

Under subsection (f)(1) the notices required by subsections (a), (b), and (c) respecting the manufacturing or processing of a chemical substance are to include the following: (1) the name of the substance; (2) insofar as reasonably ascertainable, (A) its chemical iden-

ity and molecular structure, (B) proposed categories of use and amount proposed to be manufactured for each such category, and (C) description of byproducts; (3) a reasonable estimate of the amount of the substance to be manufactured or processed ; and (4) test data in the possession or control of the person giving the notice which relate to the health or environmental effects of the substance. Reasonably ascertainable should be interpreted to mean that which can be obtained without unreasonable cost or burden. Such a notice is, subject to section 14, to be made available for examination by interested persons.

Under subsection (f) (2) the Administrator is required to publish in the Federal Register a notice which (1) identifies a chemical substance for which a notice or data has been submitted under subsection (a), (b), (c), or (d), (2) identifies its uses or intended uses, and (3) if data has been submitted, describes the nature of the tests performed and the data developed. Such a notice is to be published not later than five working days after the date of the receipt of the information. Unless the Administrator determines that the public interest requires a more specific identification, chemical substances shall be identified in the Administrator's notice by generic class.

Regulation Pending Development of Information

There will be instances in which the Administrator will have insufficient information to make a reasoned evaluation of the health and environmental effects of a chemical substance for which notice has been submitted under subsection (a), (b), or (c) (that is a new chemical substance, a chemical substance to be manufactured or processed for a significant new use, or a listed chemical substance). The Administrator may determine that without such information the substance, because of the proposed volume of production of such a substance, the nature or extent of the human or environmental exposure which may be expected, the similarity with substances known to be associated with an unreasonable risk to health or the environment, or other relevant factors, may cause or significantly contribute to such a risk.

Subsection (g) provides the authority under which such a chemical substance may be regulated (that is, be made subject to manufacture

ing, processing, or distribution prohibitions or limitations, or labeling or disposal requirements) while information is developed to permit a reasoned evaluation of its health and environmental effects and to determine if such regulation should be continued.

Under subsection (g) (1) the process for regulation of a substance under this subsection is begun by an application made by the Administrator, acting through attorneys of the Environmental Protection Agency, to a district court of the United States for the issuance of an injunction to prevent the manufacture, processing, or distribution in commerce of such substance. The district courts are granted jurisdiction to grant such an injunction if the court finds that information available to the Administrator is insufficient to permit a reasoned evaluation of the effects of manufacture, processing, distribution in commerce, use, or disposal of the substance, or any combination of such activities on health or the environment and in the absence of such information, such activity may cause or significantly contribute to an unreasonable risk to health or the environment.

In granting jurisdiction to the Federal district courts, the Committee intends that the two-part standard set out in subsection (g) (1) (A) (i) and (ii) for the issuance of an injunction totally supplant the traditional elements which a party ordinarily must show before a court will exercise its equitable jurisdiction to grant an injunction. The Committee does not intend that the Administrator be required to make any showing other than that which is required for the court to make the two findings described in subsection (g)(1)(A)(i) and (ii). Upon such a showing, the Administrator is entitled to an injunction. See *FTC V. National Commission on Egg Nutrition* (517 F. 2d 485 (7th Cir. 1975)). Application of any other standard by the court will frustrate the purposes of the section.

If the court issues an injunction, the Administrator has five days within which to begin the proceeding for the issuance of a rule to apply to the substance one or more of the requirements described in section 6(a). The purpose of the proceeding is to determine which of the requirements described in section 6(a) (i.e., manufacturing, processing, or distribution limitations or prohibitions, labeling or disposal requirements) is necessary to apply to adequately protect health or environment from the risk found by the court. The reference to section 6(a) is a reference only to the kinds of requirements described therein and is not to be construed as imposing upon the Administrator the duty to make any of the findings contained in section 6 or to meet any other requirement of that section other than the procedural requirements of section 6(c) (2) and (3).

The proceeding is to be conducted in accordance with the procedures

described in paragraphs (2) and (3) of section 6(c). The proceeding is to be an expedited one in that a requested hearing is to be held within 15 days of receipt of a request for such a hearing (unless the parties agree to a different time) and the Administrator is to make a decision on the rule within 30 days of the conclusion of the hearing.

Subsection (g) (3) permits any person to petition the Administrator to initiate a proceeding to amend or repeal a rule issued under subsection (g). Thus, when data sufficient to permit a reasoned evalu-

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ation of the health or environmental effects of the substance have been developed, a person subject to the section 5(g) rule could petition the Administrator to amend or repeal the rule if appropriate in light of the data developed. Within thirty days, the Administrator must by order either grant or deny the petition. If the petition is granted, the Administrator shall promptly initiate a proceeding, in accordance with paragraphs (2) and (3) of section 6(c) for the amendment or repeal of the rule. It should be noted that granting the petition does not obligate the Administrator to modify or repeal the rule as requested. Granting a petition only triggers the requirement to initiate a proceeding. Final action by the Administrator will, of course, depend on the record developed during the proceeding.

Petition for Standards for the Development of Test Data

Under subsection (h) a person intending to manufacture or process a substance for which notice is required under subsection (a), (b), or (c) and who is not required by a rule under section 4 to submit test data on such substance may petition the Administrator to prescribe standards for the development of test data for such substance. The Administrator must act on the petition within 60 days of its receipt, and, if the Administrator grants the petition, the Administrator must prescribe such standards within 75 days of granting the petition. This provision is included primarily to assist persons intending to manufacture or process a listed chemical substance for which test data is required by subsection (d) and to assist persons who wish to develop data to make the continued imposition of a requirement under subsection (g) no longer necessary.

The Committee anticipates that such manufacturers or processors

will first consult informally with the Administrator's technical staff to obtain guidance respecting the testing of the substance. Only if such consultation fails to be productive should a petition be necessary. Of course, the Administrator could issue a rule requiring testing of a substance under section 4 even though the Administrator had previously prescribed a standard for the development of test data in response to a petition under subsection (h) .

Exemptions

I Subsection (i) prescribes the situations in which a chemical substance may be manufactured or processed without regard to the notice and test data submission requirements of subsections (a), (b), (c), and (d).

Paragraph (1) provides the authority for an exemption with respect to the manufacturing and processing of a chemical substance for test marketing purposes. To obtain such an exemption an application must be submitted to the Administrator. The application must satisfactorily demonstrate to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal for test marketing purposes of the substance for which the application is submitted will not cause or significantly contribute to any unreasonable risk to health or the environment. Such an exemption may be granted upon such restrictions as the Administrator considers appropriate. The Administrator is to act upon such an application within 45 days of its receipt.

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Under paragraph (2), an exemption from the test data submission requirements of subsection (d) (2) may be obtained for a chemical substance which is equivalent to a chemical substance for which data has been submitted in accordance with such subsection if submission of data for the substance to be exempted would be duplicative of data already submitted to the Administrator. The person requesting the exemption will have the burden of showing that the substances for which the exemption is requested is equivalent to the substance for which data has been submitted and that submission of data would be duplicative. If an exemption is granted under this paragraph during the reimbursement period for the previously submitted data, then the

person who submitted such data is to be reimbursed by the person receiving the exemption for a portion of the cost incurred in developing such data. The requirements of section 4 respecting reimbursement also apply to reimbursement provided under this paragraph.

Subsection (i) (3) specifically exempts from the notification requirements of subsections (a) , (b) , and (c) those chemical substances manufactured or processed or proposed to be manufactured or processed in small quantities (as defined by the Administrator by rule) for scientific experimentation or analysis or for chemical research or analysis, including research and analysis for the development of the substance or another chemical substance into a commercial product. All persons engaged in such experimentation, research, or analysis for a manufacturer or processor must be notified of any risk to health which the manufacturer or processor has reason to believe may be associated with the substance.

The exemption is necessary to insure that research and innovation, both academic and commercial, is not unduly impeded by the requirements of section 5. For example, researchers in laboratories in colleges and universities, in government agencies, and elsewhere may have important need for new substances on short notice. The subsection (i)(3) exemption will insure that the person w^ho manufactures such new substance for the researcher will be able to provide the substance to the researcher without having to wait the ninety days required by the notification period. Further, researchers working for a manufacturer trying to develop a product may need to make several changes in the substance. It would be unrealistic to require that the Administrator be notified 90 days in advance of each change made in the substance during the course of the research or the development period.

The research, analysis, and experimentation performed upon a chemical during its developmental period should give a manufacturer the opportunity to evaluate the physical, chemical, production, and performance characteristics of the substance. Since the exemption applies only to substances manufactured or processed in small quantities and since the research and analysis will be supervised or conducted by technically qualified individuals and since all the individuals exposed to the chemical substance will be made aware of potential health effects there should not be any unreasonable risk to health presented as a result of the exemption.

In limiting the exemption to chemicals manufactured or processed in "small" quantities, your Committee recognizes that the term "small"

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cannot be viewed in an absolute sense. The amount of the chemical substance which must be manufactured or processed for research and analysis may vary in relationship to the kind of use for which the chemical substance is being developed. Obviously a manufacturer must be able to produce a chemical in sufficient quantities during the developmental period to adequately test and evaluate the chemical for its intended use. For instance, laboratory reagents may be tested in terms of grams, while textile fibers or paper processing materials may have to be manufactured in much greater quantities in order to be adequately evaluated.

The Committee also recognizes that a manufacturer may not be able to fully evaluate a potential product in-house. For example, a manufacturer may have to use an outside testing laboratory or make the product available to a potential industrial user to complete the analysis or experimentation. The fact that the other industrial user may pay for the costs of the substance does not necessarily signal the end of the development period. So long as the purchaser is continuing the research and evaluation of the substance by individuals technically qualified to analyze and evaluate the physical, chemical, and performance characteristics of the substance, the exemption continues to apply. Again, such technically qualified individuals would be made aware of potential health and environmental effects. However, the exemption does not permit the use of the substance in products in a test market situation.

Subsection (g) (4) is designed to prevent a substance from being treated as a new chemical substance solely on the basis of a change of the inert ingredients of the substance. Under this exemption, if a substance has been included in the inventory under section 8, the substance which is identical to that substance except for its inert ingredients is not to be treated as a new chemical substance and consequently subject to the notice requirements of subsection (a).

Paragraph (5) authorizes the Administrator, upon application, to issue a rule to exempt the manufacturer of a new chemical substance from the requirements of this section (or any part of such requirement) if the Administrator determines that the chemical substance will not cause or significantly contribute to an unreasonable risk to health or the environment. A rule under this paragraph is to be promulgated in accordance with the rulemaking procedures contained in paragraphs (2) and (3) of section 6(c).

Definition

Subsection (j) provides that for purposes of section 5, the terms "manufacture" and "process" means to manufacture or process for commercial purposes. Since the term "manufacture" is defined to include "import", persons who intend to import substances for commercial purposes will be treated the same as a domestic manufacturer under section 5.

By use of the term "for commercial purposes" the Committee does not intend to restrict coverage to substances manufactured or processed "for sale". Any commercial purpose, such as use as a chemical intermediate in a manufacturing process, is sufficient to bring the manufacture or processing of a substance within the ambit of section 5. The

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Committee realizes that there are certain minor reactions occurring incidental to the mixing process or upon storage of a mixture, such as the cross-linking of polymers. Such a minor reaction may result in what would technically be considered a "new" chemical substance. However, since the "new" substance is not manufactured for commercial purposes per se it would not be subject to the notification provisions of this section.

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SECTION 6, REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND

MIXTURES

Section 6 empowers and directs the Administrator to take action to protect the public from hazardous chemical substances and mixtures. Such action shall be taken against existing chemical substances, new chemical substances, and mixtures when there is a reasonable basis to conclude that the substance or mixture causes or significantly contributes to or will cause or significantly contribute to an unreason-

able risk.

11 Scope of regulation

Section 6(a) provides that if the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture (or any combination of such activities) causes or significantly contributes to or will cause or significantly contribute to an unreasonable risk to health or environment, the Administrator shall by rule take regulatory action necessary to adequately protect against the

unreasonable risk. Absent such a finding, the Administrator may not take action under section 6(a).

This standard for taking action recognizes that factual certainty respecting the existence of an unreasonable risk of a particular harm

may not be possible and the bill does not require it. Such uncertainty is particularly likely to occur when dealing with the long term or chronic effects of a substance or mixture. For example, cancer does not appear immediately after exposure to a carcinogenic substance or mixture, but instead there may be a latency period of several years before the cancer appears. With mutagens, the effects may not become apparent until generations have passed. When, as here, regulatory action is intended to be taken to prevent the occurrence of harm in the future as well as protect against presently visible harm, such action often must be based not only on consideration of facts but also on consideration of scientific theories, projections of trends from currently available data, modeling using reasonable assumptions, and extrapolations from limited data. Further, regulatory action may be taken even though there are uncertainties as to the threshold levels of causation. Thus, the bill requires a reasonable basis to conclude that a substance or mixture causes or significantly contributes to or will cause, or significantly contribute to an unreasonable risk to health or environment. Such a judgment may be based upon items such as toxicological, physiological, epidemiological, biochemical, or statistical research or studies or extrapolations therefrom. A finding by the Administrator that there is such a reasonable basis must include adequate reasons and explanations for the Administrator's conclusion. It does not, however, require the factual certainty of a "finding of fact" of the sort associated with adjudication.

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The term "significantly contribute to an unreasonable risk" is used throughout the bill. The Committee has used such term because it recognizes that an individual substance or mixture may not be the sole identifiable factor which may cause an unreasonable risk. Because of the multiple avenues by which humans and the environment are exposed to a substance or mixture and because substances and mixtures do not occur in the environment in isolation, risks may result from complex interactions or because of cumulative effects. Thus the bill authorizes actions against a substance or mixture which is only a contributing factor to an unreasonable risk. The bill specifies that the contribution be significant, for the Committee does not intend to authorize action against a contributing factor which is only de minimus. However, the Committee recognizes that in many instances it will be impossible for the Administrator to show the quantity of contribution to a particular risk made by a particular substance or mixture, and the Committee does not intend that the Administrator be required to do so in such situations. Nor does the Administrator have to show that a substance or mixture is the predominant contributing factor. Because of potential cumulative or synergistic effects, even a small contribution may be significant. Moreover, because of the dispersion and transformation of chemical substances and mixtures in the environment, the substance or mixture may contribute to a risk indirectly or directly. The considerations discussed in this paragraph would, of course, apply whenever the phrase is used in the bill.

A section 6 (a) rule may consist of any one or more of the following: (1) a requirement prohibiting the manufacturing, processing, or distribution in commerce of the substance or mixture or limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce; (2) a requirement prohibiting the manufacture, processing, or distribution in commerce of the substance or mixture for a particular use or prohibiting the manufacture, processing, or distribution in commerce of the substance or mixture for a particular use in excess of a specified level of concentration; (3) a requirement limiting the amount of the substance or mixture which may be manufactured, processed, or distributed in commerce for a particular use or a particular use in a concentration in excess of a specified level; (4) a requirement that the substance or mixture or any article containing it be marked with or accompanied by appropriate warnings and instructions; (5) a requirement that the manufacturers and processors of the substance or mixture make and retain records of the processes used to manufacture or process the substance or mixture; (6) a requirement regulating the manner or method of disposal

of the substance, mixture or any article containing it by its manufacturer, processor, or by any commercial user; and (7) if a requirement described in clause (1), (2), or (3) is imposed, a requirement that the manufacturers and processors of the substance or mixture provide notice of the risk to persons in possession of the substance or mixture and to the public. The Committee recognizes the inherent interests of the States and political subdivisions respecting disposal of hazardous chemicals within their jurisdiction. As a result, the Committee has limited the Administrator to prescribing only those disposal requirements which do not violate any law of a State or a po-

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litical subdivision of a State. In addition, any disposal requirement shall require persons subject to it to notify each State and political subdivision in which a required disposal may occur.

While the bill authorizes the Administrator to prohibit or limit the distribution in commerce of substances or mixtures and to prohibit or limit the distribution in commerce of substances and mixtures for a particular use, such authority does not authorize the Administrator to regulate the manner or method of transporting hazardous chemical substances or mixtures in commerce. For example, the loading, unloading, and storage in connection with transportation in commerce are regulated under the Hazardous Materials Act of 1974, and it is not the Committee's intent to grant the Administrator any regulatory authority under section 6(a) with respect to such loading, unloading, or storage.

The Committee recognizes that the requirements prescribed by the Administrator under this section may provide protection for employees in the workplace. For example, by prohibiting the manufacture of a substance, risks to employees involved in the manufacturing of the substance would be eliminated. However, the Committee wishes to emphasize that none of the authorities included in section 6(a) should be construed as authorizing the Administrator to issue workplace standards directly regulating such matters as the airborne concentrations of a substance to which employees may be exposed or the manner in which an employee is permitted to handle a substance. There is no authority in the bill for the Administrator to issue rules respecting personal protective equipment for employees, work practices in hazardous operations, or procedures for emergency situations.

Such direct regulation of the workplace falls under the jurisdiction of the Occupational Safety and Health Act of 1970 not under this bill.

The Committee intends that any requirement prescribed under section 6(a) be the least burdensome possible for those subject to the requirement and for society while providing an adequate margin of protection against the unreasonable risk. The Committee expects that the determination of the least burdensome requirement will be based on information submitted to the Administration during the rulemaking proceeding and other information which is readily available to the Administrator. The Committee does not intend that needed regulation be unreasonably delayed while the Administrator develops quantitative data comparing the costs of control methods. Because different environmental or health conditions in different areas of the country may require different forms of regulation to protect against an unreasonable risk, the bill permits a requirement to be limited in application to specified geographic areas.

Protection against adulterated or contaminated substances and mixtures

Subsection (b) of section 6 authorizes the Administrator to take action to prevent the adulteration or contamination of substances and mixtures. If the Administrator has good cause to believe that a particular manufacturer or processor is manufacturing or processing a substance or mixture in a manner which unintentionally results in the substance or mixture causing or significantly contributing to or to

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being likely to cause or significantly contribute to an unreasonable risk, then the Administrator is authorized to take certain action. The Administrator may by order require the submission of a description of the relevant quality control procedures. Further, if after a hearing in accordance with section 554 of title 5, United States Code, the Administrator determines on the record that the quality control procedures are inadequate, the Administrator may order the revision of the quality control procedures. In addition, if the Admin-

istrator determines that the inadequate procedures have resulted in the distribution of a chemical substance or mixture which causes or significantly contributes to an unreasonable risk, the Administrator may require the person subject to the order to provide notice of the risk associated with the substance or mixture and to replace or repurchase any substance or mixture produced under the defective quality control procedure as is necessary to protect health or environment.

Considerations iii promulgating section 6 (a) rules

Section 6(c) requires the Administrator to consider all relevant factors in promulgating any rule under subsection (a) respecting a substance or mixture. Findings must be made with respect to the effects of the substance or mixture on health and the magnitude of human exposure to the substance or mixture, the effects of the substance or mixture on the environment and the magnitude of environmental exposure, the benefits of the substance or mixture for various uses and the availability of other substances or mixtures for such uses, and the reasonably ascertainable economic consequences of the rule taking into account the impact on small business. In making the finding respecting the reasonably ascertainable economic consequences, the Committee anticipates that the Administrator's consideration will include, but not be limited to, major effects of the rule on the national economy and the rule's effect on technological innovation, the environment, and the public health. Of course, because basic information regarding economic effects on the regulated industry is within the particular expertise of the industry, the Committee expects the industry to come forward with such data. The economic consequences of a rule should include the positive impact a regulatory limitation or proscription will have on the development and use of substitutes as well as the negative impact on the manufacturer or processor of the regulated substance. Likewise, the economic savings to society resulting from the removal of an unreasonable risk must be a key element in any consideration of economic consequences. The Committee does not intend that a chemical which causes or significantly contributes to an unreasonable risk should be permitted to be marketed solely because it would cause economic costs to producers if it were not permitted to be sold.

An additional finding is required if the Administrator determines that the risk to health or the environment could have been eliminated or reduced to a sufficient extent by actions taken under another Federal law administered in whole or in part by the Administrator. In such a situation, the Administrator must make a finding that it is in the public interest to take action under the bill rather than under such other Federal law. The fact that a risk could be subject to regulation

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under one of the other Federal laws administered by the Administrator does not trigger the additional finding requirement. Instead, the Administrator must determine that the risk could be eliminated or reduced to a sufficient extent under the other law before the finding is required. It is particularly appropriate that this initial decision be vested in the Administrator since the determination involves Acts administered by the Administrator and thus is clearly within the expertise of the Administrator. In making the finding, the Administrator is to take into consideration all aspects of the risk, the authorities available to enforce actions under the Toxic Substances Control Act and such other laws, a comparison of the estimated costs of complying, and the relative efficiency of actions under the respective laws. The consideration of comparative costs of complying with action under this bill and under other laws should be based upon information readily available to the Administrator. Consideration of the relative efficiency of actions under this Act and under other laws should include consideration of the time and resources needed to take such actions.

The purpose of the Committee in requiring "findings" with respect to the considerations listed in subparagraphs (A), (B), (C), and (D) of subsection (c) (1) is to assure that the basis for the Administrator's rule is publicly enumerated. Section 553 of title 5, United States Code, which would otherwise solely govern the promulgation of such a rule, requires that an agency incorporate in any rule adopted a concise general statement of its basis and purpose. By requiring such findings, the Committee is emphasizing that those key considerations enumerated in subparagraphs (A), (B), (C), and (D) of subsection (c) (1) will be addressed in such a statement of basis and purpose. The findings need not be detailed or voluminous, nor does the Committee expect the findings to be based solely on factual evidence. The Committee recognizes that, particularly with respect to such issues as the effects of a substance or mixture on health or the environment, the Administrator's findings may necessarily deal with projections from imperfect data, experiments and simulations, educated predictions, differing assessments of possible risks, etc. The findings are to be issued at the time the rule under subsection (a) is promulgated, and there will not be any judicial review of such findings separate and apart from the review of the rule issued under section 6(a).

Procedures for promulgating section 6(a) rules

Rules under section 6(a) are to be promulgated pursuant to the procedures of section 553 of title 5 of the United States Code, except that the Administrator is required to give interested persons an opportunity for the oral presentation of data, views, or arguments, and in certain instances an opportunity for cross-examination must be provided.

If the Administrator determines that it is necessary to resolve disputed issues of material fact, then an interested person is entitled to conduct or have conducted by the Administrator such cross-examination as the Administrator determines (1) to be appropriate in view of any need for expedition in the rulemaking proceeding, the nature of the issues involved, the number of participants and the nature of

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their interests, and (2) to be required for a full and true disclosure with respect to disputed issues of material fact. By limiting the cross-examination to disputed issues of material fact, the Committee intends to limit cross-examination to those issues characterized as issues of adjudicative fact the truth or falsity of which is subject to evidentiary proof and which could reasonably be expected to affect the outcome of the rule. The burden of showing that any issue is a "disputed issue of material fact" rests on the person seeking to engage in cross-examination.

In view of the large number of persons who may be interested in a rulemaking proceeding, the Committee felt it was necessary to give the Administrator the express authority to group, for cross-examination purposes, persons with the same or similar interests and provide for their representation by a single representative. Further, the Administrator may determine to conduct such cross-examination on behalf of such a group. If a person who is a member of a group is unable to agree upon group representation, the person shall not be denied the opportunity to conduct or have conducted cross-examination as to issues affecting the person's particular interest if the person satisfies the Administrator that the person made a good faith effort to agree

upon group representation and if the Administrator determines that there are substantial and relevant issues which are not adequately presented by the group representative.

It was the judgment of the Committee that more effective, workable and meaningful rules will be promulgated if interested persons do have the opportunity to make oral presentations, and where appropriate and necessary, have an opportunity to conduct cross-examination and present rebuttal evidence. However, it is not the Committee's intent to create a cumbersome, timeconsuming administrative procedure which will delay necessary regulation. Thus, not only does the Committee limit the instances in which cross-examination is required to those in which the Administrator determines that it is necessary and appropriate, but also the Committee authorizes the Administrator to issue procedural rules for the conduct of oral presentations (including cross-examination) and to impose time limits on such presentations as may be appropriate in view of any need for expedition, the nature of the issues involved, and the number of participants and the nature of their interests.

In order to provide to the extent possible that all relevant interests be represented in rulemaking proceedings so that the rules adopted best serve the public interest, the Administrator is authorized to provide compensation for reasonable attorneys' fees, expert witness fees, and other costs of participating: in the rulemaking proceeding. Such fees and costs may be provided to any person who represents an interest which will substantially contribute to a fair determination of the issues to be resolved in the proceeding if the economic interest of the person is small in comparison to the costs of effective participation by that person in the proceeding or if the person demonstrates to the satisfaction of the Administrator that the person does not have sufficient resources to participate in the proceeding in the absence of compensation. In determining if a person represents an interest which will substantially contribute to a fair determination of the issues, the Ad-

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ministrator is to take into account the number and complexity of the issues and whether representation of such interest will contribute to widespread public participation and to representation of a fair bal-

ance of interests for the resolution of the issues.

In determining whether compensation should be provided and the amount of such compensation, the Administrator shall take into account the financial burden which will be incurred as a result of participation. However, the Committee does not intend to imply that in all instances a person must be able to demonstrate a financial burden before the Administrator may provide the person with compensation. Demonstration of financial burden is required unless a person has an economic interest which is small in comparison to the costs of effective participation in the proceeding. Thus when the economic interest is small, no showing of financial burden is required. However, in light of the possibility that there may be competing requests for assistance in connection with proceedings under this section, a consideration of financial burden will be relevant in determining who should be the recipients of compensation and the amount of compensation. In considering the financial burden to be incurred, the Administrator should not look solely at the costs of participating in the section 6 proceeding, but should instead view such costs in light of the overall activities of the person applying for compensation and the person's resources. For example, a person requesting compensation could show that such person represents interests which may require participation in other judicial or administrative proceedings and that such participation might have to be curtailed or limited because of a commitment of resources to the proceeding with respect to which such request made and the Administrator should consider such information.

A determination of reasonable attorneys' and expert witnesses' fees should not be influenced by the fact that a person is a salaried employee of a public interest or foundation funded organization. The Committee intends that reasonable fees be those which are commensurate with those at which such professionals would normally be compensated for performance of similar services. The fact that attorneys or experts may be employed by citizens' groups or foundations at salaries or hourly rates which may be below the standard commercial rates such professionals might normally receive is not relevant to any computation of the rate of compensation under the bill. Even in situations where a lawyer or expert initially renders services without expectation of receiving any compensation, fees are to be awarded at prevailing market rates. It may well be that an attorney will agree to provide representation of an interest in a proceeding because of a belief that such representation furthers a public interest. Representation of such interests should not have to rely upon the charity of counsel. This intent reflects the well-settled judicial rule that fee awards are to be made without reference to the fee arrangements that exist between an attorney and client. As the court stated in *Miller v. Amusement Enterprises, Inc.*, 426 F. 2d 532, 538-539 (5th Cir. 1970) :

What is required is not an obligation to pay attorneys' fees. Rather what – and all – that is required is the existence of a relationship of attorney and client, a status which exists wholly independently of 'compensation.

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Similarly, the United States Court of Appeals for the District of Columbia Circuit has ruled that fee awards in litigation undertaken to further the public interest must be computed so as to bring the attorneys' rate of compensation up to that of the prevailing market rate. See *Wilderness Society v. Morton*, 495 F. 2d 1026, 1037 (D.C. Cir. 1974) , reversed on other grounds, sub nom. *Alyeska Pipeline Co. v. Wilderness Society*, 421 U.S. 240 (1975), and *National Treasury Employees V. Nixon*, 521 F. 2d 317, (1975). Provision is made in section 19 (judicial review), section 20 (citizens' civil action), and section 21 (citizens' petition) for the award of reasonable attorneys' and expert witnesses' fees in actions under such sections. The considerations enumerated here respecting a determination of the reasonableness of a fee also apply to those sections.

Effective date of section 6 (a) ndes

Subsection (d) states that the Administrator is to specify in any rule under subsection (a) the date on which it shall take effect. Such effective date is to be as soon as feasible. In certain circumstances a proposed rule may be declared effective immediately upon its publication in the Federal Register. If the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of a substance or mixture subject to the proposed rule is likely to result in an unreasonable risk of serious or widespread harm to health or the environment before such effective date and that making the proposed rule immediately effective is necessary to protect the public interest, then the Administrator may declare the rule effective immediately upon its publication in the Federal Register. However, if the proposed rule would prohibit the manufacture, processing, or distribution of a substance or mixture, a court must have first granted relief in an action under section 7 with respect to the risk before the Administrator may make a rule prohibiting the manufacture, processing or distribution of a substance or mixture immediately effective. It is because of the severity of a rule which prohibits the manufacture, processing, or distribution in commerce of a substance or mixture, that

the Committee required an action be brought under section 7 (imminent hazard) to have a Federal district court find that the substance or mixture is an imminent hazard. However, because the Committee recognizes the difficulties in bringing such an action against all persons who may be engaged in the manufacture, processing, or distribution of a substance or mixture, the Committee has required that such an action be brought against only one such person under section 7 or that the Administrator have brought an in rem action against a substance, mixture, or article under section 7. Once a court finds an imminent hazard in the action under section 7, a banning rule of general applicability may then be made immediately effective with respect to all others.

If a proposed rule is made immediately effective, the Administrator must expeditiously provide for an opportunity for a hearing on the rule. If a hearing is requested, the Administrator shall commence the hearing within five days from the date of receipt of the request for the hearing, unless the Administrator and the person making the request agree upon a later date. The hearing must be conducted in accordance

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with the procedures set out in subsection (c) (2) and (c) (3). After the hearing is concluded, the Administrator must within ten days, either affirm, modify, or revoke the rule.

SECTION 7, IMMINENT HAZARD

Section 7(a) grants the Administrator authority to bring a district court action for seizure of an imminently hazardous chemical substance, mixture, or article containing such substance or mixture. Actions are also authorized against any person who manufactures, processes, or distributes in commerce an imminently hazardous chemical substance, mixture, or article.

If the Administrator has not used the authority provided in section 6(d) (2) (A) (i) to make a section 6(a) rule immediately effective in order to protect against an imminently hazardous chemical substance, mixture, or article, the Administrator must bring an action under section 7. The Committee has required such action in order to insure that protection is provided against imminently hazardous substances, mixtures, and articles. Of course, there may be instances in which the

Administrator may put a rule into effect immediately under section 6(d) (2) (A) (i) and will also bring an action under section 7 in order to obtain the forms of relief available under section 7 which are not available under section 6. For example, section 7 authorizes the seizure of imminently hazardous substances, mixtures, or articles containing them, and under section 7 the court may require the recall, repurchase, or replacement of imminently hazardous items in addition to any other relief necessary to protect health or the environment.

Subsection (b) gives the United States district courts jurisdiction to grant such temporary or permanent relief as may be necessary to protect health or the environment from the imminent hazard. Such relief may include a requirement that manufacturers, processors, or distributors provide notice of the risk to the public and to any known purchasers, recall, and replace or repurchase the substance, mixture, or article. Seizure and condemnation of the substance, mixture, or article is authorized.

Subsection (c) relates to venue, service of process, and consolidation.

Subsection (d) provides that where appropriate, the Administrator shall initiate a proceeding for the promulgation of a rule under section 6(a) concurrently with the filing of an action under this section.

Under subsection (e) the Administrator may direct attorneys of the Environmental Protection Agency to appear and represent the Administrator in any action under this section.

Subsection (f) defines the term "imminently hazardous chemical substance or mixture". The term means any chemical substance or mixture which causes or significantly contributes to an imminent and unreasonable risk of serious or widespread harm to health or the environment. Such a risk shall be considered imminent if it is shown that the manufacture, processing, distribution in commerce, use, or disposal of the substance or mixture or any combination of such actions is likely to result in such harm to health or the environment before a final rule under section 6 can protect against the risk. Such protection would not necessarily occur upon the effective date of a rule under section 6.

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Instead, consideration must be given to the time it may take to im-

plement and enforce such a rule.

It should be noted that while the unreasonable risk of harm must be imminent, the physical manifestations of the harm itself need not be. An imminent hazard may be found at any point in the chain of events which may ultimately result in damage to the health or environment. The observance of harm is not essential to establish that an imminent hazard of such occurrence exists. Obviously, action under the section must be able to occur early enough to prevent the final injury from materializing.

SECTION 8, REPORTING AND RETENTION OF INFORMATION

Subsection (a) of section 8 authorizes the Administrator to promulgate rules under which each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance shall maintain such records and submit such reports to the Administrator as the Administrator may reasonably require. The Administrator also is authorized to promulgate rules under which manufacturers and processors (other than small manufacturers and processors) of mixtures shall maintain records and submit reports, but only to the extent the Administrator determines is necessary for the effective enforcement of the bill. The authority to require the maintenance of records and submission of reports by manufacturers of chemical substances in small (quantities solely for scientific experimentation or analysis or for chemical research or analysis on such substance or another substance is similarly limited to reports and records necessary for the effective enforcement of the bill. The Committee has specified a different standard for requiring reporting for manufacturers or processors of mixtures and research substances because the Committee anticipates that in implementing its regulatory functions the need for information from such manufacturers and processors will not be as great as it will be with respect to other manufacturers or processors.

As a further limitation, section 8(a) (1) (A) specifies that the Administrator may not require the maintenance of records or the submission of reports with respect to changes in the proportions of the components of a mixture unless the Administrator finds that such recordkeeping or reporting is necessary for the effective enforcement of the bill. A mixture manufacturer may make an infinite number of changes in the proportions of substances comprising a mixture, and the Committee wishes to protect such manufacturers from having to document all such changes unless such changes could affect health or the environment. In most instances, the information relevant for the Administrator for the enforcement of the bill will be the particular substances used in a mixture and the range of proportions. Documentation of each specific alteration in proportion would in

most instances be unnecessarily burdensome and have little relevance to the effective enforcement of the bill.

The Administrator must promulgate rules to obtain the information necessary to compile the list of existing chemical substances re-

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quired under subsection (b) not later than one hundred and eighty days after the effective date of the bill.

Paragraph (2) of subsection (a) provides examples of the kinds of information which the Administrator may require to be reported. Included are the common or trade names, chemical identity, and molecular structure insofar as known to the person making the report or insofar as reasonably ascertainable ; the categories or proposed categories of use, insofar as known to the person making the report or insofar as reasonably ascertainable; reasonable estimates of the amount of each substance and mixture to be manufactured or processed and, insofar as known to the person making the report or insofar as reasonably ascertainable, a reasonable estimate of the amount of the substance or mixture to be manufactured or processed for each category or proposed category of use ; a description of the byproducts resulting from the manufacture, processing, use, or disposal, insofar as known to the person making the report or insofar as reasonably ascertainable ; all existing data concerning the adverse environmental and health effects of such substance or mixture, insofar as known to the person making the report; and estimates of the number of persons who will be exposed to the substance or mixture in work places and the duration of such exposure, insofar as known to the person making the report. Information should be considered reasonably ascertainable if the manufacturer or processor required to obtain the information can do so without incurring unreasonable costs or burdens.

To the extent feasible, the Administrator shall not require unnecessary or duplicative reporting. The Committee realizes that record-keeping and reporting may be a time-consuming and resource-consuming undertaking. Under section 3503 of title 44 of the United States Code (the Federal Reports Act), the Office of Management and Budget is required to review the collection of information required by the Environmental Protection Agency to assure that such information is obtained with a minimum of burden on business enterprises

and other persons and that unnecessary duplication is avoided. The Committee intends that every effort be made to realize this objective. For instance, where information respecting the chemical identity and molecular structure of chemicals comprising a mixture is obtained from the manufacturers of the chemical components, it would be duplicative for the Administrator to require similar reporting from the mixture manufacturer, and should if feasible be avoided. Further, every effort should be made to utilize information reasonably available from other Federal entities rather than seeking the same information from manufacturers and processors.

The Administrator should consider the vast size of the chemical industry in developing proposed rules for reporting. There are approximately 1,000 companies in the basic chemical industry. In addition, there are 3,100 allied establishments and another 7,400 companies which process chemical substances and mixtures. Clearly, indiscriminate reporting requirements could result in an inundation of unnecessary and duplicative information.

Because reporting and recordkeeping requirements under section 8 (a) may impose a particularly heavy burden on small manufacturers or processors, the Committee bill provides an exemption from such

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reporting and recordkeeping for small manufacturers and processors. However, the Administrator may by rule require a small manufacturer or processor of a chemical substance to submit information respecting the substance to the Administrator for purposes of compiling the inventory of existing chemical substances required under section 8(b). In addition, the Administrator may by rule require small manufacturers or processors of a chemical substance or mixture subject to a proposed rule or a final rule under sections 4, 5(g), 5(c), or 6 to maintain records and submit reports on such substance or mixture. In addition, if relief has been granted in an imminent hazard proceeding under section 7 with respect to a substance or mixture, the Administrator may by rule require a small manufacturer or processor of the substance or mixture to maintain records and submit reports on the substance or mixture. Thus, reporting and recordkeeping by small manufacturers and processors is to be held to a minimum. At the same time the Administrator will not be denied information necessary for determining whether to promulgate a rule under sections 4, 5, or 6 or

necessary for the enforcement of such a rule or an order issued in an action brought under section 7.

The Administrator, after consultation with the Small Business Administration, shall by rule prescribe standards for determining what manufacturers and processors will be considered "small" manufacturers and processors. In prescribing such standards, the Committee anticipates that the Administrator will take into account such relevant factors as the number of employees, the resources reasonably available for recordkeeping or reporting, the volume of production of substances and mixtures for which reporting or recordkeeping may be required in relation to the volume of such production by others, and whether a company is independently owned and operated. In the case of a company which is owned or controlled by another company, such factors are to be applied to both companies.

Subsection (b) requires the Administrator to compile, keep current, and publish an inventory of existing chemical substances manufactured or processed for commercial purposes in the United States. The inventory is to be used by manufacturers and processors to determine if a chemical substance is a "new" substance subject to the premarket notification requirements of section 5. The Administrator is to initially publish the inventory within one year after the effective date of the bill.

Subsection (b) provides that the inventory shall at least include each chemical substance which any person reports under section 5 or under section 8(a) is manufactured or processed in the United States or was manufactured or processed in the United States within three years before the effective date of the rules promulgated under section 8(a) for purposes of compiling the subsection (b) inventory. However, the Administrator, to alleviate reporting requirements and expedite the compilation of the initial list, may wish to utilize reports of commercially produced chemical substances prepared by other governmental offices and departments, such as the International Trade Commission and the Bureau of Mines. However, the Administrator may not rely exclusively upon such reports, but must give manufacturers and processors the

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Opportunity to report substances manufactured or processed for commercial purposes which are not included within such reports.

In submitting reports with respect to existing chemical substances which the Administrator will use in compiling the inventory, a manufacturer may report substances which are produced only intermittently but which are a part of the manufacturer's product line. Many manufacturers, particularly those who produce in batch lots, may not be currently producing the full range of substances they customarily offer. However, so long as the manufacturer has produced the substance for commercial purposes within the three year period described in section 5(b)(1), the manufacturer should report the substance and it should be included in the inventory.

Paragraph 5(b) provides that to the extent consistent with the purposes of this bill, the Administrator may in compiling and maintaining the inventory, list a category of chemical substances rather than list individually each chemical substance within the category. By listing a category of chemical substances, minor modifications or variations in the formulation or structure of a chemical substance which would have insignificant health or environmental consequences would not automatically be subject to the notification requirements of section 5. For instance, the Administrator could use categories so that reporting would not be required as a result of changes such as the following: polymers or co-polymers which vary only in the proportion of starting materials or catalysts used, or in molecular weight, molecular weight distribution, chain structure or crystallinity; changes within an existing chemical substance in the proportions of colorants, stabilizers, antioxidants, fillers, solvents, carriers, surfactants, plasticizers, and other adjuvants which are themselves reported as existing substances; variations in the proportion of alloyed metals in iron and steel products and other metal alloys; variations in naturally occurring substances or mixtures (such as crude oil, natural gas, minerals, or ores) and the resulting variations in extracts or refined products therefrom; variations in reported reactive mixtures whose commercial or end-use product is electric energy (batteries); and salts which result from the combination of an existing inorganic anion with an existing inorganic cation.

The Committee realizes that many chemical companies, particularly small ones, are able to compete in the chemical industry only by continually reformulating or making slight changes in existing chemical substances. It would be extremely burdensome on them as well as on the Administrator if every insignificant change were subject to the premarket notification requirements of section 5. By using categories in the inventory, the Administrator will be able to minimize such burdens. However, the Committee also realizes that minor modifications of innocuous compounds may produce highly toxic chemicals. Thus, the use of categories should be limited to areas where the effects of such minor modifications are well understood to have insignificant

health and environmental consequences.

Subsection (c) specifies that any person who manufactures or processes or distributes in commerce a chemical substance or mixture or proposes to engage in such an activity shall, as required by the Administrator by rule, maintain records of adverse reactions to health or the

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environment alleged to have been caused by the substance or mixture. The Administrator may require that records relating to the alleged adverse reactions to the health of employees be retained for up to fifty years, and that other records be retained for up to five years. Upon request, each person who is required to maintain such records shall permit inspection of the records and submit copies to the Administrator.

Subsection (d) authorizes the Administrator to promulgate rules requiring persons who manufacture, process, or distribute in commerce or who propose to manufacture, process, or distribute in commerce a chemical substance or mixture to submit lists of health and safety studies conducted or initiated by or for such person or known to such person, and to submit copies of such studies. In addition, the Administrator may by rule require any person who has possession of such a study to submit copies of the study to the Administrator.

Subsection (e) requires any person who manufactures, processes, or distributes in commerce a chemical substance or mixture to immediately inform the Administrator of any information which reasonably supports the conclusion that the substance or mixture causes or significantly contributes to a substantial risk to health or the environment. However, if the person has actual knowledge that the Administrator has already been adequately informed of, the information, notification of the Administrator is not required. The requirement of subsection (e) is to insure by statute that the Administrator is immediately informed of such information, and it is not intended to limit the authority of the Administrator under subsection (a) to require reporting of data concerning the adverse environmental and health effects of a substance or mixture.

Subsection (f) specifies that for purposes of section 8, the terms "manufacture" and "process" mean manufacture or process for com-

mercial purposes. Section 3(7) defines "manufacture" to mean "import, produce, or manufacture". Thus the provisions of section 8 apply to persons who manufacture, process, or import chemical substances or mixtures solely for commercial purposes.

SECTION 9, RELATIONSHIP TO OTHER FEDERAL LAWS

Because other Federal laws to some extent provide for regulation of toxic chemicals, it is necessary to define the relationship between the regulatory authority of this bill and that provided under other Federal laws. It is the intent of the Committee that any overlapping or duplicator[^] regulation be avoided while providing for the fullest possible measure of protection to health and the environment.

Section 9(a) sets out the relationship between the bill and other Federal laws not administered by the Administrator. If the Administrator has reason to believe that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture (or any combination of such activities) causes or significantly contributes to or is likely to cause or significantly contribute to an unreasonable risk and if the Administrator determines that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administra-

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tor, then the Administrator is required to report to the agency which administers such law a description of such risk. Such description shall include a specification of the activity or combination of activities which the Administrator has reason to believe so causes or contributes to such risk. The report shall include a detailed statement of the information on which it is based, shall be published in the Federal Register, and shall request the agency to which it is made -

(1) To determine if the risk described in the report may be prevented or sufficiently reduced by action taken under its law, and

(2) If it determines it may be so prevented or reduced, to issue an order declaring whether or not the activity specified in the report causes or significantly contributes to such risk.

The agency receiving the request from the Administrator shall issue the requested order and determination within such time as the Administrator specifies in the request. However, the Administrator must give the other agency at least ninety days.

If the other agency takes one of two alternative courses of actions specified in section 9(a)(2), then the Administrator is barred from acting under section 6 or 7 with respect to the risk about which the Administrator notified the other agency. First, if the other agency issues an order declaring that the activity specified in the report does not cause or significantly contribute to the risk described in the report, the Administrator may not take any action under section 6 or 7 with respect to such risk. Alternatively, if within ninety days of the publication in the Federal Register of the other agency's response to the Administrator's request, the other agency initiates action under its law which is adequate to protect against such risk, the Administrator is precluded from taking any action under section 6 or 7 with respect to such risk.

The requirement that the other agency initiate action is not intended to indicate that formal action by the other agency be undertaken within the specified time period, for time constraints may preclude any formal regulatory actions within such period. So long as the other agency has officially initiated an action which will culminate as soon as practicable in effective regulatory action to protect against the unreasonable risk and sets forth a general time schedule of steps for such action, the requirements of section 9(a) (2) (B) should be deemed satisfied. However, the provisions of section 9(a)(2)(B) would not be satisfied by the merely open-ended possibility of action by the other agency.

Subsection (b) indicates the relationship between the bill and other law administered in whole or in part by the Administrator. Under subsection (b) if a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in another Federal law administered by the Administrator, the Administrator is required to use the other law unless the Administrator determines that it is in the public interest to protect against the risk by taking action under the bill.

Other laws administered by the Administrator mandate specific actions by the Administrator. For instance, the Federal Water Pol-

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lution Control Act establishes a specific timetable within which the Administrator is to establish effluent limitations, list categories of sources, and establish standards of performance for new sources within such categories. The Committee wishes to emphasize that nothing in the bill should be construed to relieve the Administrator from complying with any such statutory mandates.

Subsection (c) provides that for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970, the Administrator in exercising any authority under the bill shall not be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health. Consequently authorities granted under the bill will not preempt action under such Act.

Subsection (d) requires the Administrator to consult and coordinate with the Secretary of Health, Education[^] and Welfare and the heads of other appropriate Federal departments, agencies, and instrumentalities in order to achieve the maximum enforcement of the bill while imposing the least burden of duplication. The Administrator must report annually to the Congress on actions taken to coordinate with other Federal departments, agencies, and instrumentalities and on actions taken to coordinate the authority under the bill with authority granted under other laws administered by the Administrator.

SECTION 10, RESEARCH, COLLECTIOX, DISSEMIXATIOX, AND UTILIZATION OF DATA

Section 10(a) requires the Administrator, in consultation and cooperation with the Secretar^{^^} of Health, Education, and Welfare and heads of other appropriate departments and agencies to conduct such research and monitoring as is necessary to carry out the purposes of the bill. The Committee has required consultation and cooperation with other agencies and departments in order to insure that the Administrator does not duplicate the efforts of other agencies in conducting research under the bill. Such duplication should be avoided both in research conducted by the Administrator as well as in research conducted pursuant to contracts entered into by the Administrator.

Section 10(b) requires the Administrator to establish and coordinate the activities of an interagency committee to design, establish, and coordinate a system for the collection, dissemination, and use of data submitted to the Administrator. The Administrator is to estab-

lish and coordinate a retrieval system for toxicological and other scientific data which could be useful to the Administrator in carrying out the purposes of the bill. The system shall be developed for use by all Federal and other departments and agencies with responsibilities in the area of regulation or study of chemical substances and mixtures and their effects on health or the environment. The Committee expects that in developing the retrieval system the Administrator will utilize existing Federal data systems to the fullest extent possible.

Presently the collection of data on chemicals which may be harmful is fragmented among several Federal departments and agencies. The Committer* feels that there is an urgent need for the development of a systematic bank of information which can be queried by any

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regulatory agency faced with a problem respecting a substance or mixture or by any agency or department interested in research on a substance or mixture. One of the major problems confronting regulatory agencies is the uncertainties regarding the total exposure of humans or the environment to a chemical substance or mixture. Exposure to a chemical may come simultaneously from several different sources or through two or more media. As pointed out by the National Academy of Sciences in its report, Decision Making for Regulating Chemicals in the Environment[^] it is essential that each agency's standards reflect appreciation of such multiple exposures.[^] The development of a comprehensive data system should help make this possible.

SECTIOX 11, INSPECTIONS

Subsection (a) authorizes the Administrator or a duly designated representative to conduct inspections for the purposes of enforcing the bill or any rule or order promulgated under the bill. Inspections are authorized of any establishment, facility, or other premise in which chemical substances or mixtures are manufactured, processed, stored, or held before or after distribution in commerce and of any conveyance used to transport a substance or mixture in connection with its distribution in commerce. An inspection may be made only

upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge of the premises or conveyance to be inspected. Separate notices must be given for each inspection, but not for each entry made during the period covered by an inspection. Inspections are to be commenced and completed with reasonable promptness and shall be conducted at reasonable times, within reasonable limits, and in a reasonable manner.

Subsection (b) sets out the scope of the inspections. An inspection shall extend to all things within the premises or conveyance bearing on whether the requirements of the bill have been complied with. However, no inspection may extend to financial data, sales data other than shipment data, pricing data, personnel data, or research data (other than research data required by this Act), unless the nature and extent of such data are described with reasonable specificity in the written notice.

SECTION 12, EXPORTS

Subsection (a) of section 12 provides that with certain exceptions this bill (other than section 8 (relating to reporting and recordkeeping)) shall not apply to any chemical substance, mixture, or article containing a substance or mixture if it can be shown that such chemical substance, mixture, or article is being manufactured, processed, sold, or held for sale, for export from the United States, unless such chemical substance, mixture or article was, in fact, manufactured, processed, sold, or held for sale, for use in the United States. Thus, for example, a manufacturer facing an enforcement proceeding for manufacturing a substance for domestic use in violation of the bill could

Decision Mailing for Regulating Chemicals in the Environment, Committee on Principles of Decision Making for Regulating Chemicals in the Environment. Environmental Appeals Board. Commission on Natural Resources. National Research Council, National Academy of Sciences, p. 39 (July 1975).

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not claim the benefits of the exemption under this section in order to export the noncomplying substance.

In order to qualify for the export exemption, a chemical substance, mixture, or article or container in which it is enclosed when distri-

buted in commerce must bear a stamp or label stating that it is intended for export.

The export exemption shall not apply to any chemical substance, mixture, or article if the Administrator finds that it will cause or significantly contribute to an unreasonable risk to health within the United States or to the environment of the United States. The Administrator may require testing: under section 4 of an otherwise exempt chemical substance or mixture to determine whether it causes or significantly contributes to an unreasonable risk to health within the United States or to the environment of the United States.

Subsection (b) provides that if any person exports or intends to export to a foreign country a chemical substance or mixture for which (1) the submission of data is required under section 4 or 5(d), (2) a rule has been proposed or promulgated under sections 5 or 6, or (3) an action is pending or relief has been granted under section 7, the person shall notify the Administrator. The Administrator must furnish to the government of the country of destination timely notice of the availability of data submitted under section 4 or 5 or of the rule, action, or relief under section 5, 6, or 7.

SECTION 13, ENTRY INTO CUSTOMS TERRITORY OF THE UNITED STATES

Subsection (a) provides that the Secretary of the Treasury is to refuse entry into the United States of any chemical substance, mixture, or article containing such substance or mixture if it fails to comply with any rule in effect under the bill, or if it is offered for entry in violation of section 5, a rule or an order under section 5 or 6, or an order issued in an action under section 5 or section 7. The Secretary of the Treasury is required to notify the consignee of any chemical substance, mixture or article which is refused entry. The Secretary is to cause its disposal or storage if it has not been exported within 90 days from the date the consignee receives notice of refusal of entry. Of course, the Committee intends that the Secretary consult with the Administrator prior to taking such action. The Secretary may not release to the consignee any substance, mixture, or article refused entry, except the Secretary may, pending a review by the Administrator of the entry refusal, release the substance, mixture or article to the consignee on execution of bond for the amount of the full invoice of the substance, mixture or article together with the duty thereon. The consignee shall be liable to the United States for liquidated damages equal to the full amount of the bond if the substance, mixture or article is not returned to the custody of the Secretary of the Treasury when demanded. The Secretary of the Treasury, after consultation with the Administrator, is to issue rules for the enforcement of this section.

SECTION 14, DISCLOSURE OF DATA

In order to insure that the Administrator have full and complete access to information relevant to achieving the objectives of the bill,

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H.R. 14032 gives the Administrator broad information gathering authority. However, the Committee recognizes that some information which the Administrator may obtain will be of tremendous competitive value to the person providing it. Accordingly, section 14 contains specific prohibitions against release of such information so that the competitive position of those supplying the information will be protected.

Except for certain authorized disclosures, subsection (a) prohibits the Administrator or any representative of the Administrator from disclosing any information reported to or otherwise obtained under this bill which is exempt from disclosure under section 552 of title 5 of the United States Code (commonly referred to as the Freedom of Information Act) because of subsection (b) (4) of that Act. That subsection provides that the mandatory disclosure provisions of the Freedom of Information Act do not apply to matters that are "trade secrets and commercial or financial information obtained from a person and privileged or confidential." Thus any information which falls within the term "trade secrets and commercial or financial information obtained from a person and privileged or confidential" is generally protected from disclosure by section 14. Such information may, however, be disclosed to officers and employees of the United States in connection with their official duties for protection of health or the environment or for specific law enforcement purposes. Such information may also be disclosed to contractors with the United States and employees of such contractors if in the opinion of the Administrator disclosure is necessary for the satisfactory performance of the contract. Such information may also be disclosed when relevant to any proceeding under this Act, except that disclosure shall be made in a manner designed to preserve confidentiality to the extent practicable without impairing the proceeding.

The Committee adopted the language of subsection (b) (4) of the Freedom of Information Act (5 U.S.C. 552(b)(4)) as the criterion for information which merits confidential treatment for several reasons. Since there is a body of case law interpreting in subsection

(b)(4), the confidentiality criterion will be more definite. Further, since the Administrator must handle requests for information under both this bill and the Freedom of Information Act, use of the same standard will promote uniformity in the handling of such requests. As a result, there should be greater certainty as to the rights of industry to have data withheld and the rights of the public to obtain data.

Subsection (b) (1) of section 14 provides that subsection (a) does not prohibit the disclosure of any health and safety study submitted under the bill or any data submitted from such a study with respect to (1) any chemical substance or mixture which on the date the information is to be disclosed has been offered for commercial distribution or (2) any substance or mixture for which testing is required under section 4 or for which notification is required under section 5. However, if a health and safety study contains (1) data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or (2) data disclosing the portion of a mixture comprised by any of the chemical substances in the mixture and if such data would

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otherwise be entitled to protection from disclosure under subsection (a), then such data is not to be disclosed. In referring to data "disclosing the portion of the mixture comprised by any of the chemical substances in the mixture," the Committee intends to protect confidential trade secret information respecting the specific formulation of a mixture. However, the Committee does not intend to prohibit the Administrator from disclosing the chemical substances comprising the mixture by their order of quantity in the mixture.

Subsection (b) (2) provides that if a request is made under the Freedom of Information Act for health and safety information obtained under this bill, the Administrator may not deny the request on the basis of the exemption provided in subsections (b) (3) or (b) (4) of 5 U.S.C. 552. Thus, health and safety information which is not subject to the prohibition on disclosure prescribed by section 14(a) of the bill is not exempt from disclosure under subsection (a) of section 552 by virtue of subsection (b) (4) of that section. In addition, in considering a request under the Freedom of Information Act, the Administrator may

not disregard section 14(b)'s specific exemption for health and safety information from section 14 (a) 's prohibition on disclosure and assert that section 14(a) provides a statutory exemption from disclosure of such information.

The purpose of subsection (b) is to clarify that health and safety information is not entitled to confidential treatment either under subsection (a) or the Freedom of Information Act. The subsection should not be construed to imply that in the absence of such a provision, health and safety information would be entitled to such confidential treatment.

Subsection (c) provides that any person submitting data under the bill may designate that data which the person believes is entitled to confidential treatment. Such data may be submitted separately from the other data. If the Administrator proposes to release data which has been so designated, the Administrator shall notify in writing and by certified mail the person who submitted the data. If the release of data is made pursuant to a request under the Freedom of Information Act, the notice must be given immediately upon approval of the request by the Administrator. Such immediate notification is required so that any disclosure required under the Freedom of Information Act shall not be unduly delayed by the requirements of this subsection. The Administrator may not release the designated data until the expiration of 30 days after the person submitting the data has received the notice.

Subsection (d) provides criminal penalties for officers and employees of the United States and former officers and employees who knowingly and willfully disclose information protected from disclosure by section 14. Penalties of up to one year imprisonment or a fine of up to \$5,000 or both are provided. Since this subsection provides for criminal penalties, section 1905 of title 18 of the United States Code (respecting criminal penalties for disclosure of confidential information) is waived.

Subsection (e) provides that all information reported to or otherwise obtained by the Administrator under the bill shall be made available upon written request of any duly authorized committee of the

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Congress to such committee. It is the Committee's view that the inherent authority of Congress, as the constitutionally established legislative branch, assures access to such information, and thus the provision is not necessary to assure such access. Rather, the provision was included merely to give expression to such power and sets forth procedures for the exercise of the power.

SECTION 15, PROHIBITED ACTS

Section 15 makes it unlawful for any person to fail or refuse to comply with any section of the bill, or any rule, order or requirement promulgated under the bill. Specifically, the section forbids any person to fail or refuse to comply with any rule or order promulgated under section 4, any requirement prescribed by section 5, or any rule or order promulgated under section 5 or 6. It also forbids any person to use for commercial purposes a chemical substance or mixture which the person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5, a rule or order under section 5 or section 6, or an order issued in an action under section 5 or 7. The term used for commercial purposes is intended to be interpreted broadly to include any use in manufacturing, processing, or distribution in commerce or any other activity for commercial purposes. Further, the section forbids any person to fail or refuse to establish or maintain records, submit reports, notices or other information or permit access to or copying of records as required by the bill or any rule under the bill. In addition, this section forbids any person to fail or refuse to permit entry or inspection as required by section 11.

SECTION 16, PENALTIES

Section 16 states the penalties for violations of section 15 of the bill.

Subsection (a) provides that any person who violates a provision of section 15 shall be liable for a civil penalty of up to \$25,000 for each such violation. Each day a violation continues shall constitute a separate violation. A civil penalty is to be assessed by the Administrator by an order made on the record after opportunity for a hearing in accordance with the provision of section 554 of title 5 of the United States Code. The opportunity for a hearing shall be provided by giving written notice to any person who may be subject to the order.

The notice shall inform the person that the Administrator proposes to issue an order assessing a civil penalty. The Administrator must provide the person an opportunity to request, within fifteen days of receipt of the notice, a hearing on the order. Although commission of one of the acts prohibited by section 15 automatically makes one subject to the assessment of a civil penalty, the Administrator may take

into consideration certain mitigating circumstances in determining the amount of the civil penalty. The Administrator shall consider the nature, circumstances, extent, and irreversibility of the violation. The Administrator shall also consider the ability of the violator to pay, the effect on the violator's ability to continue to do business, any history of prior violations, the degree of culpability, and other matters as justice may require. The Administrator is granted discretion to com-

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promise, modify, or remit any civil penalty which may be imposed under subsection (a). Although no time period is provided in the statute, it is anticipated that any compromise, modification, or remission would occur within a reasonable time after assessment of the civil penalty.

Any person who requested a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing such a penalty may file a petition for judicial review of the order with the United States Court of Appeals for the District of Columbia or for any other circuit in which the person resides or transacts business. The petition must be filed within thirty days after the date the order making the assessment is issued.

Actions for collection of civil penalties shall be brought by the Attorney General.

Subsection (b) provides that any person who knowingly or willfully violates any provision of section 15 shall be subject upon conviction to a fine of not more than \$25,000 for each day of violation or imprisonment for not more than one year, or both.

Under subsection (c) the Administrator is authorized to require any person who has manufactured, processed, or distributed in commerce a chemical substance or mixture in violation of a requirement under paragraph (1) or (2) of section 6(a) to give notice of the risk associated with the substance or mixture. Such person may be required to give such notice to processors or distributors in commerce and, the extent reasonably ascertainable, to any other person in possession of or exposed to such substance or mixture. Such person may also be required to give public notice of the risk and to either replace or repurchase the substance or mixture. The determination that the person has manufac-

tured, processed, or distributed in commerce a chemical substance or mixture in violation of a requirement under section 6(a)(1) or (2) must be made by order made on the record after opportunity for an agency hearing.

SECTION 17, SPECIFIC ENFORCEMENT AND SEIZURE

Section 17 provides for injunctive enforcement of requirements of the bill. It also provides for seizure of any chemical substance or mixture which was manufactured, processed, or distributed in commerce in violation of the bill or any rule or order under the bill. Seizure is also provided for any article containing such a substance or mixture.

Subsection (a) provides that the United States district courts will have jurisdiction to restrain any violation of section 15 (prohibited acts) or to restrain any person from manufacturing or processing a chemical substance before the expiration of any applicable period under section 5. In addition, the district courts are granted jurisdiction to restrain any person from taking any action prohibited by a rule or order under section 5 or 6 or to compel the taking of any action required by or under the bill. This subsection also contains provisions relating to venue, service of process and subpoena of witnesses.

Under subsection (b) any chemical substance or mixture which was manufactured, processed or distributed in commerce in violation of the bill or of any rule or order promulgated under the bill or any

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article containing such substance or mixture shall be liable to be proceeded against for seizure and condemnation. Actions for such seizure and condemnation may be brought in any United States district court within the jurisdiction of which such substance, mixture, or article is found, and the proceedings shall conform as nearly as possible to proceedings in rem in admiralty.

SECTION 18, PREEMPTION

Section 18(a) provides generally that nothing in the bill shall effect the authority of a State or political subdivision to establish or continue in effect regulation of any chemical substance, mixture or article containing a chemical substance or mixture. However, except as other-

wise provided, rules under section 5 and 6 shall preempt nonidentical State and local requirements respecting the same chemical substance, mixture, or article containing a substance or mixture, if the State or local requirement addresses the same risk to health or environment associated with the chemical substance, mixture, or article. Similarly, if the Administrator establishes a testing rule under section 4, no State or political subdivision may establish or continue in effect a testing rule for purposes similar to those for which the testing is required under section 4.

However, rules under section 6(a)(5) relating to disposal do not preempt any State or local requirements. Further, if a State or local requirement is adopted under the authority of the Clean Air Act or any other Federal law, the Federal rule shall not preempt the State or local requirement. Thus, for instance, State emission standards, effluent limitations, or other regulatory requirements adopted under the Clean Air Act or Federal Water Pollution Control Act would not be preempted by rules issued under this bill, even though the State or local requirement were more stringent. This would be the case if a State limitation, standard, or requirement were adopted, submitted, and approved as part of a State implementation plan required under Federal law. Similarly, the preemption would not apply to a State or local limitation, standard, or requirement if it were adopted under the State or local government's authority which is preserved by a provision of Federal law, such as a section 116 of the Clean Air Act or sections 1414(e) or 1424(c) of the Public Health Service Act (relating to safe drinking water) .

The Committee recognizes the traditional role of the State and local governments in providing for the protection of their citizens. As a result in addition to the specific exemptions from the preemption provision, the Committee bill provides a means whereby a State or political subdivision may seek an exemption from the Federal preemption in order to provide a higher degree of protection for their citizens than that provided by regulations under this bill. Under subsection (b) , the Administrator may by rule exempt from the preemption provisions a requirement of a State or political subdivision if three conditions are satisfied. First, compliance with the State or local requirement must not cause a violation of the applicable requirement under the bill. Second, the State or political subdivision requirement must provide a significantly higher degree of protection from the risk. Third, the State

or local requirement must not through difficulties in marketing, distribution, or other factors, unduly burden interstate commerce.

SECTION 19, JUDICIAL REVIEW

Section 19 sets out the procedures for judicial review of rules issued under sections 4, 5, or 6 of the bill. Subsection (a) provides that petitions for judicial review must be filed within 60 days following the promulgation of a rule under section 4, 5, or 6. Such petitions are to be filed with the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which the petitioner resides or in which the petitioner's principal place of business is located. The subsection contains provisions for filing the record of the proceedings on which the rule was based. The Committee anticipates that ordinarily a certified list of the record may be provided in accordance with applicable appellate rules of procedure unless the court requests otherwise.

The record means any rule, any transcript required of any oral presentation, any written submission of interested parties and any other information which the Administrator considers to be relevant to the rule and with respect to which the Administrator, on or before the date of promulgation of the rule, published a notice in the Federal Register identifying the information. Such notice need only list the information ; it need not summarize such information.

By so defining the record, the Committee intends that the public be fully apprised of the basis for the Administrator's action, l^he Administrator should include in the record those documents in the Administrator's possession which are of material relevance to the rule, including, of course, those which contradict as well as support the Administrator's position. The Committee expects that the Administrator will, throughout the proceedings for the issuance of a rule, keep current and make available upon request a listing of information to be included in the record, as well as permit access to and copying of documents to be included in the record.

Subsection (b) describes when the Court may require the Administrator to provide an opportunity for the petitioner to adduce additional data, views or arguments. The petitioner must show that such data, views, or arguments are material and that there are reasonable grounds for the petitioner's failure to adduce such data, views, or arguments in the proceeding before the Administrator.

Subsection (c) grants the court jurisdiction to review the rule in accordance with chapter 7 of title 5 of the United States Code and to grant appropriate relief. Any rule promulgated by the Administrator

under section 4, 5, or 6 is to be affirmed unless the determination or findings required to be made under the applicable section are not supported by substantial evidence on the record taken as a whole. Thus, it is the intent that the traditional presumption of validity of an agency rule would remain in effect. The Committee recognizes that in rulemaking proceedings which are essentially informal and which involve both determinable facts and policy judgments derived therefrom, the traditional standard for review is that of "arbitrary and capricious." The use of the substantial evidence standard for such rulemaking is not, however, without precedent, and the courts have

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adequately adapted to it.[^] The Committee has chosen to adopt the "substantial evidence test," for the Committee intends that the reviewing court engage in a searching review of the Administrator's reasons and explanations for the Administrator's conclusions. However, the Committee does not intend to imply that the Court is to substitute its judgment for the policy judgment of the Administrator.

The judgment of the court shall be final subject to review by the Supreme Court. Further, such judgment may include an award of costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such is appropriate. Such costs of suit and fees may also be awarded by the Supreme Court in its decision on review of any such judgment.

Subsection (d) provides that the remedies provided in this section shall be in addition to and not in lieu of any other remedies provided by law.

SECTION 20, citizens' CIVIL ACTIONS

Section 20 authorizes actions by individuals to restrain violations of the bill and to compel the Administrator to perform any statutory duty arising under the bill. Such citizen actions can provide an important aid in enforcing the bill. In adopting the provision, your Committee is following the ample precedent established in other Federal laws. The Clean Air Act, Federal Water Pollution Control Act, Noise Control Act, the Consumer Product Safety Act, and title XIV of the Public Health Service Act (relating to safe drinking water) all contain similar provisions. In addition a number of States

authorize citizen enforcement actions.

Subsection (a) authorizes any person to commence a civil action to (1) restrain violations of the bill or any rule prescribed under section 4 (testing), section 5 (manufacturing and processing notices) and section 6 (regulation), or (2) compel the Administrator to perform any nondiscretionary act or duty under the bill. Actions shall be brought in the district court in which the alleged violation occurred or in which the defendant resides or has his or her principal place of business. The district courts shall have jurisdiction without regard to the amount in controversy or the citizenship of the parties. Citizen suits against persons alleged to be in violation of the bill or a rule issued under section 4, 5, or 6 may be brought against the United States and against any other governmental instrumentality or agency, but only to the extent permitted by the Eleventh Amendment to the Constitution. The section does not authorize the collection of damages in any such suit.

Under this provision, the person bringing the suit serves as a private attorney-general to protect the public interest. Thus it is important that the plaintiff be a competent and "appropriately" interested representative of the public interest. The Committee believes that the wisest means of assuring this is to rely upon the court's inherent power to dismiss collusive suits and upon the broad rights of intervention in suits under this section.

J[^]See Industrial Union Department, AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir.

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To assist persons bringing suits under the section and similar sections of other laws administered by the Administrator, the Committee recommends that the Administrator adopt uniform policies and procedures: (1) governing the Administrator's role in such suits as intervenor or amicus ; (2) specifying the extent to which the Administrator will comment on proposed consent orders; and (3) providing for cooperation with parties instituting civil enforcement actions to insure that the Administrator's expertise and factual data is made available to such parties to the fullest extent possible.

Subsection (b) specifies certain limitations on the commencement of a civil action under this section. Prior to the commencement of a civil action to restrain a violation of the bill or a rule under the bill, the plaintiff must give 60 days notice to the Administrator and the alleged violator. If the Administrator has instituted and is diligently prosecuting a civil action against the alleged violator to compel compliance, no suit may be brought under the section. However, if the Administrator's action is not commenced until after the notification, the person who gave notification may intervene in the Administrator's suit as a matter of right.

Sixty days notification to the Administrator is also a prerequisite to the commencement of an action against the Administrator to compel the performance of a nondiscretionary act or duty, except in the case of an action involving an imminent hazard. In the case of the alleged imminent hazard, the notification period is 10 days.

Subsection (c) authorizes the Administrator to intervene as a matter of right in any civil action under this section to which the Administrator is not a party. The award of the costs of suit and reasonable fees for attorneys and expert witnesses is authorized, if appropriate.

Nothing in this section shall restrict the right of any person under any statute or the common law to seek enforcement of the bill, or any rule under the bill, or to seek other relief.

Subsection (d) provides that, upon application of the defendant, a court may consolidate two or more civil actions brought under subsection (a) involving the same defendant and the same issues or violations when such actions are pending in two or more judicial districts.

SECTION 21, citizens' PETITIONS

Section 21 provides an important mechanism for public initiation of actions to protect the health and environment. Under section 21(a) j any person may petition the Administrator to initiate a proceeding] for the issuance, amendment or repeal of a rule under section 4, 5(c), or 6(a).

Subsection (b) sets out the procedures for such citizen petitions. Any petition is to be filed in the principal office of the Administrator, and it must set forth the facts which the petitioner claims establish that it is necessary to issue, amend, or repeal a rule under section j 4, 5(c), or 6(a). A petition for amendment or repeal of an existing rule should contain newly discovered, noncumulative information which was not presented for the Administrator's consideration in promulgating the rule or on any appeal of the rule, and failure to include such information would be adequate basis for denying the peti-

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tion. Otherwise, the provisions of this section could vitiate the procedures provided in section 19 for review of a rule under section 4, 5, or 6.

The Administrator may hold public hearings or conduct any investigational proceeding appropriate to determine whether or not a petition should be granted. Within 90 days the Administrator must either grant or deny the petition. If the petition is granted, the Administrator shall promptly commence an appropriate proceeding to take the action requested. If the petition is denied, the Administrator must publish in the Federal Register the reasons for the denial.

If the Administrator denies the petition, or if the Administrator fails to act on the petition within the specified 90-day period, the petitioner may commence a civil action in a United States district court to compel the initiation of the requested rulemaking proceeding. Such action must be filed within 60 days.

Subsection (b)(4)(B) sets out provisions applicable to the civil action in the case of a petition requesting the issuance of a rule under Section 4, o(c), or 6(a). Subsection (b) (4) (B) does not apply with respect to civil actions respecting petitions for amendment or repeal 3f rules. Subsection (b) (4) (B) provides the petitioner for the issuance of a rule with an opportunity for a de novo proceeding before the 30urt. If the petitioner makes certain requisite showings, the court ^hall order the Administrator to initiate the requested action unless the court finds that the failure of the Administrator to initiate the [●equested action was not unreasonable.

In the case of a petition for the issuance of a rule \nder section 4, he petitioner must show that the manufacture, distribution in commerce, processing, use or disposal of the substance or mixture to be mbject to the rule may cause or significantly contribute to an unreasonable risk to health or the environment. If the petition was for the issuance of a rule under section 5fc), the petitioner must Show that the manufacture, processing, distribution in commerce, ise or disposal of the substance requested to be subje-ct to the rule ●auses or significantly contributes to or may cause or significantly contribute to an unreasonable risk to health or the environment. If

he petition requests the issuance of a rule under section 6(a), the petitioner must show that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use or disposal of the substance or mixture causes or significantly contributes to or will cause or significantly contribute to an unreasonable risk to health or the environment.

If the petitioner makes the requisite showing, the court shall order the Administrator to initiate the requested rulemaking action unless the court finds that the failure of the Administrator to initiate such action was not unreasonable. In making the latter determination, the court is to consider the priorities of the Administrator, the resources available to the Administrator to take the action requested by the petitioner, and other relevant factors. The Committee intends that the court carefully review the Administrator's priorities and resources to determine if the failure of the Administrator to initiate the requested action was unreasonable in light of the risk demonstrated by the petitioner.

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Although the court may order the Administrator to initiate the requested rulemaking proceeding, the court may not determine what the final outcome of the rulemaking proceeding should be nor does the court's determination that a proceeding should be commenced relieve the Administrator of any responsibility to make any findings which are requisite in the exercise of any of the authorities under sections 4, 5 or 6. Costs of suits and reasonable fees for attorneys and expert witnesses may be awarded if the court determines it is appropriate. The remedies provided by section 21 shall be in addition to, not in lieu of, other remedies provided by law.

SECTION 22, NATIONAL DEFENSE WAIVER

Section 22 provides that the Administrator shall waive compliance with any provision of the bill upon a request and a determination by the President that the waiver is necessary in the interest of national defense. If a waiver is provided the Administrator must maintain a written record of the basis for the waiver and make the record available for in camera examination when relevant in a judicial proceeding under the bill. The Administrator is to publish a Federal Register notice informing the public that the waiver was granted for national

defense purposes unless upon request of the President, the Administrator determines to omit the publication because it would be contrary to the interests of national defense. In such a situation the Administrator shall submit notice to the Armed Services Committees of the Senate and House of Representatives.

SECTION 23, EMPLOYEE PROTECTION

Section 23 provides protection for employees who may cooperate with the Administrator.

Subsection (a) prohibits any employer from discharging any employee or otherwise discriminating against any employee with respect to compensation, terms, conditions, or privileges of employment because the employee (or persons acting under request of the employee) has commenced, caused to be commenced, or is about to commence a proceeding under the bill. Protection is also provided for any employee who has testified, or is about to testify in any such proceeding, or has assisted or participated in a proceeding or any other action to carry out the purposes of the bill.

Under subsection (b) any employee who believes that he or she has been discharged or otherwise discriminated against in violation of the section may file a complaint with the Secretary of Labor. The Secretary shall conduct an investigation of the alleged violation. The investigation must be completed within thirty days of the receipt of the complaint. Both the complainant and the person alleged to have committed the violation shall be notified in writing of the results of the investigation. Within ninety days of the receipt of the complaint, the Secretary shall, unless there is a settlement respecting the complaint, issue an order providing appropriate relief or denying the complaint. Such order shall be made on the record after notice and opportunity for agency hearing. If the Secretary determines that a

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violation of this section has occurred, the Secretary shall order the person who committed the violation to take affirmative action to abate it, to reinstate the complainant along with compensation including back pay, terms, conditions, and privileges of the complainant's employment ; compensatory damages ; and where appropriate, exemplary damages. Costs and expenses reasonably incurred by the complainant

in bringing the complaint may also be assessed.

Subsection (c) provides for judicial review of an order of the Secretary. Any adversely affected person may obtain review of the Secretary's order in the United States Court of Appeals for the circuit in which the violation allegedly occurred. The petition for review must be filed within 60 days from the issuance of the Secretary's order and review shall conform to chapter 7 of title 5 of the United States Code.

Subsection (d) provides for enforcement of orders by the Secretary in the district court for the district in which the violation occurred. The district courts are granted jurisdiction to grant all appropriate relief. Such actions shall be heard and decided expeditiously.

Subsection (e) provides that the section shall not apply to any employee who deliberately caused a violation of any requirement of the bill, unless the employee was acting under directions from the employer.

SECTION 24, EMPLOYMENT EFFECTS

Section 24 (a) provides for continuing evaluations of the potential effects on employment of any rule or order under section 4, 5 or 6 or a requirement of section 5.

Subsection (b) authorizes the Administrator upon request of an employee to investigate any discharge or layoff or threatened discharge or layoff or other adverse effects on employment allegedly resulting from a rule or order under section 4, 5 or 6 or a requirement of section 5. The Administrator shall if requested by any interested person hold public hearings on any matter involved in the investigation unless the Administrator determines that there are no reasonable grounds for holding such hearings. The person requesting the hearing must be notified in writing of any determination not to hold a requested hearing.

If public hearings are held, the Administrator must provide at least five days notice to the person making the request for the investigation and to any person identified in such requests. A transcript shall be made of the hearings and each employee who requested a hearing and the employer of such employees shall be required to present information respecting the adverse effects or threatened adverse effects. Upon completion of the investigation, the Administrator shall make findings of fact and any recommendations deemed appropriate. Such findings and recommendations shall be made available to the public.

Subsection (b) also provides for subpoenas, oaths and payment of witness fees.

SECTION 2 5, STUDIES

Subsection (a) requires the Administrator to conduct a study of all Federal laws administered by the Administrator to determine whether and under what conditions, if any, indemnification should be accorded any person as a result of action taken by the Administrator

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under such laws. The General Accounting Office is to review and comment on the adequacy of the study.

Subsection (b) requires the Council on Environmental Quality to coordinate a study of the feasibility of establishing a standard classification system of chemical substances and related substances and a standard means for storing and obtaining rapid access to information respecting such substances.

SECTION 2 6, ADMINISTRATION OF THE ACT

Section 26(a) provides that upon request by the Administrator, each Federal department and agency is authorized to make its services, personnel, and facilities available to the Administrator to assist in the administration of the bill and to furnish to the Administrator such information, data, estimates, and statistics and to allow the Administrator access to all information in its possession as the Administrator may reasonably determine to be necessary for the administration of the bill.

Subsection (b) provides that the Administrator may by rule require the payment of reasonable fees from any person required to submit data under section 4 or 5 to defray the cost of administration of the bill. The fee may not exceed \$2,500. In setting the fee the Administrator must take into account the ability to pay of the person required to submit the data and the cost of the Administrator of reviewing the data. Such fees may be shared in cases where the expenses of testing are also shared.

Subsection (c) authorizes the Administrator to take action with respect to categories of chemical substances or mixtures rather than with respect to individual chemical substances or mixtures. For example, if under section 4(a) the Administrator finds that the manufacture, distribution in commerce, processing, use, or disposal of a

category of chemical substances may cause or significantly contribute to an unreasonable risk, that there are insufficient data and experience with respect to that category, and that testing of that category of substances is necessary to develop data, the Administrator could issue a section 4(a) testing rule respecting the category of chemical substances. Of course, once test data has been submitted by a manufacturer or processor with respect to a substance within the category, such data may provide a basis for manufacturers and processors of other chemical substances within the category to apply as provided in section 4(c) for an exemption from the testing requirement and thereby unnecessary time and expense could be saved the affected manufacturers and processors by not having to test each minor modification of substances within the category. j

It should be noted that in taking action under any provision of the bill respecting a category of chemical substances, the Administrator will not have to make the requisite finding for such action with respect to every chemical within the category. j

The Committee agrees with the National Academy of Science recommendation that the EPA adopt, whenever scientifically possible, a generic approach for the regulation of chemicals.^

* "Decisionmaking for Regulating Chemicals in the Environment", p. 43 (1975).

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The subsection defines the terms category of chemical substances and category of mixtures. *

Subsection (d) directs the establishment within the Environmental Protection Agency of an identifiable office to carry out the following:

(1) The provision of technical and other nonfinancial assistance to manufacturers and processors respecting the requirements of the bill which they must meet.

(2) Informing manufacturers and processors of the policy of the agency respecting the application to them of the requirements of the bill.

(3) Informing manufacturers and processors of the means and methods by which they may comply with such requirements.

The office to be created should provide an important means of insuring that manufacturers and processors are fully informed of the provisions of the bill. The services of the office should be particularly helpful to small and medium-sized manufacturers and processors which typically do not have an extensive legal staff to deal with the complexities of the bill and rules promulgated under it, and the Committee intends that the assistance office focus its efforts on helping such small and medium-sized manufacturers and processors. The office should answer general inquiries concerning procedural and substantive requirements of the bill and rules promulgated under it as well as respond to requests respecting the policy of the agency respecting the application of requirements to a specific manufacturer or processor. In addition, the Committee anticipates that the office will provide assistance to manufacturers and processors by referring them to other offices within the agency when it is necessary for inquiries to be handled by another office. Of course, the provisions of section 14 respecting disclosure of data would apply to any information received by the assistance office from a manufacturer or processor.

In addition to responding to inquiries, the office should through publication of pamphlets, circulars, and other methods conduct general educational efforts designed to reach manufacturers and processors and inform them of the requirements of the legislation, j Certain regulatory statutes contain provisions granting general rulemaking authority to the agencies administering the statutes. See, e.g., section 701 of the Federal Food, Drug, and Cosmetic Act. However, such provisions have been construed to grant such agencies substantive rulemaking authority'. The bill contains specific grants of substantive rulemaking authority to the Administrator (see, e.g., sections 4, 5, 6, and 8) and the Committee does not intend that the Administrator have any substantive rulemaking authority which is not specifically granted. A general rulemaking authority is not needed to authorize the issue of procedural, interpretative, or similar administrative rules,¹ consequently, such a provision is not included in the bill.

SECTION 2 7 , DEVELOPMENT AND EVALUATION OF TEST METHODS

This section provides authority for the conduct of and financial assistance for projects for the development and evaluation of inexpensive and efficient methods for determining and evaluating the health

1 See authorities cited in *Morrow v. Cuiifton*, 326 F.2d 36. 44 (1963).

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and environmental effects of chemical substances and mixtures, which methods may be used in developing test data to comply with a section 4 testing rule. The Secretary of Health, Education, and Welfare will, in consultation with the Administrator and acting through the office of the Assistant Secretary for Health, administer this section.

The Secretary is to make annual reports to Congress respecting grants and contracts made under this section and is to periodically publish in the Federal Register reports describing the progress and results of projects assisted by such grants and contracts.

In adopting this section the Committee has indicated its intent that efforts should be made to develop and evaluate inexpensive and efficient testing methods. Such methods could significantly reduce the cost and time involved in complying with testing rules under section 4.

SECTION 2 8, AUTHORIZATION OF APPROPRIATIONS

Section 28 authorizes to be appropriated to the Administrator for i carrying out the bill \$11,100,000 for the 1978 fiscal year, \$10,100,000 for the 1979 fiscal year, and \$11,100,000 for the 1980 fiscal year. No part of the funds so authorized to be appropriated shall be used to construct any research laboratories.

SECTION 2 9, ANNUAL REPORT

Section 29 requires the Administrator to prepare and submit to the President and the Congress annually a comprehensive report on the administration of the bill. The report shall include information regarding testing required under section 4; notices under section 5; action taken under section 5(g) ; rules issued under section 6; judicial actions taken under the bill; and a summary of major problems encountered in the administration of the bill and recommendations for additional legislation.

SECTION 30, EFFECTIVE DATE

Section 30 provides that the effective date of the bill shall be October 1, 1977.

PROGR.VM Oversight

The bill provides new authority for the Administrator of the Environmental Protection Agency. Consequently, no oversight activities have been conducted by the committee with respect to such authorities and no oversight reports have been made by the Committee's Subcommittee on Investigations and Oversight or the Committee on Government Operations.

Inflationary Impact Statement

Pursuant to rule XI, clause 2(1) (4) of the Rules of the House of Representatives, the Committee makes the following statement regarding the inflationary impact of the reported bill :

Information available to the Committee indicates that the inflationary impact of the bill would be extremely slight. The Environ-

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mental Protection Agency has estimated that the annual cost of the legislation to the regulated industry will range between \$80 to \$140 million. The General Accounting Office reviewed the EPA estimate and concluded that it was probably realistic, although testing costs could be somewhat higher than estimated by EPA, resulting in total annual costs to industry of \$100 to \$200 million.

Taking into account such annual costs to industry of \$100 to \$200 million and projected EPA expenditures of \$11 million annually, the inflationary impact of the legislation should be extremely small. These annual costs are equivalent to about one percent of the annual cost of \$20 billion which will be expended for water and air pollution controls during the 1973-1982 period, as estimated by the Council of Environmental Quality. A study performed by Chase Econometrics, Inc., Macroeconomic Aspects of Federal Control Programs, concludes that an annual expenditure of \$20 billion during the 1973-1982 period would result in an average annual rate of increase of 0.2 percent for the Wholesale Price Index. 0.1 percent for the GXP Price Index, and 0.2 percent for the Consumer Price Index. Since the estimated expenditure for this bill is only a fraction of that utilized in the Chase Econometrics, Inc. study, the inflationary impact would be substan-

tially lower than that projected in that study. As a result, the Committee concludes that the inflationary impact of costs of the bill will be extremely slight.

COXGRESSIOXAL BLTXSET OFFICE CoST ESTIMATE

July 1, 1976.

1. Bill Number: H.R. 14032.
- i 2. Bill Title : Toxic Substances Control Act.

3. Purpose of Bill :

This bill establishes procedures and authorizes the appropriation of funds to regulate potentially toxic chemical substances. It mandates the Administrator of the Environmental Protection Agency (EPA) to develop regulations to ensure adequate testing of potentially toxic chemicals. It requires that the Administrator be notified of the impending introduction of any new chemical or significant new uses of existing ones, and empowers him to delay such introduction up to ninety days. The bill also authorizes the Administrator to issue rules which prohibit or limit the manufacturing, processing, or distribution of dangerous chemicals or mixtures, and to carry out inspections. Various guidelines and procedures are established for the Administrator to follow in implementing the bill, as well as for citizens' civil actions and petitions to the Administrator.

The bill authorizes appropriations of \$11.1 million for fiscal year 1978, \$10.1 million for fiscal year 1979, and \$11.11 million for fiscal year 1980 for the purpose of carrying out this Act. This is an authorization bill, which requires subsequent appropriation action.

4. Cost Estimate : This bill would authorize appropriations for the toxic substances control program for fiscal years 1978 through 1980. The budget impact of this bill is shown below

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[In millions of dollars]

Fiscal year-

1978

1979

1980

1981

1982

1983

Authorization level

11.10

10.10

11.11

Estimated cost..

8. 30

9. 50

10. 80

2.70

0. 90

0.11

All costs in this bill fall within Function 300.

5. Basis of Estimate : The Office of Toxic Substances in EPA, which will implement this bill, estimates that general abatement and control activities (e.g., promulgating testing guidelines and monitoring new chemical introductions) will require seventy-five percent of the authorized amounts. Research projects are estimated to require twenty percent of the funds, and enforcement efforts, five percent. EPA anticipates the following spending rates for these types of accounts.

PERCENTAGE OUTLAY DISTRIBUTION

Year 1

Year 2

Year 3

Year 4

Abatement and control

84

12

4

Research

45

35

15

5

Enforcement . . .

60

27

10

3

6. Estimate Comparison : None.

7. Previous CBO Estimate : None.

8. Estimate Prepared By: Leo J. Corbett (225-5275)

9. Estimate Approved By :

James L. Blum,
Assistant Director for Budget Analysis.

Agency Reports . ;

Environmental Protection Agency,

Washington, D.C., June 27, 1975.

Hon. Harley O. Staggers,

Chairman, Committee on Interstate and Foreign Commerce, House of
Representatives, Washington, D.C.

Dear Mr. Chairman : This is in response to your requests of June 3,
1975 and June 17, 1975, for the views of the Environmental Protection
Agency on H.R. 7229 and H.R. 7664. Similar versions of the "Toxic
Substances Control Act," pending before your Committee.

This Agency and other concerned Federal departments and agencies
have just recently completed the development of the Administration's
position on S. 776, a similar version of the Toxic Substances Control
Act that is pending before the Senate Commerce Committee. Because
many of the provisions in the House bills are identical or similar to
provisions in the Senate bill, and in order to expedite our comments
to you with regard to this legislation, we are submitting our detailed
comments on the Senate bill to you. These comments on the similar
Senate legislation and our testimony now scheduled to be presented!

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before your Subcommittee on Consumer Protection and Finance on
July 10, 1975. will constitute our report to you on the toxic substances
control legislation.

Subject to adoption of the Administration's recommendations on this legislation as set out in our attached report on S. 776, and as will be included in our testimony before the Subcommittee, we would urge enactment of the Toxic Substances Control Act.

My staff and I stand ready to assist your Committee in any way possible toward the enactment of satisfactory legislation to control hazardous substances.

We are advised by the Office of Management and Budget that there is no objection to the submission of this report from the standpoint of the program of the President.
Sincerely yours,

John R. Quarles, Jr.,
Acting Administrator.

Enclosure.

Environmental Protection Agency,

Washington, June 25, 1975.

Hon. Warren G. Magnuson,
Chairman Committee on Commerce,
U.S. Senate, Washington, D.C.

Dear Mr. Chairman : This is in response to your request of March 6, 1975, for the views of the Environmental Protection Agency on S. 776, the "Toxic Substances Control Act."

We are in accord with the objectives of S. 776 and the general approach taken in the bill to control toxic substances. As we testified before your Subcommittee on the Environment on March 10, 1975, the bill contains the authorities which we believe are essential for effective toxic substances control legislation. We urged the enactment of toxic substances control legislation and indicated that we would have suggestions on some of the specific provisions of S. 776 when we submitted our report.

We note that S. 776 contains significant improvements over some of the toxic substances control bills that have been before the Committee the past four years. Many of these improvements are consistent with past EPA recommendations. It is not our intention in our report by concentrating on suggested revisions to the bill to detract from or fail to recognize the effort and improvements already evident in S. 776.

We have already stated in our testimony our objection to the provision that would preclude the Administrator from forwarding any budget estimates, legislative proposals, comments on legislation, or testimony to the Office of Management and Budget prior to the transmission of these same materials to the Congress. We also stated in our testimony that to designate by statute the specific responsibility of an Assistant Administrator may tend to create a problem of internal management.

We will discuss below a number of additional areas in S. 776 where we have particular problems and where we believe amendments are in order. These proposed amendments are set out in an attachment to this letter along with a number of important additional amendments and brief explanations of each. We urge that all of these amendments be favorably considered by the Committee.

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This report on S. 776, including the attached proposed amendments were jointly developed with the other concerned Federal departments and agencies and represents the views of the Administration on S. 776.

POLICY OF ADMINISTRATION

We are proposing that the "Declaration of Policy" section of the bill include recognition of the role of this legislation in complementing and supplementing a number of present Federal programs that deal with various aspects of toxic substance control. We are also proposing that the general requirement of the bill for consultation and coordination make specific reference to this policy statement. Such amendments would be of great assistance in the day to day administration of this legislation, both by assuring due regard for the responsibilities of other agencies, and by helping to establish the atmosphere of cooperation and interchange which is vital to the successful operation of comprehensive toxic substances legislation.

In line with this policy, and because of the special role of the Occupational Safety and Health Act of 1970 in providing workers with

protection from unsafe or unhealthful working conditions which may be created through the manufacture, distribution or use of toxic substances, we are also proposing some language for the bill and some language for the Committee report to assure that there will be no question about the respective regulatory jurisdictions of EPA and the Department of Labor.

DEFINITIONS

We are proposing that the definition of "chemical substance" be amended to provide the Administrator with some flexibility to exclude, in appropriate situations, certain substances from the definitions and thus from the requirements of the Act or from particular provisions of the Act. It would be almost impossible to draft the bills to exempt certain substances from the Act or, as more likely the case, from certain provisions of the Act in each situation where such is necessary. Scientific laboratory reagents are an example. Here it may very well be appropriate to exclude such products from the testing and regulatory provisions, but not necessarily the reporting and adverse effects provisions when they are used by certain research or scientific laboratories; on the other hand, we would not likely wish to exclude high school laboratories from any labeling requirements. An exclusion may also be in order for a substance not manufactured in commercial quantities. An excessive burden and inconvenience to the industry or the user would be averted with this flexibility in the Act.

We anticipate that the Administrator would exercise his discretion to exclude from the definition of chemical substances most substances manufactured in less than commercial quantities for the purpose of testing. Thus, most substances manufactured in less than commercial quantities would be exempt from the testing provisions of the bill. The proposed amendment would however enable EPA to require testing in those cases where the potential threat to health and the environment showed such testing to be necessary.

We are also proposing to add to the Act a definition for a "new chemical substance." This is necessary in order that chemical substances which were used in previous years for some purpose, and such

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use discontinued, do not become classified as existing chemicals, and

thus exempt from certain requirements relating to new substances.

TESTING

The testing provisions provide that standards for test protocols would be promulgated, rather than the test protocol itself. Testing would be required only for substances which the Administrator determines may present an unreasonable risk to health or the environment, where there are insufficient data to conclude that such a risk does or does not exist, and where testing would assist in making such a determination.

There is a provision in the testing requirement of the bill that we foresee as an undue burden upon the Administrator. While we agree that provision should be made for the sharing of testing costs in the event that there is more than one manufacturer of a substance for which testing is required, we are very reluctant to become involved in designating which manufacturer (or possibly a third party) should conduct the tests if the parties cannot reach an agreement. We are therefore recommending deletion of the provisions authorizing the Administrator to designate which party should do the testing.

A further amendment we are proposing with regard to the testing provisions is a specific requirement that the Administrator must consider alternative methods for meeting the standards for test protocols proposed by a manufacturer, such as one that might be less costly or more effective. This would insure that industry is allowed to use the best test protocols in meeting the testing standards.

PREMARKET SCREENING

We are proposing an amendment which will delete the authority in the bill to treat a rule proposed under section 6 during the premarket review period of a product as a final rule. Thus a chemical substance or product may be manufactured and distributed after the premarket review period unless a restriction is obtained under the imminent hazard provision of the Act. The substance or product, however, remains subject to all other provisions of the Act and a rule proposing restrictions on the substance or product may be proposed immediately during the premarket review period under section 6 and the rulemaking proceedings initiated at that time.

If it appears that the manufacture, processing, or distribution of a chemical substance or product will result in any unreasonable threat to human health or the environment prior to the completion of the rulemaking proceedings, action may be taken to restrict or ban it under the imminent hazard provisions of the bill, thus preventing it from becoming a threat to health or the environment.

QUOTAS

Another difficulty we have with S. 776 concerns the requirement that the Administrator provide for the assignment of quotas in any regulation limiting the amount of a substance which may be manufactured, imported, or distributed. The mandatory requirement of a quota sys-

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tern would make the regulatory process vastly more cumbersome and difficult to administer. Thus, we recommend that the quota provision be deleted. The Act already provides that when it is necessary to adopt a rule with respect to a chemical substance to protect against an unreasonable risk, the Administrator shall select the least stringent requirement practicable consistent with protection of health and the environment. In our view, restrictions limiting the amount of a substance that may be manufactured would be the most stringent requirement, other than a total ban, and the establishment of quotas would seldom be necessary. Nevertheless, we strongly recommend against becoming involved in the establishment of quotas for various manufacturers, even in such limited situations.

ECONOMIC IMPACT

S. 776 would require that the Administrator consider a number of relevant factors in promulgating rules with respect to a chemical substance. We are proposing that a specific provision be added that he also must consider the economic impact of such action, including, but not limited to, consideration of the effects on business, employment, and the national economy. Consideration of these factors are already inherent in the requirement that he consider all relevant factors. This amendment is submitted in lieu of other proposals that have already been made for the mandatory preparation of detailed economic impact statements at the time a regulation is promulgated.

HEALTH AND SAFETY STUDIES

We are proposing a revision of the requirement for the submission of health and safety studies, or lists of such studies, in order to provide some flexibility in this requirement. This should lessen the burden to industry in compiling the lists or submitting the studies, and to

EPA in not being overburdened with information it does not need or cannot effectively use. The amendment would require submission of lists of on-going and new studies, rather than the study, with a right to require the submission of a given study. It would authorize the Administrator to provide by regulation the types of studies to be included on the lists and the number of years for which prior studies must be listed. The amendment would also provide that a person would list studies which he knows are being made or have been made.

CONFIDENTIAL INFORMATION

We are recommending that the confidentiality provision, section 15 of S. 776, be amended in several respects. First, the substantive criterion for withholding data as confidential should be the test established by the Freedom of Information Act, 5 U.S.C. 552(b)(4). Our proposed amendment would have the effect of requiring nondisclosure of information obtained under the Toxic Substances Control Act which may be withheld under 5 U.S.C. 552(b) (4), i.e., "trade secrets and commercial or financial information obtained from a person and privileged or confidential." This will make the confidentiality standard more definite (because there exists a body of case law interpreting 5 U.S.C. 552(b) (4)) , and will promote uniformity.

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In addition to the exemption for disclosure to Federal officers and employees, a separate provision should allow disclosure to EPA contractors and their employees, under appropriate safeguards and after appropriate EPA findings that disclosure is necessary. EPA accomplishes a great deal of its Investigatory and analytical tasks by contract. If contractors are not allowed access to information under this bill. EPA could not perform its duties satisfactorily without substantial manpower increases. The recently-enacted Privacy Act, 5 U.S.C. 552a. provides that, for purposes of the section of the Privacy Act which imposes penalties on Government employees for wrongful use or disclosure of information entitled to confidentiality. Government contractors and their employees are to be considered Government employees (5 U.S.C. 552a (m)). AVE recommend inclusion of such a provision in the toxic substances bill. Our proposed amendments allow disclosure to contractors, and include a penalty for wrongful disclosure of information by Government employees (including contractors and their employees).

AVE also believe that the provisions relating to qualified scientists and individual names are not necessary. The term ''qualified scientists'' would be difficult to interpret, and in any event a scientist would have no greater rights under the subsection than would any person under our (proposed) basic confidentiality criterion. We believe that the Federal Privacy Act and the Freedom of Information Act provide ample i)rotection of the rights of individuals whose names appear in health and safety records.

Finally, w^th regard to access of information by Congress, we believe that such confidential information should be made available upon written request.

EXEMPrOX FROM FEDERAL PREEMPTION

We do not recommend the provisions of S. 776 which would allow State and local agencies to petition the Administrator for exemption from the I^ederal preemption requirements. State and local agencies would be allowed to regulate any toxic substance until such time as the Administrator puts into effect regulations for testing or restricting a substance. Thereafter, they could impose only a total ban on a substance. In view of the fact that the bill authorizes the Administrator to regulate with respect to geographic areas there would appear to be no need for a State or local agency to duplicate any regulations with respect to a substance after Federal regulations are in effect.

INTERAGENCY COOPERATION AND COORDINATION

Several amendments are being proposed to the Act to provide for the maximum cooperation and coordination among the several agencies of the Federal Government which have programs and responsibilities concerned with toxic substances. These amendments also would clarify that the Act is intended to complement and supplement existing laws and regulations such as the occupational health and safety requirements.

A number of Federal agencies, particularly the Department of Health, Education, and Welfare and the Occupational Health and Safety Administration of the Department of Labor have extensive

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responsibilities relating to toxic substances and human health and would stand to benefit from various provisions of the Act. For example, test results and other data generated in this area would, of course, be valuable to them and should be made available to all agencies concerned.

We are also recommending that the provision contained in previous bills before the Congress directing the Council on Environmental Quality to coordinate a study on the feasibility of establishing a standard classification system for chemical compounds and means of obtaining rapid access to information on such substances be restored to the Act. This section provides CP^Q the lead in establishing information systems in a manner currently being initiated. This is being done in conjunction with the agencies that would have been represented on the interagency committee as set out in the provision proposed to be deleted.

APPROPRIATIONS

We wish to make clear that our budget requests over the past several years have included funds to handle work anticipated to be required under toxic substances legislation, in the expectation that it would by now have been a reality. Consequently, considerable ground work has been laid and we anticipate that activities during fiscal year 1976 can be met within the \$8 million requested in the President's budget. Furthermore, we would point out that EPA wishes to remain in accord with the President's stated policy of holding new spending to an absolute minimum. Consequently we would point out that the authorization levels in S. 776 are in excess of amounts required to implement its provisions.

We have outlined above in our letter a number of the proposed amendments to the Act which we consider important; the attachment contains both these and additional amendments which we believe are of equal importance. We strongly believe that the adoption of these amendments would improve and strengthen the legislation and enable EPA to protect the health and the environment to the greatest practical extent while at the same time relieving the industry as well as the Government of some burdensome requirements.

With the favorable consideration of these proposed amendments, we would urge the enactment of S. 776.

My staff and I stand ready to assist your Committee in any way possible.

We are advised by the Office of Management and Budget that there

is no objection to the submission of this report from the standpoint of the program of the President.

Sincerely yours,

John R. Quarles, Jr.,
Acting Administrator.

Toxic Substances Control Act

PROPOSED AMENDMENTS BY EPA AND OTHER FEDERAL AGENCIES TO S. 7 7G

7. Definitions

a. Page 4, lines 1 and 2, delete the language "or in some other way suitable for formation of a group for the purposes of this Act".

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Explanation. – This amendment would delete the open-ended authority to designate almost- any grouping as a "category of chemical substances".

b. Page 4, line 5, delete paragraph (3) and insert new paragraph (3).

"(3) 'Chemical substance' means any chemical substance which (A) has an organic or inorganic particular molecular identify; (B) is any combined or uncombined radical or element; or (C) is any mixture; Provided, however, the Administrator may by regulation exclude from this definition as it applies to this Act, or to any provision of this Act, certain categories of chemical substances such as scientific laboratory reagents and samples, or chemical substances not manufactured in commercial quantities."

Explaiiotiori. – This amended definition of a "chemical substance" would provide the Administrator with flexibility to exclude, in appropriate cases, substances from the requirements of the Act, or a particular provision, where it does not need to be regulated, cannot be effectively regulated, or where meeting the requirements might be an undue burden. Scientific laboratory reagents, samples, and other chemical substances manufactured in less than commercial quantities are examples.

We urge the following language be included in the committee report with respect to this definition :

"Chemical substance would be defined to permit the Administrator The flexibility to provide by regulation for exempting chemical substances in certain categories or in less than commercial quantities from certain provisions of the bill. With respect to those chemical substances, it is anticipated that the Administrator will exercise his discretion to exclude, and thereby exempt, most of them from the testing provisions of the bill. The Administrator retains the authority to require testing in those cases where he finds a potential threat to health and the environment which indicates that such testing is necessary."

c. Page 5, line 2, delete the period and insert a semicolon after "studies" and delete remainder of paragraph; and on line 12, delete "study" and inspj-f stuHv, including health and safety data developed pursuant to such study,".

Explanation. - Correspondence relating to alleged adverse effects on health and similar reports are already required to be maintained in the section SCd) regarding records, and an amendment is proposed to authorize the Administrator to require submission of such records. There is no need to include unconfirmed complaints and notices in the definition of health and safety data and confusion results when this is attempted. It is also proposed to specifically provide that a health and safety "study" includes health and safety data developed pursuant to such a study.

d. Page 6, insert after line 14 the following and renumber other paragraphs accordingly.

"(15) 'new chemical substance' means any chemical substance which has not been manufactured or imported in commercial quantities into the United States during the 18-month period immediately prior to the effective date of this Act, regardless of its commercial production or importation in the United States prior to such time."

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Explanation. - A definition of "new chemical substance" is necessary in order that chemical substances that were used in prior years and

were discontinued do not become classified as existing chemicals for purposes of the Act.

2. Testing

a. Page 9, after Une 8, insert new paragraph (4) as follows :

"(4) The Administrator will consider alternative methods for meeting the standards for test protocols proposed by any person or governmental entity which is a manufacturer, processor, or importer of such chemical substance."

Explanation. - This amendment would specifically direct the Administrator to consider alternative methods for meeting the standards for test protocols proposed by a manufacturer, such as less costly or more effective test protocols.

b. Page 9, line 14, delete the last two sentences in paragraph (1) beginning with "If", and insert in lieu thereof : "If such an arrangement is made the Administrator shall be notified and the remaining such persons shall be exempted from requirements to perform tests."

Explanation. - We do not believe that the Administrator should become involved in designating which party (or a third party) should perform tests if the parties cannot agree among themselves. If a cost-sharing arrangement is made for one of the parties to do the testing, however, provision should be made to exempt the other parties from the testing requirements.

c. Page 11, line 15, insert after "arguments," the following: "and permit cross-examination to such extent and in such manner as in his discretion he determines is necessary and appropriate in view of the nature of the issue involved, the number of the participants and the nature of the interests of such participants,".

Explanation. - This amendment would permit limited cross-examination as is provided in the section 6 rulemaking procedures to restrict toxic chemicals.

3. Premarket screening; imminent hazard

a. Page 12, line 3, after "substance" add the following sentence: "Subsequent submission or request for submission of additional information shall not be regarded as changing the date of such notice."

Page 13, line 4, delete entire subsection (c) ; on line 25, delete beginning with "Unless" through "90 days" on line 2, page 14, and insert in lieu thereof "Ninety days"; renumber following subsections ac-

cordingly.

Page 14, line 10. after "substance" insert "before or,"

Page 22, line 13, after "environment," insert "that should be corrected immediately, and".

Explanation. - These amendments will delete the authority in the bill to treat a rule proposed under section 6 during the premarket review period of a product as a final rule. Thus a chemical substance or product may be manufactured and distributed after the premarket review period unless a restriction is obtained under the imminent hazard provision of the Act. The substance or product, however, remains subject to all other provisions of the Act and a rule promulgating

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restrictions on the substance or product may be proposed immediately during the premarket review period under section 6 and the rule-making proceedings initiated at that time.

If it appears that the manufacture, processing, or distribution of a chemical substance or product will result in any unreasonable threat to human health or the environment prior to the completion of the rule-making proceedings, action may be taken to restrict or ban it under the imminent hazard provisions of the bill, thus preventing it from becoming a threat to health or the environment.

The other amendments would clarify the date premarket notice commences, that restrictive rules under section 6 may be promulgated before or after manufacture or distribution of a substance, and that an imminent hazard is a risk that should be corrected immediately.

4. Restrictions on hazardous chemical substances

a. Page 17, line 23, delete "condition" and insert in lieu thereof "circumstances", and insert the following language in the committee report with respect to section 6 of the bill :

"The provisions of section 6 of S. 776 provide EPA with regulatory authority which will complement and supplement existing authority to control hazardous substances but not to preempt authority already vested by statute in other Federal departments or agencies.

Proposed new section 9(b) would preclude EPA from taking action under sections 6 and 7 which the Secretary of Labor could take under the Occupational Safety and Health Act. Thus, for example, the Administrator of EPA could not, under section 6(a)(8) require that a substance be labeled so as to prescribe requirements for its safe and healthful use which apply solely to workers in their place of employment. The Department of Labor, pursuant to the Occupational Safety and Health Act of 1970, already has authority to prescribe safe and healthful working conditions. Similarly, section 6(b)(2) shall not be construed to allow the Administrator of EPA to establish occupational safety and health standards.*

Explanation. - The clarification to paragraph 6(a)(2), together with the addition of legislative history with respect to paragraphs 6(a) (3) and 6(b) (2), will assist in implementation of the bill's policy to "complement and supplement" existing authority. These changes will assist in avoiding overlap between EPA and the Department of Labor's workplace safety and health authority.

b. Page 18. line 17. page 20, line 23, page 21. lines 6 and 12, delete "adulterated" (or "adulteration") and insert in lieu thereof "contaminated" (or "contamination").

Explanation. - We believe that the term "contaminated" (or "contamination") would more clearly express the intent of these provisions instead of "adulterated" which is often understood or defined as an intentional act.

c. Page 19, line 1. delete entire paragraph (3).

Explanation. - We believe that the Administrator should not become involved in assigning quotas to industry. The mandatory requirement of a quota system would make the regulatory process vast / more cumbersome and difficult to administer. The Act already provides that when it is necessary to adopt a rule with respect to a chemical sub-

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stance to protect against an unreasonable risk, the Administrator shall select the least stringent requirement practicable consistent with protection of the health and the environment. It is expected that the establishment of quotas would seldom, if ever, be necessary as such

would be a most stringent requirement. Nevertheless, we strongly recommend against becoming involved in the establishment of quotas,
d. Page 20, after line 15, insert the following :

"(4) the economic impact of such action, including, but not limited to. consideration of the effects on business, employment, and the national economy."

Explanation. - This amendment would specifically require the Administrator to consider economic impact in promulgating regulations, already inherent in the requirement that he consider all relevant factors. This would be in lieu of proposals that have been made for the mandatory preparation of detailed economic impact statements for issuance at the time any regulation is promulgated.

5. Suits by U.S. attorneys instead of by Administrator

Page 22, line 17, delete all after "may" through "so," line 19 and insert in lieu thereof :

"request a United States Attorney to petition an appropriate district court of the United States".

Page 39, line 3, delete "Administrator or the".

Page 46, line 7, delete "Administrator (or Attorney General on his behalf) " and insert in lieu thereof "Attorney General".

Page 46, line 8, after "commenced" delete "and is diligently prosecuting" on lines 8 and 9.

Explanation. - These amendments would carry out the long-time policy of having the Justice Department responsible for litigation instead of each Agency. In the citizen suit provisions, we believe that it is sufficient if the Attorney General has commenced an action and that it is not necessary to impose a further requirement that he be diligently prosecuting it, a concept which is at best difficult to litigate and at worst could lead to counter-productive court action.

6. Submission of records; health and safety studies

a. Page 25, line 3, add at end of sentence :

"The Administrator may require copies of such records pursuant to his responsibilities under sections 4, 5, 6, and 7 of this Act."

Explanation. - While the bill provides that records of adverse health effects caused by chemical substances are required to be main-

tained, no provision is made to require submission of such records. This amendment would correct that omission.

b. Page 25, line 4, delete subsection (e) and insert in lieu thereof: "(e) Health and Safety Studies. The Administrator shall promulgate regulations under which he may require any person who manufactures, processes, or distributes in commerce any chemical substance (or with respect to paragraph (3), any person who has possession of a study) to submit to him -

"(1) Lists of health and safety studies in process on or initiated after the date of enactment of this Act, conducted by or for such person, or known to such person ;

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" (2) Lists of health and safety studies conducted by or for such person, or known to have been made by any person, prior to the date of enactment of this Act ;

"(3) Copies of any such studies appearing on a list submitted pursuant to paragraphs (1) or (2), or otherwise known by him." Explanation. - This amendment would revise the provision requiring industry to report on or submit all health and safety studies. It would require submission of lists of on-going and new studies rather than the study, with a right to require submission of studies. It would authorize the Administrator to provide by regulation for the types of studies to be included on the lists, and the number of years of prior studies for particular types of studies; and would require a person to also list studies which he knows are being made or have been made.

7. Additional exemptions ; additional limitation on authority

a. Page 26, line 8, delete "or"; line 10, after "Act)" insert a comma and add "cosmetics (as such term is defined in section 201 (i) of the Federal Food, Drug, and Cosmetic Act),"; line 18, replace the period with a semicolon, and add the following :

"(3) any source material, special nuclear material or byproduct material as defined in the Atomic Energy Act of 1954 (42 U.S.C. 2011), as amended, and regulations issued pursuant thereto; or

"(4) tobacco and tobacco products."

Explanation. – We believe that cosmetics should also be exempted and materials regulated under the AEC Act, and do not believe that tobacco and tobacco products should be regulated under the Toxic Substances Control Act.

b. Page 26, after line 18, add new subsection (b) as follows, and renumber other subsections accordingly :

"(I) Notwithstanding any provision of this Act, the Administrator shall have no authority under sections 6 and 7 of this Act to take any action which the Secretary of Labor is authorized to take pursuant to the Occupational Safety and Health Act. In exercising authority pursuant to this Act, the Administrator shall not, for the purposes of applying section 4(b)(1) of the Occupational Safety and Health Act, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health."

Explanation. – The purpose of these changes is to eliminate the possibility of jurisdictional conflicts between EPA and the Department of Labor where actions taken by one authority might otherwise preclude or duplicate action of the other.

S. Interagency cooperation, and coordination

Page 3, after line 17, add the following new paragraph :

“(5) such authority over chemicals be exercised in such a manner as to complement and supplement existing Federal policies, regulations, and public laws regarding the protection of health and the environment, including occupational health, consumer safety, food, drug, and cosmetic authorities.”

Page 28, line 3, delete the sentence after "coordination. – " and insert in lieu thereof :

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"In administering the provisions of this Act, the Administrator shall consult and coordinate with the relevant agencies and instrumental-

ties of the Federal Government in accordance with the policies set forth in section 2 (b) of this Act."

Page 80, line 2, delete the last sentence of subsection (a) and insert in lieu thereof :

"The Administrator is authorized to make contracts and grants for research and monitoring as necessary to carry out the purposes of this Act in consultation with the Secretary of Health, Education, and Welfare on such contract and grant programs."

Page 30, line 7, delete entire subsection (b) and insert new subsection (b) as follows :

"(b) The Council on Environmental Quality in consultation with the Administrator, the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate departments or agencies, shall coordinate a study of the feasibility of establishing (1) a standard classification system for chemical compounds and related substances, and (2) a standard means for storing and for obtaining rapid access to information respecting such materials. A report on such study shall be published within 18 months after enactment of this Act."

Explanation. - These proposed amendments are intended to clearly set forth that it is the policy of the Act that there be the maximum cooperation and coordination among the several agencies of the Federal Government which have programs and responsibilities concerned with toxic substances; that the Act is intended to complement and supplement existing laws and regulations such as the Federal occupational health and safety requirements ; and that appropriate provisions are made to establish and to have access to information relating to chemical compounds.

A number of Federal agencies, particularly the Occupational Health and Safety Administration of the Department of Labor have extensive responsibilities relating to toxic substances and human health and would stand to benefit from various provisions of the Act. The testing of chemicals as they relate to the programs of these agencies and the test results and other information and data generated by the legislation would, of course, be valuable to them and must be made available.

One of these amendments specifically provides that the EPA Administrator will consult with the Secretary of Health, Education, and Welfare on any contract and grant programs for carrying out the research and monitoring activities under the Act, but not necessarily on each individual contract or grant.

We are also recommending that the provision contained in the previous bills before the Congress directing the Council on Environmental Quality to coordinate a study on the feasibility of establishing a standard classification system for chemical compounds and means of obtaining rapid access to the information on such substances be restored to the Act. This section provides CEQ to have the lead in establishing information systems in a manner currently being initiated. This is done in conjunction with the agencies that would have been represented on the interagency committee as set out in the provision proposed to be deleted.

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9. Additional assistant administrator

Page 28, line 15, delete subsection (a), renumber subsections (b) and (c) accordingly.

Explanation. – This amendment would delete the provision for a special category Assistant Administrator for Toxic Substances.

10. Administrative inspections

Page 31, line 6, insert "(a)" after "Sec. 12", and after line 21 insert new subsection (b) :

"(b) Notwithstanding the provisions of subsection (a), the Administrator shall have authority to inspect financial data records pertaining to testing costs when he orders contribution or reimbursement for the costs of performing tests in connection with the provisions of sections 4(c) and 5(f)."

Explanation. – Sections 4(c) and 5(f) authorize the Administrator to determine the equitable contribution or reimbursement of testing costs where more than one person benefits from the testing. This amendment would authorize access to financial data on testing costs in order for the Administrator to carry out the requirement to apportion the costs among those benefiting from the testing.

11. Disclosure of confidential information

Page 34, line 18, delete entire section 15 and insert in lieu thereof

the following revised section :

"confidentiality

"Sec. 15. (a) General. - Any information reported to, or otherwise obtained by, the Administrator or his representative under this Act, which is exempt from mandatory disclosure by reason of section 552 (b) (4) of title 5, United States Code, shall be entitled to confidential treatment and shall not be disclosed by the Administrator or by any officer or employee of the United States, except that such information may be disclosed -

"(1) to officers and employees of the United States in connection with their official duties ;

"(2) to contractors with the United States and employees of such contractors, if in the opinion of the Administrator such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States entered into on or after the effective date of this Act for the performance of work in connection with this Act ;

"(3) when relevant in any proceeding under this Act, except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding; or

"(4) to the extent that the Administrator determines it is necessary to protect health or the environment.

"(b) Access by Congress. - Notwithstanding any limitation contained in subsection (a) or any other provision of law, all information reported to or otherwise obtained by the Administrator or his representative under this Act shall be made available upon written request of any duly authorized committee of the Congress.

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"(c) Criminal Penalty for Wrongful Disclosure. - (1) Any officer or employee of the United States, or former officer or employee of the United States, who by virtue of his employment or official position has obtained possession of, or has access to, material which is entitled to confidential treatment under subsection (a), and who

knowing that disclosure of the specific material is prohibited by this section, willfully discloses the material in any manner to any person not entitled to receive it, shall be guilty of a misdemeanor and fined not more than \$5,000.

"(2) For the purposes of this subsection (c), any contractor with the United States who is furnished information pursuant to subsection (a) (2), and any employee of any such contractor, shall be considered to be an employee of the United States."

Explanation. - This section should be amended in several respects. First, the substantive criterion for withholding data as confidential should be the test established by the Freedom of Information Act, 5 U.S.C. 552(b) (4). Our proposed amendment would have the effect of requiring nondisclosure of information obtained under the Toxic Substances Control Act which may be withheld under 5 U.S.C. 552 (b)(4), i.e., "trade secrets and commercial or financial information obtained from a person and privileged or confidential." This will make the confidentiality standard more definite (because there exists a body of case law interpreting 5 U.S.C. 552(b) (4)), and will promote uniformity.

In addition to the exemption for disclosure to Federal officers and employees, a separate provision should allow disclosure to EPA contractors and their employees, under appropriate safeguards and after appropriate EPA findings that disclosure is necessary. EPA accomplishes a great deal of its investigatory and analytical tasks by contract. If contractors are not allowed access to information under this bill, EPA could not perform its duties satisfactorily without substantial manpower increases. The recently-enacted Privacy Act, 5 U.S.C. 552a, provides that, for purposes of the section of the Privacy Act which imposes penalties on Government employees for wrongful use or disclosure of information entitled to confidentiality. Government contractors and their employees are to be considered Government employees (5 U.S.C. 552a (m)). We recommend inclusion of such a provision in the toxic substances proposed bill. Our amendments allow disclosure to contractors, and include a penalty for wrongful disclosure of information by Government employees (including contractors and their employees) .

We also believe that the provisions relating to qualified scientists and individual names are not necessary. The term "qualified scientists" would be difficult to interpret, and in any event a scientist would have no greater rights under the subsection than would any person under our (proposed) basic confidentiality criterion. We believe that the Federal Privacy Act and the Freedom of Information Act provide ample protection of the rights of individuals whose names appear in health and safety records.

Finally, with regard to access of information by Congress, we believe that release of such confidential information should be upon written request.

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12, State exemption from Federal preemption
Page 42, line 14, delete subsection (b) .

Explanation. - This amendment would delete the provision that would allow State and local governments to petition to be exempted from Federal preemption requirements.

13. Citizen suits for discretionary action

Page 45, line 13, delete language after "Act" through line 16, and insert in lieu thereof :

"which is not discretionary with the Administrator."

Explanation. - This amendment would make the provision conform with the usual citizen suit provision and not authorize suits against the Administrator for discretionary acts. It would thus prevent the possibility of every decision of the Administrator from being re-decided in the district courts.

H, Indemnification study

Page 52, line 17, delete all of section 25 and renumber section 26 accordingly.

Explanation. - This amendment would delete the requirement for a study on Federal indemnification under laws administered by EPA. We believe sufficient information already exists to recommend against indemnification under programs administered by EPA.

15. /Submissions of budgets and testimony to Congress
Page 54, line 15, delete all of subsection (c).

Explanation. - This amendment would delete the requirement that Agency budget requests, testimony and comments on legislation must

not be submitted to OMB prior to submission to Congress. We continue to object to this provision.

IG. Additional miscellaneous amendments

Page 2, line 16, add after "substances": "which may present an unreasonable risk to health or the environment".

Page 3, line 8, insert after "to" the following: "ensure that adequate testing is conducted by those persons who manufacture, import or process, too".

Page 5, line 17, after "ecological studies" insert "monitoring studies,".

Page 8, line 4, delete "proscribed" and insert "prescribed".

Page 8, line 20, insert after "that" "one or more of the following".

Page 8, line 24, insert after "synergistic properties," "persistence,".

Page 10, line 6, delete "section 5(g)" and insert "section 5(f)".

Page 22, line 12, delete "any".

Page 22, line 13, delete "threat" and insert in lieu thereof "risk".

Page 29, line 15, delete the period and add "if appropriate.".

Page 33, line 20, delete "delivery" and insert in lieu thereof "release"; line 22, delete "three months" and insert in lieu thereof "90 days"; and on line 25, delete "delivery" and insert in lieu thereof "release".

Page 34, line 1, after "decision" insert "by the Administrator"; line 4, delete "article, together with the" and insert in lieu thereof "article as set forth in the Customs entry plus the estimated" ; line 5, delete

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"forfeiture of" and insert in lieu thereof "liability for assessment of liquidated damages equal to"; line 6, delete "refusal" and insert in lieu thereof "failure"; line 10, delete "delivery" and insert in lieu thereof "release"; line 11, insert a comma after "payment" and delete "of" and the comma after "charges" ; and on line 16, delete "of subsection (a)".

Page 39, line 5, "section 17," should read "section 16,".
Explanatimi. – These amendments are technical corrections or are otherwise self-explanatory.

U.S. Environmental Protection Agency,

Washington^ D.C.^ February 5, 1976.

Hon. Harley O. Staggers,

Chairman^ Committee on Interstate and Foreign Commerce^ House
of Representatives^ Washington^ B.C.

Dear Mr. Chairman : On November 13, 1975, Mr. James T. Lynn, Director, Office of Management of Budget advised Congressman McCollister of your Subcommittee on Consumer Protection and Finance that the Administration had reassessed its previous position with regard to the toxic substances control legislation and would support H.R. 7664 with some modification.

Enclosed are the Administration's proposed amendments for modifying H.R. 7664. The enclosure summarizes several of the more significant proposals to amend H.R. 7664 and contains all of the proposed amendments and a brief explanation of each.

These proposed amendments to H.R. 7664 were jointly developed with the other concerned Federal departments and agencies and represent the views of the Administration on the toxic substances control legislation.

With the favorable consideration of these proposed amendments we would urge the enactment of H.R. 7664.

Sincerely yours,

Russell E. Train, Administrator.

Enclosure.

Proposed Amendments to H.R. 7664, the "Toxic Substances Control Act of 1975" by Mr. McCollister

Summarized below are several of the significant proposals to amend H.R. 7664. A number of other amendments have also been developed which would improve the effectiveness of the bill. All of the proposed amendments are set out and explained in the pages following this

summary.

definitions

We are proposing that the definition of "chemical substance" be amended to provide the Administrator with some flexibility to exclude, in appropriate situations, certain substances from the definitions and thus from the requirements of the Act or from particular provisions of the Act, It would be almost impossible to draft the bill to exempt certain substances from the Act or, as more likely the case, from certain provisions of the Act in each situation where such is appropriate.

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Scientific laboratory reagents are an example. Here it may Very well be appropriate to exclude such products from the testing and regulatory provisions, but not necessarily the reporting and adverse effects provisions when they are used by certain research or scientific laboratories; on the other hand, we would not likely wish to exclude high school laboratories from any labeling requirements. An exclusion may also be in order for a substance not manufactured in commercial quantities. An excessive burden and inconvenience to the industry or the user would be averted with this flexibility in the Act.

TESTING

There is a provision in the testing requirement of the bill that we foresee as an undue burden upon the Administrator. AVhile we agree that provision should be made for the sharing of testing costs in the event that there is more than one manufacturer of a substance for which testing is required, we are very reluctant to become involved in designating which manufacturer (or possibly a third party) should conduct the tests if the parties cannot reach an agreement. We are therefore recommending deletion of the provisions authorizing the Administrator to designate which party should do the testing.

We are also proposing: that tlie criterion by which the Administrator would require testing be revised so as to authorize the requirement when a chemical mav pose an unreasonable risk to health or the environment, rather than when "necessary to protect against unreasonable risk to health or the environment". When the latter positive situation occurs, presumably the Administrator would take action

under section 6.

PREMARKET NOTIFICATION

Section 5 of H.R. 7664 provides that within eighteen months after enactment of the Act the Administrator shall by rule compile a list of chemical substances (or chemical substances with respect to a particular use or uses) which the Administrator finds are likely to pose substantial danger to health or environment. Substantial danger to health or the environment is defined to mean an unreasonable risk of death, or widespread or severe personal injury or illness, or of widespread or severe harm to the environment. If a new chemical substance or a significant new use of a chemical substance is on the list, the Administrator would receive 90 days premarket notification from the manufacturer or processor. The substantial danger test above is so strict that it would place an impossible burden on the Administrator to know or predict in advance when such a new chemical or new use will come about, and any substance placed on the list would almost certainly be subject to the imminent hazard provisions of section 7 upon manufacture. We are proposing instead an "unreasonable risk" standard for promulgating the list. This would not have the defects outlined above and would focus premarket notification on harmful chemicals and not require notification on all new substances.

QUOTAS

An amendment is being proposed to the quota provisions of H.R. 7664 to provide cooperative action with the Secretary of Commerce

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where quotas have to be established. The Act provides that when it is necessary to adopt a rule with respect to a chemical substance to protect against an unreasonable risk, the Administrator shall select the least stringent requirement practicable consistent with protection of health and the environment. Restrictions limiting the amount of a substance that may be manufactured would be the most stringent requirement, other than a total ban, and the establishment of quotas would

seldom be necessary. However, in the event quotas have to be established we recommend that the Secretary of Commerce be involved in setting them.

ECONOMIC IMPACT

H.R. 7664 would require that the Administrator consider a number of relevant factors in promulgating rules with respect to a chemical substance. We are proposing that a specific provision be added that he also must consider the economic impact of such action, including, but not limited to, consideration of the effects on business, employment, and the national economy. Consideration of these factors is already inherent in the requirement that he consider all relevant factors. We suggest this amendment in lieu of the mandatory preparation of detailed economic impact statements at the time a regulation is promulgated and suggest the economic impact statement provision be deleted.

REPORTING INITIAL MANUFACTURE

We propose to amend the provisions requiring manufacturers, importers, and processors to make reports to the Administrator so as to give the Administrator the authority to require when appropriate that the manufacturer of a new chemical substance submit a report on that substance on the day its manufacture for commercial purposes begins. Only by this means will the Administrator be able to maintain a complete inventory of chemical substances. An inventory[^] is necessary if the Administrator is to have any idea what chemicals are being marketed and which may need to be regulated.

HEALTH AND SAFETY STUDIES; ADVERSE REACTIONS

We are proposing that a provision be added to the reporting section requiring the submission of lists of health and safety studies. The amendment would require submission of lists of on-going and new studies, rather than the study, with a right to require the submission of a given study. It would authorize the Administrator to provide by regulation the types of studies to be included on the lists and the number of years for which prior studies must be listed. The amendment would also provide that a person would list studies which he knows are being made or have been made. We are also suggesting a provision be added to the reporting section requiring records of adverse reactions to human health or the environment be available for submission to the Administrator at his request.

SMALL BUSINESS EXEMPTION

We recognize that there may be a need due to a financial burden

for exempting some small businesses from some of the reporting re-

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quirements of the Act. At the same time, some businesses manufacture such toxic substances that they need to be regulated no matter how small they are. Therefore, we propose an amendment which provides the Administrator with authority to exempt a small business concern from the reporting provisions for reasons of undue financial burden but requires the report of initial manufacture and prohibits exemption where a chemical substance may present an unreasonable risk to health or the environment, making it subject to sections 4(a) (testing), 5(a) (list of "risk" chemicals), or 6(a) (regulation of "risk" chemicals). The Administrator is required to consult with the Administrator of the Small Business Administration in defining "small business concern".

RELATIONSHIP OF OTHER LAWS

The bill would in some instances provide authority to regulate toxic chemical substances which it may be possible to regulate under a law administered by another agency. When this occurs, there is the question of which authority should govern. We propose that authority not be exercised under section 6 (regulation of chemicals) and section 7 (imminent hazards) where action is more appropriate under the law of some other agency. Other agencies would be requested by the Administrator to determine if a risk is presented or is likely to be presented by a chemical substance or mixture, and if such risk can be prevented or reduced to a sufficient extent by actions under their law. The agencies would then either determine that the substance or mixture does not pose or is not likely to pose an unreasonable risk to health or the environment or initiate action to protect against such a risk.

Questions which could occur over the validity of actions taken under the Toxic Substances Control Act where other authorities exist would be avoided under this amendment.

EXEMPTION FROM FEDERAL PREEMPTION

We do not recommend the provisions of H.E. 7664 which would allow State and local agencies to petition the Administrator for exemp-

tion from the Federal preemption requirements. State and local agencies would be allowed to regulate any toxic substance until such time as the Administrator puts into effect regulations for testing or restricting a substance. Thereafter, they could impose only a total ban on a substance. In view of the fact that the bill authorizes the Administrator to regulate with respect to geographic areas there would appear to be no need for a State or local agency to duplicate any regulations with respect to a substance after Federal regulations are in effect.

Proposed Amendments to H.R. 7664, the Toxic Substances Control

Act

AUTHORITY to exempt IN DEFINITION

Page 4, line 2, delete the period after "mixture" and insert a semicolon and the following :

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"Provided, however, the Administrator may by regulation exclude from this definition as it applies to this Act, or to any provision of this Act, certain categories of chemical substances, including laboratory reagents, catalysts, selected mixtures, and chemical substances not manufactured in commercial quantities."

Explanation. - This amended definition of a "chemical substance" would provide the Administrator with flexibility to exclude, in appropriate cases, a substance from the requirements of the Act, or from a particular provision (not already excluded) where such substance does not need to be regulated, cannot be effectively regulated, or where meeting the requirements might be an undue burden.

NEW CHEMICAL SUBSTANCES

Page 4, after line 19, insert the following as paragraph (8) and renumber paragraph (8) as paragraph (9).

"(8) The term "new chemical substance" means any chemical substance not included in the inventory of chemical substances compiled and published under section 8(b)."

Explanation. - H.R. 7664 needs to be modified to ensure that the Administrator may issue a requirement for re)ortingof "new chemical substances" at the time of manufacture. A "new chemical substance" can be defined by reference to the inventory of all existing chemical substances to be published by EPA according to section 8(b) as amended.

TESTING SECTION 4

1. Standards for Test Protocols

a. Page 6, line 17, change title of section 4 to "STANDARDS FOR TEST PROTOCOLS"

Expla7iatioii. Conforming amendment (see Explanation in b. below).

b. Page 6, lines 18-25, delete all of subsection (a) and insert in lieu thereof the following:

Section 4. (a) If the Administrator determines that -

(1) the manufacture, distribution in commerce, processing, use or disposal of a chemical substance may pose an unreasonable risk to health or the environment ; and

(2) that testing such chemical substance is necessary to detremine whether an unreasonable risk to human health and the environment does or does not exist; then he may, by rule, prescribe standards for a test protocol for such substance, and require, in accordance with subsection (d), that one or more persons formulate a test protocol for such substance in accordance with such standards, and perform the tests required by such protocol.

Explanation. - If the Administrator could demonstrate that testing is "necessary to protect against unreasonable risk to health or the environment" (H.R. 7664), presumably he could take restrictive action under section 6. The revised section 4(a) is a far more appropriate^ determination for issuing a testjjig requirement in that it

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reflects the uncertainty of the risk that would prompt the Administrator to require testing.

The revised language permits the Administrator to prescribe the standards for a test protocol rather than the protocol itself, which would be developed by the affected manufacturer in accordance with the standards. The advantage is flexibility, in that the protocol can be more closely tailored to the chemical substance and the questions it poses; and through standards the Agency can require results of testing rather than specific testing methods.

In addition, instead of being required in each instance to follow narrowly defined procedures for testing, the industry should have the flexibility when appropriate to develop efficient test protocols in accordance with the Administrator's standards.

c. Page 7, line 9 to 14. Delete lines 9 to 14 and insert in lieu thereof the following:

(3) the extent to which testing of such substance may result in the development of data upon which the effects of such substance or mixture on health or the environment can reasonably be determined or predicted:

(4) the existence of data concerning the effects of the chemical substance or mixture on health or the environment ;
and

Explanation). – These two amendments do not alter the intent of the original provisions but conform the language to the use of "standards for test protocols" instead of "test protocols."

d. Page 7, line 21. Delete line 21 through "tests" and substitute the following:

(c) Standards for a test protocol may require that such protocol may include, but is not limited to, tests

Explanation. – It is necessary to make clear that standards for test protocols do not necessarily entail development of specific test protocols but rather methodologies or guidelines for development of test protocols. It is also necessary to make clear that the test protocol is not limited to those tests specifically named.

e. Additional conforming amendments to sections 5 and 8.

Page 11, line 14: delete "in accordance with a test protocol" and insert in lieu thereof "under a test protocol, in accordance with standards".

Page 11, line 15: insert a comma after "4".

Page 12, line 1: delete "in accordance with a test protocol" and insert in lieu thereof "under a test protocol, in accordance with standards".

Page 12, line 2 : insert a comma after "4".

Page 12, line 11: insert "standards for a" after "applicable".

Page 12, line 12: delete "has" and insert in lieu thereof "have".

Page 12, lines 13 and 17-18: insert "standards for" before "a test protocol".

f. Additional conforming amendments to section 3, DEFINITIONS :

Page 5. lines 3-16, definition of "test protocol": delete the dash on line 3 and subparagraph heading "(A)" on line 5; delete the comma

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at the end of line 9 and insert in lieu thereof a period ; and delete lines 10-16.

Page 4, line 23 : insert a new paragraph after new paragraph (9) as follows and renumber subsequent paragraphs accordingly Vi :

(10) the term "standards for a test protocol" means standards prescribing the nature and quality of a test protocol, including :

(A) the manner in which test protocols are to be developed to determine the human health and environmental effects of a chemical substance,

(B) any analysis that is to be performed on test data de-

veloped, and

(C) any requirements to be met in the design of any test protocol necessary to insure the reliability and adequacy of test data developed.

2. Designating who should perform testing

Page 8, line 11, delete the last sentence in paragraph (d) beginning with "If" through line 21, and insert in lieu thereof :

If such an arrangement is made the Administrator shall be notified and the remaining such persons shall be exempted from requirements to perform tests.

Explanation. - AVE do not believe that the Administrator should become involved in designating which party (or a third party) should perform tests if the parties cannot agree among themselves. If a cost-sharing arrangement is made for one of the parties to do the testing, however, provision should be made to exempt the other parties from the testing requirements.

5. Timely submission of test data.

Page 8, line 22: delete section (e) and insert in lieu thereof:

(e) Any manufacturer, processor, or importer who is required to perform the tests called for in a test protocol under this section shall promptly transmit to the Administrator the test data developed pursuant to such test protocol.

Explanation. - This amendment Avill ensure that the test data shall be promptly transmitted to the Administrator after completion.

PREMARKET NOTIFICATION LIST

a. Page 10, line 1, Section title, after "SCREENING", delete remainder of section title.

b. Page 10, line 8, after "finds", delete remainder of paragraph through line 13, and add in lieu thereof the following :

may pose an unreasonable risk to health or the environment.

c. Page 15, line 13, after "substances", delete "as likely to pose substantial danger" and add in lieu thereof "which may pose an unreasonable risk".

Explanation. – The substantial danger test in the current provision is so strict that no substance would be placed on the list unless at the same time it was subject to regulations applicable to a Hazardous

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Chemical Substance under section 6 and an Imminent Hazard under section 7. The proposed "unreasonable risk" standard for the list would focus premarket notification on harmful chemicals and not require notification on all new substances.

AMENDMENTS TO SECTION 6 – REGULATIONS

1. Assigning Quotas

Page 18, line 13, delete "uses, shall include provision for" and insert in lieu thereof "uses shall be prescribed by the Administrator in consultation with the Secretary of Commerce. The Secretary of Commerce in consultation with the Administrator shall by rule provide for".

Page 18, line 14, after "quotas" add "to the extent necessary".

Page 18, line 19 and 20, delete "The Administrator shall by rule prescribe criteria which" and insert "Such criteria".

Page 18, line 22, after "the" delete "market shares, productive capacity," and insert "current and past market shares, productive capacity, captive consumption,".

Explanafio)}}. – This amendment is being proposed to the quotas provisions of H.R. 76fU to provide cooperative action with the Secretary of Commerce where quotas have to be established. The Act provides that when it is necessary to adopt a rule with respect to a. chemical substance to protect against an unreasonable risk, the Administrator shall select the least stringent requirement practicable consistent with protection of health and the environment. Restrictions limiting the amount of a substance that may be manufactured would be the most stringent requirement, other than a total ban, and the establishment of quotas would seldom be necessary. However, in the event quotas have to be established we recommend that the Secretary of Commerce be involved in setting them.

2. Economic Impact Analysis

Page 19, line 11: delete "and"; Page 19, line 13: delete the period and insert in lieu thereof: "; and"; Page 19, after line 13: add a new subparagraph 4 as follows:

(4) the economic impact of such action, including but not limited to, consideration of effects on business, employment, and the national economy.

Page 21, line 21 : delete all of subsection (g) .

Explanation. - This amendment would specifically require the Administrator to consider economic impact in promulgating regulations, already inherent in the requirement that he consider all relevant factors. This would be in lieu of the mandatory preparation of detailed economic impact statements for issuance at the time any regulation is required, which provision is deleted by the amendment.

AMENDMENTS TO SECTION 8, REPORTS

/. Reporting Initial Manufacture

- a. Page 24, line 23, after "any" insert "person who is a".
- b. Page 24, line 25 – page 25, line 1 : delete "and at such more frequent time" and insert in lieu thereof "or such times".

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Explanation, - Authority should be provided in the legislation enabling the Administrator to learn of the existence of a new chemical substance as soon as manufacture begins. This is minimal authority, intended to inform him of the initiation of the manufacture of a new chemical substance. Therefore, the amendment authorizes the Administrator to require of a chemical manufacturer that he initially reports on the day on which manufacture of a new chemical begins and provides the other specified information. This amendment would also permit the reporting time in periods useful to the Administrator and geared to the different types of reports which he has authority to request. Such periods may be more or less frequent than one year.

2. Reporting Adulteration

Page 25, line 16 : Between lines 16 and 17 insert a new subparagraph (E) as follows, and renumber subsequent subparagraphs accordingly :

(E) Records pertaining to quality control procedures and adulteration as defined in subsection 6(e).

Explanation. – While subsection 6 (e) authorizes the Administrator to require a manufacturer or processor to submit a description of quality control procedures, there should be additional authority to obtain records pertinent to such procedures, such as those demonstrating the procedures are being followed, and to incidents of adulteration.

3. Reporting Health and Safety Studies: Adverse Reactions

Page 25, line 1, after "require," insert "on any chemical substance manufactured, imported, or processed,".

Page 25, after line 21, insert the following :

(G) Health and safety information including:

(i) lists of health and safety studies in progress on or initiated after the date of enactment of this Act, conducted by or for such person, or known to such person ;

(ii) lists of health and safety studies conducted by or for such person, or known to have been made by any person, prior to the date of enactment of this Act ;

(iii) at the request of the Administrator, copies of any such studies appearing on a list submitted pursuant to paragraphs (i) or (ii), in the possession or control of such person.

(H) Records of adverse reactions to human health or the environment or adverse results in health and safety studies known or alleged to have been caused by the chemical substance. Such records may consist of, but not be limited to, consumer allegations of 'personal injury or harm to health, reports of occupational disease or injury, and reports of complaints of injury to the environment submitted to the person by individuals or governmental agencies. The Administrator may require copies of such records pursuant to his responsibilities under sections 4, 5, 6, and 7 of this Act.

Explanation.– The proposed amendment would require the sub-

mission of lists of health and safety studies and would require submission of lists of on-going and new studies rather than the study itself with a right to require the submission of a given study. It would authorize the Administrator to provide by regulation the types of

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studies to be included on the lists and the number of years for which prior studies must be listed. The amendment would provide that a person would list studies which he knows are being made or have been made. The amendment also provides that records of adverse reactions to human health or the environment be available for submission to the Administrator at his request.

4. Exemptions from Reporting Requirements

a. Page 24, lines 22 and 23 : delete ''Except as provided in subsections (b) and (c), the'' and insert in lieu thereof ''The''.

b. Page 26, line 6: after line 6, insert a new paragraph (4) as follows :

(4) (A) The Administrator may, by rule, exempt from or modify for any manufacturer, importer, or processor who is a small business concern all or part of the reporting requirements of this section where such requirements would cause an undue financial burden on such small business; provided, however, no exemption or modification shall be authorized until after the initial reporting is made under this section and such exemption or modification shall discontinue when there is a significant change in the amount of the substance manufactured, imported or processed from the amount last reported.

(B) No exemption or modification of reporting requirements shall be authorized under paragraph (4) (A) with respect to a chemical substance or an article containing such substances -

(i) for which a testing re[quirement has been prescribed under section 4(a) of this Act ;

(ii) which is contained in the list of chemical sub-

stances which the Administrator has by rule identified and published in the Federal Register under section r)(a) of this Act ; or

(iii) which is covered by a rule under section 6 of this Act.

(C) For purposes of this subsection the Administrator shall define a small, business concern, in consultation with the Administrator of the Small Business Administration.

c. Page 27: Delete all of subsection (c) and renumber subsection (d) as (c).

Explanation. – Subsection (b) of the existing H.I.\. 7664 is a small business reporting exemption provision. The amendment would eliminate that blanket exemption and provide that there is authority to exempt for reasons of undue financial burden. Subsection (c) of the existing H.R. 7664 requires the Administrator to make specified exemptions, an authority which is provided for in the amendment to the definition of "chemical substances" at page 4, line 2.

5. Inventory

a. Page 26, line 7. delete entire section (b) and insert in lieu thereof:

(b) The Administrator shall compile, keep current, and publish an inventory of each chemical substance which any person reports under subsection (a) which is manufactured

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or processed in the United States. A chemical substance shall be included in such an inventory as of the earliest date (as determined by the Administrator) on which such substance was manufactured or processed in the United States.

Explanation. – Such an inventory would be useful to the Administrator in conducting his responsibilities under the Act.

RELATIONSHIP TO OTHER LAAVS

1. Page 28, after line 8 : insert a new paragraph (2) as follows, and renumber subsequent paragraphs accordingly :

(2) any source material, special nuclear material, or by-product material as defined in the Atomic Energy Act of 1954 (42 use 2011). as amended, and regulations issued pursuant thereto ;

Explanation. – The amendment adds a class of materials to the exemption provision, as those materials are already adequately regulated under existing law.

2. Page 28, line 24: delete all of subsections (b), (c), and (d) and insert the following subsections in lieu thereof.

(b) Laws Not Administered by the Administrator :

(1) If the Administrator has reason to believe that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture poses or may pose an unreasonable risk to health or the environment, and if such risk may be prevented or reduced by action taken under a law not administered by the Administrator, the Administrator shall request the agency which administers such law (A) to determine if there is such a risk and (B) if the agency determines that there is such risk to determine if such risk may be prevented or reduced to a sufficient extent by action taken under such law. Any such request shall be accompanied by a detailed statement of the information on which it is based. The agency receiving the request shall make the requested determination within such time as the Administrator specifies in the request, but such time specified may not be less than ninety days from the date the request was made. The report of an agency in response to a request made under this paragraph shall be accompanied by a detailed statement of the findings and conclusions of the agency respecting the determinations requested to be made.

(2) If the Administrator makes a request under paragraph (1) with respect to a chemical substance or mixture and the agency to which such request was made either –

(A) determines that such substance or mixture does not pose or is not likely to pose an unreasonable risk to health or the environment, or

(B) initiates, within the time specified in the request under paragraph (1) in response to such request, action

under the law (or laws) administered by such agency to protect against such a risk,

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the Administrator may not take any action under section 6 or 7 of this Act with respect to such substance or mixture.

(3) If the Administrator has initiated action under section 6 or 7 with respect to a chemical substance or mixture which was the subject of a request made to an agency under paragraph (1), such agency shall before taking action under the law (or laws) administered by it to protect against such risk to health or the environment associated with such substance or mixture consult with the Administrator* for the purpose of avoiding duplication of Federal action against the risk.

(c) Laws Administered by the Administrator— The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. The Administrator shall use the authorities contained in such other Federal laws to protect against any risk to health or the environment associated with a chemical substance or mixture unless the Administrator determines that such risk may be more appropriately protected against under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

(d) Occupational Safety and Health. — In exercising any authority under this Act, the Administrator shall not, for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

(e) Coordination. — In administering this Act, the Administrator shall consult and coordinate with the Secretary of Health, Education, and Welfare and heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the pur-

pose of achieving the maximum enforcement of this Act while imposing the least burdens of duplication on those subject to the Act and for other purposes.

Explanation. - The proposed amendment provides that the Administrator has no authority under section 6 (regulation of chemicals) and section 7 (imminent hazards) if the following occurs. Other agencies would be requested by the Administrator to determine if a risk is presented or is likely to be presented by a chemical substance or mixture, and if such risk can be prevented or reduced to a sufficient extent by actions under another law. The agencies would then either determine that the substance or mixture does not pose or is not likely to pose an unreasonable risk to health or the environment or initiate action within 90 days to protect against such a risk. H.R. 7664 could presently be interpreted so as to draw into question many regulatory actions that would be taken under the Toxic Substances Control Act. The commitment of resources and protracted delays which could result from litigation could undermine the implementation of this legislation and seriously detract from effective use of this authority to protect health and the environment.

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ADVISORY PANELS I

Page 30, line 9 : delete all of section 10, Chemical Substances Board, i and renumber subsequent sections accordingly. ;

Explanation. - The section would add a substantial administrative j step to a complicated regulatory procedure, in that all rules to be \ proposed under sections 4, 5, and 6 (except in two specified instances) would have to be presented to the Board for a scientific report. ;

There is, of course, a need for scientific advice. However EPA al- j ready has a Hazardous Materials Advisory Committee fully qualified j and able to advise on matters pertaining to toxic substances. The \ Agency program office would be staffed with a substantial number of • qualified scientists. As with the Agency's Pesticide Program, the Ad- : ministrator would draw on the many outside sources of advice in order i to assure his decisions were soundly based in scientific knowledge, but l as a matter of course in the normal rule-making process. The academic community and sucli national groups as XAS, XSF, and XIH are sources presently relied upon. In addition, EPA will submit its draft regulations to other concerned agencies as a standard executive branch i

procedure to ensure adequate input both of a scientific and substantive nature.

INSPECTION OF RECORDS FOR REIMBURSEMENT FOR TESTING

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Page 35 after line 2 insert new subsection (b) as follows and renumber existing subsections (b) and (c) accordingly:

(b) Notwithstanding the provisions of subsection (a), the Administrator shall have authority to inspect financial data and records pertaining to testing costs when he orders contribution or reimbursement for the costs of performing tests in connection with the provisions of section 5(f). ,!

Explanation. Section 5(f) authorizes the Administrator to determine the equitable contribution or reimbursement of testing costs

where more than one person benefits from the testing. This amendment

would authorize access to financial data on testing costs in order for the Administrator to carry out the requirement to apportion the costs among those benefiting from the testing.

DISCLOSURE OF CONFIDENTIAL INFORMATION

Page 40, line 14, delete entire section 15 and insert in lieu thereof the following revised section :

CONFIDENTIALITY

Sec. 15. (a) General. - The use by any person to his own advantage, or revealing, other than to the Administrator or officers or employees of the Environmental Protection Agency who have a need to know for the performance of their official duties, or to officers or employees of another Federal agency who have a need to know for the performance of their official duties, or to the courts when relevant in any judicial

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proceeding under this Act any information acquired pursuant to this Act concerning trade secrets, information which is likely to cause substantial harm to the competitive position of the person submitting the information, or which would likely impair the Government's ability to obtain necessary information in the future is prohibited.

(b) Data from health and safety studies. – Subsection (a) does not prohibit the disclosure of –

(1) any health and safety study submitted under this Act with respect to –

(A) any chemical substance or mixture which on the date the study is to be disclosed has been offered for commercial distribution, or

(B) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5, and

(2) any data reported to, or otherwise obtained by the Administrator from such a study.

This subsection does not authorize the release of data which discloses processes used in the manufacturing or processing of a chemical substance or mixture, or proprietary formulations.

(c) Release of information to contractors. – (1) Notwithstanding any limitation in subsection (a) such information may be disclosed to contractors with the United States and employees of such contractors if in the opinion of the Administrator such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States entered into on or after the effective date of this Act for the performance of work in connection with this Act.

(d) Criminal penalty for wrongful disclosure. – (1) Any officer or employee of the United States, or former officer or employee of the United States, who by possession of, or who has access to, material which is prohibited from release under subsection (a), and who knowing that disclosure of the specific material is prohibited by this section, willfully discloses the material in any manner to any person not entitled to receive it, shall be guilty of a misdemeanor and fined not more than \$5,000.

(2) For the purpose of this subsection, any contractor with the United States and any employee of any such contractor who is furnished information pursuant to subsection (c) (1) shall be considered to be an employee of the United States.

Exjylanation. - This section should be amended in sevei'al respects. This legislation requires substantial information to be submitted to the Government upon specific request of the Administrator. In addition, the legislation does not preclude voluntary submission of information prior to or after manufacture. If individuals are not assured that trade secret and confidential information as outlined in this section will not be released except to authorized individuals it is highly likely that information which the Agency could utilize would either be difficult to obtain in a timely fashion and/or simply not available. It is

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important, however, that all information obtained pursuant to the Aa be made available to contractors of the United States if such disclosure is necessary for the satisfactory perfoi'mance of the contract. Since much of the Agency's workload undoubtedly will be contractual this provision is vital to the legislation's successful implementation.

EXVIROXMEXTAL PREDICTIOX AXD ASSESSMEXT

Page 43, line 17 insert after "resources to" "predict and".

Explatmflon. The content of section 19 should reflect the intention of the title which is to permit EPA in association with other agencies to become involved in predicting and assessing the environmental consequences of the introduction of new chemical substances into the environment.

STATE EXEMPTIOX FROM FEDERAL PREEMPTIOX

Page 45. line 14, delete subsection (b) .

Explanation. - This amendment would delete the provision that would allow State and local governments to petition to be exempted from Federal preemption requirements.

JUDICIAL REVIEW

Page 47, line 10: delete "not"; line 11 : insei't "not" after "are".

Explanation. - The amendment would provide that the Administrator's findings shall be affirmed unless not supported by the record. Thus, the person contesting the rules must show that the record does not support them, rather than this burden being on the Administrator.

Comptroller General of the United States.

Washington^ D.C.. July 11. 1975.

Hon. Harley O. Staggers,

Chairman^ Committee on Interstate and Foreign Commerce^ House of Representatives.

Dear Mr. Chairman: This refers to your letter of June 3, 1975, requesting our report on H.R. 7229, 94th Congress, the "Toxic Substances Control Act."

In general, we observe that the objective of the legislation, which is to regulate the use and dissemination of certain toxic chemicals, is similar to that of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§ 135 et seq.. (1970) as amended by Pub. L. No. 92-516, approved October 21, 1972. with respect to basic pesticides. In this connection, we note that Pub. L. No. 94-51. approved July 2, 1975, provides for the extension of the authorization of appropriations for FIFRA until September 30, 1975. The purpose of both FIFRA and H.R. 7229 is to protect human health and the environment by requiring adequate testing and other programs and procedures related to specific dangerous substances. The Administrator of the Environmental Protection Agency (EPA) would be responsible for execution of the provisions of H.R. 7229 and is also responsible for administering FIFRA. In view of the similarity of objectives and the responsibility of the EPA Administrator with

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respect both to toxic chemicals and to insecticides, fungicides and ro-

denticides, we believe it desirable that, insofar as possible, the terms and conditions under which both laws are administered should be uniform, particularly with respect to certain substances which, under the respective definitions, could be controlled under the provisions of either H.R. 7229 or FIFKA.

Therefore, with respect to the following specific provisions of H.R. 7229, the Committee may wish to consider adopting the substance of related provisions of FIFRA :

1. In section 3(4) of H.R. 7229 the term "commerce" is defined in terms of interstate commerce. Thus only toxic substances involved in interstate commerce would be covered, unlike pesticides, which are regulated under FIFRA if disseminated in intrastate commerce as well. We believe effectiveness of administration of both the toxic chemicals control law and FIFRA would be enhanced if this term is uniformly applied under both laws. Thus, we suggest the definition of commerce in H.R. 7229 be revised to conform with the concept of intrastate regulation found in FIFRA]y amending subparagraph (B) of section 3(4) to read "within a State." and adding a new subparagraph (C) to read "which affects trade, traffic, transportation, or exchange described in sub}aragraphs (A) and (1^) of this paragraph." See 7 I^S.C. § 1^Gj, Pub. L. No. 92-r)l(>, section 12. S. Rep. No. 970, 92nd Cong.. 2n(1 Sess. 40 (1972) on H.R. 10729.

2. Section 11 of H.R. 7229 provides for inspections of records and properties of persons engaged in manufacturing, processing, and distributing chemical substances controlled under the j)ioosed law by the Administrator of the EPA or his designee. AA'e believe it would be advisable, in the interest of uniformity, to auient section 11 to conform with the inspection procedui'es and authorities provided in 7 U.S.C. j< 13(C)g with respect to pesticides.

3. Subsection 17 (c) of H.R. 7229 provides for seizure of substances manufactured or distributed in violation of the pioosed law. Again, in the interest of uniformity in administi-aton of two similar and related statutes, we suggest amendment of the seizure provision of H.R. 7229 to conform with the stop sale, use, removal and seizure provisions of 7 U.S.C. g 136k, Pub. L. No. 92-516, section 13.

Section 9(b)(1) of the bill provides that the Administrator of EPA would have no authority to act under sections 6 and 7 of the proposed Act to prevent or reduce an unreasonable risk to health or the environment if : (A) the entirety of tlie risk involved is designed to be protected against by another I'ederal law not administered in whole 01' in }art by the Administratoi- : or (B) if the Administrator determines that the entirety of the risk could be sufficiently prevented or reduced by action taken undei" such other Federal law.

In the interest of clarity, we believe section 9(b)(1) should be amended to specify which other protective laws are meant. We suggest language along the lines of the following as a substitute for section 9(b)(1):

''(b) (1) The Administrator shall have no authority under sections 6 and 7 of this Act to take action to prevent or reduce an unreasonable risk to health of the environment associated with a particular chemical substance or article containing such substance if such risk to health

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or the environment could be prevented or reduced to a sufficient extent by actions taken under any other Federal law; including the Atomic Energy Act of 1954, the Clean Air Act, the Federal Water Pollution Control Act, the Federal Hazardous Substances Act, the Occupational Safety and Health Act of 1970, the Consumer Product Safety Act, subpart 8 of part F of title III of the Public Health Service Act (relating to electronic product radiation), 42 U.S.C. § 262 et seq., Pub. L. No. 90-602, October 18, 1968, and the Acts administered by the Secretary of Transportation relating to the transportation of hazardous substances.''

This was the language included in a similar provision of H.R. 5356, 93d Congress, as passed by the House of Representatives July 23, 1973, and provides a specific statement of the legislative authorities to be considered by the Administrator in determining whether action will be taken under an act such as that proposed by H.R. 7229 or another applicable statute.

Sections 10(a) and 10(b) (3) of the bill would authorize the Administrator of the Environmental Protection Agency to make contracts and grants for research and monitoring as necessary to carry out the purpose of this Act and for development of a data retrieval system suitable for carrying out the purposes of the Act. In order that this Office may have access to records connected with such contracts and grants, and to facilitate our audit of them, we recommend that the following new section be incorporated in H.R. 7229 :

"Sec. (a) Each recipient of Federal assistance under this Act, pursuant to grants, subgrants, contracts, subcontracts, loans or other

arrangements, entered into other than by formal advertising, and which are otherwise authorized by this Act. shall keep such records as the Administrator shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such assistance, the total cost of the project or undertaking in connection with which such assistance is given or used, the amount of that portion of the cost of the project or undertaking supplied by sources, and such other records as will facilitate an effective audit.

"(b) The Administrator and the Comptroller General of the United States, or any of their duly authorized representatives, shall, until the expiration of three years after completion of the project or undertaking referred to in subsection (a) of this section, have access for the purpose of audit and examination to any books, documents, papers, and records of such recipients which in the opinion of the Administrator or the Comptroller General may be related or pertinent to the grants, subgrants, contracts, subcontracts, loans or other arrangements referred to in subsection (a)."

Section 25 of the bill would require our Office to make a study of all Federal laws administered by EPA for the purpose of determining whether and under what conditions, if any, indemnification should be accorded any person as a result of any action taken by the Administrator under any law administered by the Agency. The study, which would be required to be completed "no less than 2 years from the date of enactment" * * would include an estimate of the probable costs of any indemnification programs recommended and an examination of

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all viable means of financing the cost of any recommended indemnification.

The proposed study would require intimate knowledge not only of all the laws administered by EPA but also of the manner in which such laws have been administered. Such a study would be a large and costly undertaking for our Office that might necessitate the diversion of some of our limited manpower resources from other important work. EPA already has most of the knowledge required for such a study and should be able to make it at substantially less cost than our Office. We recommend, therefore, that the Committee consider re-

quiring EPA to make the proposed study. If desired, our Office could review EPA's study and provide a report on its adequacy either to the Committee or to the Congress.

It should also be noted that there is a provision under FIFRA (section 15, Pub. L. No. 92-516), 7 U.S.C. § 136m, which authorizes EPA to indemnify pesticide manufacturers who suffer losses by reason of suspension or cancellation of their pesticide registrations. EPA'S Deputy Administrator for Pesticide Programs told us that EPA was opposed to enactment of this provision into FIFKA and that he had supported the deletion of this provision from FIFRA in testimony before the House Committee on Agriculture on June 20, 1975, in the course of oversight hearings on the Federal Environmental Pesticide Control Act, Pub. L. No. 92-516, October 21, 1972, 7 U.S.C. §§ 186 et seq. (1970), Supp. III. He also stated that no payments had been made under the indemnity provision by EPA since it was enacted on October 21, 1972. The EPA position favoring repeal of the indemnity provision was also stated by the Assistant Administrator, Water and Hazardous Materials at a hearing of the Subcommittee on the Environment, Senate Committee on Commerce on May 5, 1975.

Section 26(c) of the bill would require that copies of any budget requests, legislative recommendations, and other materials submitted to the President or to the Office of Management and Budget (OMB) in connection with carrying out the provisions of H.R. 7229 be submitted concurrently to the Congress.

It is not at all clear that the agency budget submissions, as such, would be helpful to the Congress. Agency budget submissions to OMB are subject to an intensive hearing process, field investigations, and frequently, resubmissions. In some cases where agency programs involve similar or related programs of other agencies, there is need for elimination of duplicative requests and for adjustment of the level of programs to assure effective interagency collaboration.

The Committee may wish to consider, as an alternative, making arrangements for the advance delivery of approved agency budget requests prior to the formal submission of the President's Budget. Arrangements along these lines have been made in the past with the appropriations committees in order to enable these committees to undertake hearings at an earlier date. In some cases, it has been possible to release agency budget justifications as early as the first week of December.

In this connection, we note that a similar provision was enacted as section 27 (k) of the Consumer Product Safety Act, Public Law 92-573, approved October 27, 1972, 15 U.S.C. § 2076 (k). In the light of experience it now appears that this provision places an agency ad-

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ministrator in a very difficult position due to the conflict between a congressional mandate to supply information to the Congress concurrently with submissions to the Office of Management and Budget and the provisions of 31 U.S.C. § 15 as interpreted by OMB in its Circular A-10 which require agencies to (1) prepare budgets within guidelines (funding and personnel) provided by OMB ; (2) submit budget requests to the Congress through OMB; and (3) defend budgets prepared under OMB guidelines in its congressional appropriations hearings. The problems raised by this conflict were discussed in some detail by the Chairman of the Consumer Product Safety Commission at an oversight hearing of the Consumer Subcommittee of the Senate Committee on Commerce on February 27, 1975. The Chairman summarized his views on the question by stating that "the conflict between section 27 (k) and the OMB's interpretation of the Chairman's duties as a member of the executive branch raises some very serious questions which need resolution."

Vice recommendation against enactment of the proposed provision in section 26(c) of H.R. 7229 pending resolution of the conflicts discussed by the Chairman of the Consumer Products Safety Commission to which reference is made above.

There is no provision in H.R. 7229 that EPA submit an annual report to the Congress describing its activities under the Act during the previous fiscal year. We suggest that such a provision be included in the bill.

In this regard, consideration should also be given to requiring that the annual report include an evaluation of EPA's effectiveness in carrying out its responsibilities under the Act. It is our view that program evaluation is a fundamental part of effective program administration and the responsibility for evaluations should rest initially upon the responsible agencies. In line with this concept, we believe the Congress should attempt to specify the kinds of information and tests which will enable it to better assess how well programs are working and whether alternative approaches may offer greater

promise.

Sincerely yours,

Paul G. Dembltng
(For the Corn pf roller General

of the TJ rated States).

The Gexeral Cot^nsel of the Treasury,

Washington.. August 2U 1975.

Hon. Harley O. Staggers,

Chairman. Committee on Interstate and Foreign Commerce^ House of
Representatives^Washington.D.C .

Dear Mr. Ciiatrmax: Reference is made to your request foi- the
views of this De])artment on H.R. 7229, the "'Toxic Subst^mces Control
Act."

The })il] would establish various standards, rules and procedures
under which the Administrator of the Environmental Protection
Agency would control or restrict the use or distribution of certain
chemical substances, in order to protect health and the environment.

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Section 13 of the proposed bill relates to the enforcement responsi-
bility of the Secretary of the Treasury with regard to imports of
chemical substances covered by the Act into the customs territory of
the United States. The Department recommends that section 13 be
amended as follows (language to be added is italic; language to be
deleted is bracketed) :

"Sec. 13(a) ... If a chemical substance or article is refused entry,
hereunder, the Secretary of the Treasury shall refuse [delivery] re-
lease to the consignee and shall cause the disposal or storage of any
substance or article refused [delivery] release which has not been
exported by the consignee within [three months] 90 days from the

date of receipt of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe, except that the Secretary of the Treasury may [deliver] release to the consignee such substance or article pending examination and decision by the Administrator in the matter on execution of a bond for the amount of the full invoice value of such substance or article as set forth in the Customs entry [together with] plus the estimated duty thereon, and providing for liability for assessment of liquidated damages equal to the full amount of such bond by the consignee on [refusal] failure to return such substance or article [for any cause] to the custody of the Secretary of the Treasury-, when demanded, for the purpose of excluding them from the country or for any other purpose [such consignee shall forfeit the full amount of such bond]. All charges for storage, cartage, and labor on substances or articles which are refused admission or [delivery] release under this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future entry into the United States made by such owner or consignee."

The Department has no independent knowledge of the need for the bill and no comments on its general merits. It is believed that enactment of the proposed legislation would increase Customs workload to some extent, although no unusual administrative difficulties are anticipated.

The Department has been advised by the Office of Management and Budget that there is no objection from the standpoint of the Administration's program to the submission of this report to your Committee. Sincerely yours,

Donald L. E. Ritger,
Acting General Counsel.

Committee Amendment

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SUPPLEMENTAL VIEWS BY CONGRESSMAN
JOHN D. DINGELL

I believe that it is necessary to put a specific requirement into H.R. 14032 to ensure that EPA will take prompt measures to deal with

PCB's. Unfortunately, one of the bill's shortcomings is its failure to mandate action on hazardous chemicals in a timely fashion. There is no specific directive for the Administrator to take action to control the most hazardous chemicals within a certain period of time. All of the Agency's actions are discretionary, and subject to the vicissitudes of political pressures and budget starvation. From what we can see of EPA's past record, we cannot be particularly sanguine about the Agency's ability to act quickly.

With this knowledge, brought on by retrospective studies on PCB's, it is clear that steps to control production, use, and disposal are needed, to protect the health and well-being of human and other life forms. If Japan, as the largest producer of electronic equipment, can replace PCB's with some other, more neutral component, then the U.S. can follow suit. The Toxic Substances Control Act would be considerably strengthened by providing a means to control PCB's. During the Committee consideration of H.R. 14032. I offered an amendment - which was rejected - to prescribe methods for manufacture, use, and disposal, and eventually phase-out of PCB's. This amendment is sorely needed to prevent further contamination, death and future PCB incidents.

The problems associated with widespread use and dispersal of PCB's (Poly chlorinated Biphenyls) are a prime example of the type of chemical hazard to which the Toxic Substances Control Act should immediately address itself. PCB's like their chemically similar cohort DDT, are extremely stable (long-lived) which leads to the risk of bio-accumulation and concentration in fish and other aquatic animals as well as in the tissues of man. The dangers involved for man include numbness and pain in the extremities, reduced sensitivity to pain and/or heat, slowed nervous reactions, acne-like skin eruption, temporary failure of eyesight, sense of weakness and cancer of the liver.

In 1968, in Yusho, Japan, PCB's leached into rice oil used for cooking and affected 1,000 people in varying degrees depending upon exposure levels. The intake of 0.5-2 grams by those contaminated resulted in a wide variety of illnesses, particularly affecting the skin, eyes, and nervous system. The children born of pregnant women who ingested the contaminated oil were also affected with skin disorders and were smaller in size. Although direct proof was lacking, PCB contamination was also suspected as, at least, a co-factor in some deaths and still births.

Percentages of PCB's found in the blood of Americans, both urban and rural dwellers, have been found to equal those of the Yusho incident. Disruption of the normal function of the liver from PCB's at those low levels (0.5-2 grams) causes the skin disease named after the

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victims at Yusho. Besides Yusho disease, low exposures can cause metabolic disturbances, embryo abnormalities, abortions and miscarriages. Laboratory experiments document this knowledge. The distribution of PCB is ubiquitous. Xow banned for most uses in Japan, PCB's still remain in the environment from past uses such as food container cardboards and wrappings, boat paints, fireproofing, and textile coatings.

PCB contamination of waterways is of equal severity throughout the United States, and especially in the Great Lakes area and the Northeast. Commercial fishing in Lake Michigan ceased in 1971 due to pollution from PCB's. and recently it has been feared that all commercial fishing on the Great Lakes - a \$95 million annual industry - could be sliut down because of PCB contamination. In addition, it has been warned that PCB's could cause the imminent collapse of the \$350 million-a-year sportsfishing tourist industry in the Upper Great Lakes. Early this year the Hudson River was closed as a commercial fishery- for most species of fish (particularly striped bass) due to high levels of PCB's which exceed Federal standards. It has been estimated that 22 million pounds of Hudson River striped bass are consumed each year from both commercial and sport catches.

Air is the major agent of transport for PCB's followed by water. The leaching and vaporizing of PCB's from materials and dump sites release from 1-2 thousand tons of the contaminant a year. Industrial spills have led the FDA to advise the public not to eat the fish from the Hudson River. Lake Ontario, Lake Michigan, Pensacola Sound and the Milwaukee and Ohio Rivers where gross contamination with PCB's has been measured. One hundred gallons of PCB's can contaminate 10 trillion gallons of ILO.

My amendment was improperly criticized for singling out one specific chemical for action when no other hazardous chemicals were specified for action in the bill. It is entirely proper for Congress to set priorities for action in any piece of legislation and PCB's have proven themselves dreadfully toxic and extremely persistent. Because of this, it is incumbent upon Congress to direct EPA to take prompt action on PCB's. I urge my colleagues to support my amendment on the Floor of the Hoilse during consideration of this measure.

John D. Dingell.

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SUPPLEMENTAL VIEWS OF MESSRS. MOSS, DINGELL,
METCALFE, BRODHEAD, MOFFETT, AND MAGUIRE TO
H.R. 14032, THE TOXIC SUBSTANCES CONTROL ACT OF
1976

In the most routine and necessary activities, the American public is exposed to thousands of untested chemical substances each day. The growing body of evidence indicating some of these chemicals for their damage to human health and the environment leads us to support sti ong toxic substances control legislation.

H.R. 10432 contains a number of provisions which we expect will be effective in providing this protection, and we are grateful for the efforts of those Avho crafted this compromise bill and successful shepherded it through the full committee consideration. However, we believe the compromise falls short in several key areas. The following provisions need to be strengthened in order to provide adequate protection for public health.

SECTION 4(E). ACTION BY THE ADMINISTRATOR ON ADVISORY COMMITTEE

PRIORITY LIST

Section 4(e) of H.R. 10318, the bill reported by the Subcommittee on Consumer Protection and Finance, established an interagency advisory committee to make recommendations to EPA of chemicals which should be tested. A list of chemicals, ranked in priority for action, was to be periodically submitted to EPA, and th« complete list was to be published in the Federal Register. Within 12 months of receiving the list the Administrator was required to either promulgate a rule requiring testing or to publish in the Federal Register the reasons for not taking action. H.R. 14032 changed the provision in two important respects: (1) The requirement that the list be published in the Federal Register was replaced by a requirement that the Administrator merely make the list available to the public; and (2) the requirement that the Administrator act on the recommendations within 12 months or publish reasons for not doing so was also deleted.

Removal of the data certain within w^hich the Administrator must

act or explain why he or she is not acting undermines the likelihood that the agency will deal expeditiously on the interagency advisory committee recommendations for testing of key toxic chemicals. Publication of agency decisions to act or not act pursuant to the authorities granted by this bill is also an important oversight tool for Congress and the public to determine whether the agency is properly carrying out its mission. If a chemical is important enough to be listed, it is important enough for the Administrator to consider action on it, either affirmatively or negatively, within one year of being listed.

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SECTION 5. INADEQUATE PREMARKET TESTING AUTHORITY

Section 5 of H.R. 10318 required that a manufacturer give the Environmental Protection Agency 90-day premarket notification of intent to begin commercial production. The Administrator was to review the notice and determine whether or not it contained sufficient safety information. In cases where safety information was insufficient and testing would provide that information, the Administrator was authorized to promulgate regulations to halt manufacture until adequate safety information could be developed. Under the subcommittee bill, such regulations could be made immediately effective.

H.R. 14032 changed section 5 to remove this authority to act after receiving notification. The substitute instead requires the Administrator to petition the U.S. district court to enjoin manufacture of the chemical or its distribution in commerce before the Administrator can proceed with a rulemaking under section 5(g) to impose manufacturing limitations or prohibitions.

Requiring EPA to petition the courts to prohibit marketing of a chemical about which there is inadequate safety information, rather than allowing the agency to require proper testing prior to marketing, places an unnecessary burden upon the courts and the agency. Furthermore, it places within the courts the decisionmaking which properly belongs to the Administrator.

SECTION 5. EXPLANATION BY THE ADMINISTRATOR OF WHY HE OR SHE IS TAKING ACTION OR NOT TAKING ACTION

At the expiration of the premarket notification period the Administrator has the option of initiating regulatory action or allowing the chemical to be marketed with no further action, or in some cases requiring further testing. At this point, the Administrator should give the public an explanation of what he or she has decided to do and why. The frequent complaint that Government agencies are impenetrable bureaucracies is due in part to the absence of provisions such as this which would require an explanation to the public and the Congress about a decision not to act under the discretionary provisions of the bill. It has an additional benefit in that the explanation would enhance congressional and public oversight of the Agency's decisionmaking criteria and framework.

SECTION 6. DELEGATION OF THE AUTHORITY TO ISSUE AN IMMEDIATELY EFFECTIVE RULE

The committee bill inappropriately deleted section 6(d) in H.R. 10318 which permitted the Administrator to declare a proposed action prohibiting manufacture, processing or distribution of a chemical substance or mixture to be immediately effective when such a substance poses an unreasonable risk. Such a procedure is essential to protect the public health and environment during the pendency of administrative decisionmaking. By contrast, H.R. 14032 would allow the public and the environment to be exposed to potentially lethal chemicals during agency deliberations which include hearings and limited cross-examination of witnesses. The bottomline is that lives, not short-term profits,

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are at risk during whatever time is required for EPA to act under the procedures established by H.R. 14032. This is a dramatic concession of the public interest to private, commercial concern.

Authority for expedited agency action is grounded in the Administrative Procedure Act, which the courts have routinely held gives an agency needed discretion to act quickly. The deleted section was more cautious than the APA required in that it mandated that the agency

provide an opportunity for oral presentations expeditiously after the Administrator has acted.

A common theme in recent calls for regulatory reform is complaint about cumbersome procedures. The change in this section removes the Administrator's authority to move quickly when circumstances require.

SECTION 6. CUMBERSOME FINDINGS WILL DELAY PROMPT AND EFFECTIVE ACTION

Section 6(c) of H.R. 14032 requires the Administrator to determine whether the risk could be eliminated by taking action under another Federal law administered by the Administrator. If such is the case, the Administrator must make a complicated finding that it was in the public interest to regulate under section 6(a) rather than the other law. The finding has to take into consideration all aspects of the risk, as well as make comparisons between this law and the other laws of the costs of complying, and of the "relative efficiency of actions." The procedure established by the committee bill appears likely to delay effective action by the Administrator because it imposes unnecessary and time-consuming requirements for findings as to the relative efficiency of the proceeding under this act or another statute.

SECTION 18. PREEMPTION OF STATE REGULATIONS

Section 18(a) of H.R. 10318 allowed States to ban use of chemical substances independent of any EPA action. H.R. 14032 in section 18(b) denies States the authority to regulate a risk associated with a particular chemical if the Federal Government has already acted with respect to that risk. A limited exemption to this preemptive policy is allowed if EPA determines, after substantial review, to allow a State to act to protect its citizens.

Traditionally States have been most sensitive to the health concerns of their citizens. As a consequence, States have been granted wide latitude under the Commerce clause of the Constitution to act on behalf of their citizens even when those regulated are marketing their products through the channels of interstate commerce. Congress has also enacted legislation which liberally defines the role of the States in important health and safety laws (Clear Air Act, 52 U.S.C. Section 1857(d); Federal Water Pollution Control Act, 42 U.S.C. section 1376).

Unfortunately, H.R. 14032 imposes on States a substantial barrier to action to protect their citizens when EPA has taken limited steps to regulate a particular chemical. They must apply to the Administrator for approval of their actions. This clearance can be granted only after

detailed inquiries by the Administrator, inquiries which will be directed to the States with their attendant costs. Finally, both the action

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of the State and the action of the Administrator would be reviewable in court. Such procedural roadblocks protect manufacturers but do little to protect the public.

ADDITIONAL RECOMMENDATIONS

Lack of enforcement schedule

One serious inadequacy in the Toxic Substances Control Act is the lack of any time-phased enforcement requirements. We can look for models to the air and water pollution control statutes currently in effect. If this legislation does not have careful deadlines for EPA action, the likely result will be prolonged delay and repeated postponements.

EPA should be required to publish criteria for identifying those substances for which regulations would be required, within six months. One year after publication of the criteria the Agency should be required to publish a list of all existing substances which should be regulated and to divide the list into three groups relative to the need for timely action. EPA should then issue regulations for the highest priority group within 2 years, the second group within 3 years, and the third group within 4 years. The Administrator should be required to make an annual review and revision of the lists. Under such a plan EPA would be required to issue regulations for all chemicals which were found to be posing an unreasonable risk to health or the environment within 7 1/2 years after enactment of the legislation.

It is essential for the protection of public health and the environment that the legislation seek to give the EPA a firm mandate for a comprehensive approach to protection from hazards due to chemical substances. Such will only be achieved through legislative directives and adequate financial support. As it stands now, the bill gives the EPA an imprecise directive and inadequate funding. In light of multiple hazards the public and the environment face, the lack of a precise mandate for prompt and comprehensive action renders this legislation inadequate.

Subpoena power

The committee bill does not provide the agency with subpoena power for such purposes as gathering information for investigating violations of the act, for deciding whether to take regulatory action, or for analyzing information in the agency's possession. It is inconceivable the agency can operate properly without the authority to demand information under traditional appropriate safeguards.

John E. Moss.

John D. Dingel.

Ralph H. Metcalfe.

William M. Brodhead.

Toby Moffett.

Andrew Maguike.

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MINORITY VIEWS ON H.R. 14032 TOXIC SUBSTANCES

CONTROL

The bill, H.R. 14032, which was reported by the Committee on Interstate and Foreign Commerce on June 9, would give the Administrator of the Environmental Protection Agency broad new powers over this country's chemical industry. In its barest form, the bill authorizes the EPA to require that manufacturers perform tests prescribed by the Agency, and give the Agency advance notification of its intent to market new chemicals or existing chemicals for new uses. Further, EPA is authorized to issue rules regulating the manufacturing, processing, use or disposal of a chemical as well as require that the company maintain records and submit reports as required by the EPA.

The House has passed Toxic Substances legislation in both the 92d and 93d Congresses, but this bill goes far beyond anything we have ever voted on. We are especially disappointed that the committee abandoned the approach adopted in the 93d Congress with respect to premarket notification and screening (section 5). In earlier bills,

the Administrator of EPA was authorized to compile a list of those chemicals which he finds pose a danger to health or the environment and the manufacturer of a listed chemical must then provide EPA with notice prior to marketing. In this manner the Administrator's attention would be focused on those potentially dangerous chemicals. The bill reported by the committee, on the other hand, would require that manufacturers of all new chemicals and new uses of existing chemicals notify and supply EPA with specified information 90 days prior to manufacture or marketing. EPA could extend that period another 90 days. This approach is objectionable because EPA will have to draw upon already limited staff and resources to give each reported substance or use thorough scrutiny within the time allotted. Further, we fear that EPA will be able to hold up the manufacturing of a chemical for up to 6 months for no better reason than , administrative backlog.

We fear that this legislation will prove ruinous for the small companies which make up much of this country's chemical industry. Industry estimates put the cost of this legislation at between \$358 million and \$1.3 billion annually. Even the General Accounting, Office estimated an annual cost of as much as \$200 million. Further, it , can cost as much as \$800,000 to test a single chemical. Although we i hope that EPA would not be so unreasonable as to routinely require testing of this magnitude, the costs of testing could be considerable, i and the costs of testing will fall heaviest on smaller. companies. i

Further, in the more than 100 pages making up this legislation, there is set out an incredibly complicated regulatory maze which is , guaranteed to completely baffle any layman attempting to pick his '

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way through it. And the bill will be augmented by more rules and regulations issued by the EPA. As we add these increased layers of bureaucracy, it will become more and more difficult to develop and process new chemical compounds. This will not present a great problem to the large chemical companies with their vast legal staffs. But for the small company, the time and expense of fighting the bureaucratic machine, as well as the significant costs of testing, may serve to discourage him from undertaking the project at all. This is especially

true when he is not able to predict the market a particular chemical may have.

We fear that the end result of this bill will be a long-range and insidious effect on inventiveness and innovation in the American chemical industry. Faced with extensive testing, the burden of pre-market screening, and the rigors of regulation under this bill, development and innovation in the chemical industry will inevitably be curtailed.

Although the above observations are of a general nature, we are specifically concerned about sections 20, 21, 23, and 24, and recommend that they be deleted from the legislation. We do not believe that these provisions do anything to improve the legislation but, in fact, could be used to harass companies regulated by EPA.

Section 20 provides that any person may bring a civil action against a company regulated under this act or against the EPA in order to enforce the act. Further, the bill specifies that complete costs of the suit, plus attorneys' and expert witnesses' fees, will be paid. If any individual has any idea about suing, he will find an eager lawyer who will bring this case to the already overcrowded judicial docket.

Section 21 provides that any person may petition EPA to issue a rule requiring testing or regulating of a substance. If EPA denies the petition and if the petitioner can show, by a preponderance of the evidence in a de novo proceeding in U.S. district court, that the substance may cause or contribute to an unreasonable risk, the court must order EPA to begin the requested proceeding. The citizen petition provision, with its requirement for a trial de novo, will force the Federal courts to hear complex, scientific testimony and make technical decisions more appropriately left to an expert regulatory agency. In essence, the court will be called upon to second-guess the judgment of the EPA in areas in which it has no expertise. Requiring that courts consider and decide technical and scientific factual questions rather than questions of law, not only places an undue burden on the Federal courts but also destroys the purpose for creating EPA as an expert agency. Further, this provision substantially diminishes the agency's ability to determine its priorities and channel its resources.

Section 23 is entitled "Employee Protection" and would prohibit an employer from disciplining an employee because that employee may have or is about to issue a complaint with the EPA. Of course, this means that any time there is an incompetent employee who has been put on notice that he is doing a poor job, one can anticipate that he will commence a proceeding against the company. He will, thereby, have the Secretary of Labor and the Administrator of the EPA protecting him until the case is disposed of – possibly years in the future.

This section, along with section 24, which authorizes EPA to con-

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duct investigations, issue subpoenas and hold hearings to determine the effects on employment from threatened plant closing which might be brought about by this act, provide so much potential for harassment that we strenuously object to their inclusion in any final legislation.

Finally, we note that Section 14(e) of the bill provides that information reported or obtained by the Administrator under this bill shall be made available upon written request of any duly authorized Committee of Congress. We firmly believe that such a provision is needed in that both courts and Attorneys General of the United

gress of "trade secret" information which was statutorily obtained by agencies of the United States Government would be a breach of confidentiality. A clear example of this position is enunciated in the case of *Hearst v. Black*. 87 F. 2d 68 (D.C. 1936). In this case, the Federal Communications Commission was enjoined from turning over to a Senate Committee certain material which the agency was statutorily required to treat as confidential. In the *Hearst* case there was no provision similar to section 14(e) ; if there had been *Hearst* would have had no case. Our position then is that Congress does have the power to acquire information of this sort, but not without the benefit of legislation that specifies that Congress can acquire it. The question of inherent authority is a matter for the courts to determine.

This provision in the bill raises an equally important question which the committee chose not to address. That question is: What is Congress' obligation to keep "trade secret" material confidential? This bill recognizes that there is certain information that should be kept confidential by the Executive Branch, but then Congress grants itself access to this information with no restrictions on disclosure. We believe that if Congress grants itself access to this type of material then Congress should establish the internal mechanisms that would insure

that "trade secrets" be kept confidential. Bear in mind that Congress is continually requiring the business community to turn over highly valuable and sometimes sensitive material to Federal agencies, and the business community is complying. They are complying because they understand that their trade secret and proprietary data will not be disclosed. If it becomes painfully apparent to the business community that these valuable materials will not be safeguarded, we believe that this climate of cooperation will seriously deteriorate.

States have traditionally taken

Samuel L. Devine.
James M. Collin.

HOUSE CONSIDERATION OF H.R. 14032

[Excerpt from the Congressional Record, Aug. 23, 1976, House, pp. H8803-SS63]

Toxic Substances Control Act

Mr. Pepper. ^Mr. Speaker, by direction of the Committee on Rules, I call up House Resolution 1458 and ask for its immediate consideration.

The Clerk re^d the resolution, as follows :

H. Res. 1458

Resolved, That upon the adoption of this resolution it shall be in order to move that the House resolve itself into the Committee of the Whole House on the state of the Union for the consideration of the bill (H.R. 14032) to reflate commerce and protect health and the environment by requiring? testing? and necessary restrictions on certain chemical substances and mixtures, and for other purposes. After jjeneral debate, which shall be confined to the bill and shall continue not to exceed one hour, to be equally divided and controlled by the chairman and ranking? minority member of the Committee on Interstate and Forei^ Commerce, the bill shall be read for amendment under the five-minute rule. It shall be in order to consider the amendment in the nature of a substitute recommended by the Committee on Interstate and Foreign Commerce now printed in

the bill as an original bill for the purpose of amendment under the five-minute rule and said substitute shall be read for amendment by titles instead of by sections. At the conclusion of such consideration, the Committee shall rise and report the bill to the House with such amendment*? as may have been adopted, and any Member may demand a separate vote in the House on any amendment adopted in the Committee of the Whole to the bill or to the committee amendment in the nature of a substitute. The previous question shall be considered as ordered on the bill and amendments thereto to final passage without intervening motion except one motion to recommit with or without instructions. After the passage of H.R. 14032, it shall be in order to proceed to the consideration of the bill S. 3149, section 402 of the Congressional Budget Act of 1974 (Public Law 93-344) to the contrary notwithstanding, and it shall be in order in the House to move to strike out all after the enacting clause of said Senate bill and insert in lieu thereof the provisions of H.R. 14032 as passed by the House.

Mr. Pepper. Mr. Speaker, House Resolution 1458 provides for the consideration of H.R. 14082. Toxic Substances Control Act, granting to the Administrator of the Environmental Protection Agency 'regulatory' authority to protect public health and the environment from potentially harmful chemical substances.

The resolution would permit the House to consider the legislation under an open rule with 1 hour of general debate. The rule makes the amendment in the nature of a substitute recommended by the Committee on Interstate and Foreign Commerce now printed in the bill in order as an original bill for the purpose of amendment.

The rule also makes it in order to call up the bill S. 3149 for the purpose of substituting the House-passed language, and waives points of order which could be raised under section 402 of the Congressional Budget Act- Public Law 93-844.

Section 402 prohibits consideration of authorization bills for fiscal year 1977 unless they were reported by May 15, 1976. This bill, S. 8149,

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was reported before May 15 in the Senate and thus was not in violation of the Budget Act when considered by that body.

H.R. 14032 does not contain authorizations for fiscal year 1977. The Senate bill does and when it is called up in the House it could be sub-

ject to a point of order. However, we are calling up the Senate bill solely for the purpose of inserting the House-passed language and, therefore, the waiver does not violate the spirit of the Budget Act. This assurance was given to the Committee on Rulers by the Budget Committee which has no objection to the waiver.

Mr. Speaker, there are more than 30,000 chemicals on the market and only a few thousand have been adequately tested to determine if they are safe. This number grows by about 1,000 each year, and there is no requirement that these chemicals be evaluated for health and environmental effects before they are marketed. Moreover, there is inadequate authority to regulate a chemical once it is discovered to be hazardous.

Toxic substances control legislation was passed in the House and the Senate in both the 92d and 93d Congresses, but time did not permit the conferees to resolve the differences between the House and Senate passed bills. This year, I understand the legislation passed by the Senate and that reported by the House Commerce Committee are much more similar.

H.R. 14032 has the general support of the major industry trade groups, environmental groups, citizens, and labor. I urge adoption of House Resolution 1458 so that we may proceed to the consideration of the Toxic Substances Control Act.

Mr. DeLoach. Mr. Speaker, as my colleague from Florida has explained House Resolution 1458 provides for the consideration of H.R. 14032, the Toxic Substances Control Act - a bill designed to regulate commerce and protect health and the environment by requiring testing of and restrictions on certain chemical substances and mixtures, and for other purposes. The resolution furnishes an open rule with 1 hour of general debate.

Upon the adoption of the resolution, it will be in order to consider the amendment in the nature of a substitute recommended by the Committee on Interstate and Foreign Commerce now printed in the bill as an original bill for the purpose of amendment.

The substitute shall be read for amendment by titles instead of by sections. Subsequent to the passage of H.R. 14032, it will be in order to proceed to the consideration of the bill S. 3149, section 402 of the Congressional Budget Act of 1974 notwithstanding, and to move to strike out everything after the enacting clause of the Senate bill and insert the provisions of H.R. 14032 in its place.

H.R. 14032 will require manufacturers and processors of potentially harmful chemical substances and mixtures to test the substances or

mixtures as required by rules issued by the Administrator of the Environmental Protection Agency so that their effect on health and the environment may be evaluated [Sec. 4].

It will require manufacturers of new chemical substances and manufacturers and processors of existing chemical substances for significant new uses to notify the Administrator 90 days in advance of commercial production [Sec. 5].

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The bill will authorize delays or restrictions on the manufacture of a new chemical substance if there is inadequate information to evaluate the health or environmental effects of the substance and if in the absence of such information, the substance may cause or significantly contribute to an unreasonable risk to health or the environment [Sec. 6].

Further, it will authorize the Administrator to adopt rules to prohibit, the manufacture, processing or distribution of a chemical substance or mixture, to require labeling, or to regulate the manner of disposal of a chemical substance or mixture for which there is a reasonable basis to conclude that it causes or significantly contributes to an unreasonable risk to health or environment [Sec. 6].

These provisions, and there are many more, are certainly comprehensive, but I wonder if, in our haste to deal with the onerous problems of toxic substances, if we are not paying too little attention to the ramifications of the legislation as it relates to the American chemical industry. In the more than 100 pages of this legislation, an incredibly complicated regulatory maze is mandated which is guaranteed to completely stymie any layman's attempt to wade through it. And the bill will be augmented by additional rules and regulations issued by the EPA.

As each layer of thick bureaucratic tape is applied over the hands and tools of American chemical companies, it will become more and more difficult to develop and process new chemical compounds, especially for the smaller companies involved. For them it will virtually be an impossible task. The larger chemical companies who have the means to retain vast legal staffs will, of course, be presented with only a minor problem.

But what of the small chemical companies? What are we forcing on

these companies who are struggling to compete on the market ^ Mr. Speaker, is it really responsible for us to seek to solve one major problem at the risk of creating another of similar magnitude i

The House. Mr. Speaker, has passed toxic substances legislation previously - in both the 92d and 93d Congresses. Xever before has this House made provision to place such a hea\`y burden on our competitive market where small chemical companies are concerned.

I would ask my colleagues to thoughtfully consider the consequences of the adoption of this legislation and to decide for themselves whether or not the burden is too heavy.

Mr. Speaker, in order that we may move to answer these (luestions and debate the provisions of the bill, I ask that the resolution be adopted.

Mr. Pepper. Mr. Speaker, I move the previous question on the resolution.

The previous question was ordered.

The resolution was agreed to.

A motion to reconsider was laid on the table.

Mr. Murphy of New York. Mr. Speaker, I move that the House resolve itself into the Committee of the Whole House on the State of the Union for the consideration of the bill (H.R. 14032) to regulate commerce and protect health and the environment by requiring testing and necessary restrictions on certain chemical substances and mixtures, and for other purposes.

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The Speaker. The question is on the motion offered by the gentleman from New York (Mr. Murphy).

The motion was agreed to.

IN THE COMMITTEE OF THE WHOLE

Accordingly the House resolved itself into the Committee of the "Whole House on the State of the Union for the consideration of the bill H.R. 14032, with Mr. Mann in the chair.

The Clerk read the title of the bill.

By unanimous consent, the first reading of the bill was dispensed with.

Mr. McCOLLISTER. Mr. Chairman, H.R. 14032, the Toxic Substances Control Act, is designed to give the Administrator of the Environmental Protection Agency broad, new authorities to regulate the chemical industry. That this legislation is before us today in its present form is a mark of the fine work done by the gentleman from Texas and the gentleman from North Carolina who were successful in working out many of the problems which have surrounded this bill. On two previous occasions, this body has passed similar legislation only to have the bills die in conference. I will admit that the bill leaves unaddressed some of the issues voiced by both sides to the controversy surrounding this bill, that is the environmentalists and the affected industries. Indeed, as I will discuss in a moment, I still have questions about several provisions. But, on a whole, I believe that the legislation presents a fairly well-balanced regulatory scheme which, if implemented in a reasonable fashion, will not prove to be unduly burdensome on those regulated. Therefore, I hope that we can pass this legislation and send it on to the White House in its present form.

In general, the bill would give EPA the authority to promulgate testing standards for chemical substances and mixtures, require a 90-day premarket notification period for all new[^] chemical substances, and prescribe various regulations which the chemical industry would have to meet. I want to take a moment to discuss the premarket notification provision of the legislation [Sec. 5], since this provision has been one of the most controversial sections of the bill. The bill would require manufacturers of all new chemical substances to notify EPA and provide certain specified information at least 90 days prior to manufacture or marketing. This approach of requiring premarket notification for all new substances represents, in my view, quite a departure from previous House-passed bills which would have limited])remarket scrutiny to substances which EPA found posed a danger to health or the environment. I believe that the more limited approach found in earlier House bills would serve to better focus EPA's attention and limited resources on the potentially dangerous chemicals, and I regret that we have decided to reject this more limited approach Avhich the House did adopt in both the 92d and 93d Congresses.

Section 5 is probably one of the most onerous provisions of the legislation with its requirement for premarket notification of all new chemical substances. However, this section does contain exemptions. For example, chemicals which are manufactured in small quantities for sale to laboratories for research purposes would not be subject to

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the premarket notification provisions of the bill. Further, research and analysis being performed during the developmental stages of chemicals which may ultimately be produced commercially would also be exempt from the premarket notification provisions of the bill. This exception for research and analysis related[^] to product development would exist regardless of whether the manufacturer were evaluating the product within its own plant or had made the product available to a potential customer with or without the payment of a fee. Section 5 must not be interpreted in such a way as to stifle product development and innovation, and we expect that EPA will implement Section 5 and the other provisions of the bill so that this result will not occur.

Section 6 of the bill gives EPA the authority to promulgate rules regulating the manufacture, processing, use and disposal of chemical substances and mixtures. At the outset, EPA is directed to issue the least burdensome requirement possible. For example, EPA could not ban a substance for a particular use if a labeling requirement would provide adequate protection. We have followed past practice in establishing a fairly formal rulemaking procedure, including opportunity for an oral hearing, a limited right to cross-examination, and judicial review based on the substantial evidence test. Further, EPA would be required to make certain findings before issuing a rule, including a finding as to the economic consequences of the rule taking into account the impact of the rule on small business.

The legislation does give the EPA authority to require that manufacturers maintain records and periodically submit reports. [Sec. 8] However, we also recognize that such recordkeeping can be unduly burdensome. Consequently, the legislation directs the agency to require the maintenance of reports that are nonduplicative of those required by other Federal Government agencies. Further, the legislation contains a partial exemption for small businesses from the recordkeeping requirement.

Even though, as a whole, I believe that H.R. 14032 is a well-honed piece of legislation, it does contain what I believe to be a very troublesome provision in section 21 dealing with citizens' petitions. This section would allow a private citizen to petition the YjPA to promulgate a rule requiring testing or the regulation of a particular chemical substance. Should EPA deny the petition or not act on the petition, the citizen could go to Federal court and, if he could show in a de novo

proceeding that the substance could possibly pose a risk, then the court would direct the agency to initiate the rulemaking proceeding as requested by the petitioner. A provision such as this was first inserted in the Consumer Product Safety Act and became effective in late October of 1975, with respect to the Consumer Product Safety Commission. This provision was inserted in the Product Safety Act as an experiment, and I believe that it is too soon to determine what effect, if any, the citizens' petition provision will have, not only on the workload of the agencies, but also on the caseload of the Federal courts. I believe that we should resist the temptation to insert this provision in other legislation until we have more closely examined the experience of the Consumer Product Safety Commission over a particular period of time.

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Further, I think it is inappropriate to insert this provision piecemeal into different bills. It may be that a citizens' petition provision is indeed a desirable concept and, if so, it should be made applicable to all regulatory agencies. If not, the concept should be dropped once and for all. To insert it in various bills in such a crazy-quilt fashion makes little sense, and I regret that the provision has found its way into the bill before us today.

Finally, I want to say a few words about the impact which this bill could have on small businesses. Certainly all Federal legislation falls more harshly on small businesses than on large companies who, as a rule, are better able to hire the legion of attorneys and accountants needed to cope with the myriad rules and regulations that some agencies hand down. However, we have, in this bill, made a genuine effort to deal with some of the unique problems that small businesses face. Further, we expect that EPA in implementing this bill, will pay special attention to the particular needs of small businesses. For example, in section 27 of the bill, we give EPA the authority to collect filing fees of up to \$2,500 to defray the cost of administering the act. However, these fees are to be based on ability to pay and we expect that EPA would impose lower fees, if any at all, on small companies.

Finally, we expect that EPA will establish close contact with the Small Business Administration so that EPA can more adequately

inform itself as to the particular problems faced by the small business community. Frankly, I have found that the small business community has little confidence in EPA's ability to issue sensible rules and regulations. This lack of confidence is based on EPA's past track record. If EPA will counsel with the Small Business Administration, to determine what effect its regulations will have on small companies, then this act need not have the harsh consequences that some are presently predicting. I, for one, will be closely watching EPA's performance in this regard.

Mr. Chairman, I think it probably should be said also that on both sides in the committee there was an effort made to hold to the language of the bill. I know that the conversations between the gentleman from North Carolina (Mr. Broyhill) and the gentleman from Texas (Mr. Eckhardt) will indeed be tested here and there, and some of the amendments offered may well seem to be very attractive. But I think we are obligated - we who have worked out the compromise - to hold to the language of the bill. I should have much preferred that the bill which I introduced originally would be the vehicle before us today. I regret that it is not. In any case, H.R. 14032 is the product of that labor before the Committee of the Whole today, and I hope that it passes in its present form.

I think that the distinguished gentleman in the well has underestimated his influence with respect to this bill in his very generous statement concerning myself and the gentleman from North Carolina (Mr. Broyhill). Actually he has, I think, devised many of the provisions that afford protection to small business. Perhaps we have not adopted enough to totally suit him. I suspect that that is true. Because he has been such a stalwart defender of the interests of independent small businesses on our committee, it might be difficult for us ever totally to suit him on that matter. But I think great credit must be given to the gentleman in this regard.

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There is one thing that I would like to bring out in this colloquy. The gentleman from Nebraska had referred to the premarket notification section of the bill [Sec. 5] and indeed that is perhaps the most controversial portion. He did mention certain exemptions and perhaps one other thing needs pointing out. This is on page 163 with respect to the administrative authority in identifying a chemical substance. It states ;

[Sec. 8(b)] (2) To the extent consistent with the purposes of this Act the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category- of chemical substances in which such substance is included.

I may say to the gentleman, I think this is an extremely important leeway to the Administrator. Say for instance a chemical substance is manufactured and produced inhouse in an oil and chemical refinery. That chemical substance may be a catalyst that undergoes successive changes. Under these provisions we felt that instead of requiring a 90-day notice every time a change was made that had the result of changing the chemical constituency of the substance, the single category comment.

I think that the gentleman will agree with me this is one of the provisions in which we carefully examined difficulties which could result from too rigid an act and met those possible objections.

Mr. McCoLLISTER. I do agree and I am grateful for the gentleman's could be mentioned and changes could be made within that category.

Mr. McGuiRE. Mr. Chairman, I rise in support of this landmark legislation. Everyone will agree that in considering legislation to protect the environment Congress must achieve a sensible balance between the needs of the economy and the need to protect the public health and welfare. No one will advocate shutting down the economy in order to protect the environment. And no one will advocate destroying the environment in order to protect the economy. Too often, however, the de-only satisfy one need or the other need, but not both. I strongly disagree. I believe that both needs can, should, and must be met. The fact is that society cannot live long without either. This is not to imply that satisfying lx)th needs is an easy task. It requires difficult decisions. It also requires a strong desire to work for and to achieve moderate resolutions of competing interests.

Faced with this task of resolving the conflicting needs of the economy and the environment I undertook to bring a measure a balance to the Toxic Substances Control Act. The concerns expressed by the chemical companies in New Jersey as well as those of the citizens and workers of my State, who daily face living in environment which continues to deteriorate, had to be weighed and i-econciled.

My efforts in the full Commerce Committee markup of this bill were aimed at developing new approaches which sought to alleviate the costs of compliance to chemical manufacturers and processors, especially those small and medium size companies to whom the additional costs of regulation might prove prohibitive without some kind of relief.

I sponsored three amendments to the bill in committee which were designed to approach this needed balance. All were approved. My first amendment, which redefines "mixtures" to include a broader range of formulations than did H.R. 10818, was incorporated in the drafting of the compromise bill, H.R. 14032 [Sec. 3(8)], which we are now

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considering. By redefining the mixture definition, to include certain kinds of reactive mixtures, it now more accurately differentiates between those mixtures to which the premarket notification requirements of section 5 would apply and those mixtures for which premarket notification would not be necessary. This has the effect of eliminating what would have been unnecessary regulation for a special class of mixture products which are generally produced by smaller chemical companies.

Two other amendments which I developed were unanimously approved in committee action.

The first [Sec. 26(d)] requires the Environmental Protection Agency - EPA - to establish an identifiable office to provide technical, referral and other nonfinancial assistance to chemical manufacturers and processors. In the accompanying report language it is clearly stated that this office shall concentrate its efforts on reaching out to the small and medium size chemical companies who will benefit in a great way from such an office. Details as to the status of standing regulations, outstanding public comment periods, legal assistance made available for certain provisions of the bill shared-cost testing arrangements, and so forth, will all be available to companies through this office. Another important function of the office would be to refer companies to the proper authorities in the regular Office of Toxic Substances who can handle specific problems. This concept of an identifiable office to assist small businesses may lead the way toward changes in other regulatory agencies where small businesses seem to be given less than adequate attention when regulations are proposed and implemented.

My final amendment addressed the question of which tests, from among available test methods, might be ordered by the Administrator under section 4 authority. Recent developments in the field of toxicological testing have centered on the emergence of low-cost, short-term bacteriological and mammalian cell tests for mutagenicity. These

tests show great potential for cutting down on the cost to all companies of testing their products to show what degree of hazard, if any, may be posed by their products. These test methods are in need of further refinements and the National Cancer Institute is conducting a research program into this area. My amendment authorizes the Secretary of Health, Education, and Welfare, in consultation with the EPA Administrator and acting through the Assistant Secretary for Health, to conduct and make grants and contracts for continued research into the field of low-cost and efficient test methodologies [Sec. 271.

Since the committee considered this bill the HEW appropriation for fiscal year 1977 has been announced and it directs that \$3 million be included in the budget for the National Institute for Environmental Health Sciences to expand its programs for short-term testing research and the carcinogenesis bioassay program being conducted in collaboration with the National Cancer Institute. It appears from correspondence which I have conducted with the Assistant Secretary for Health that added funds will not be needed at this time. Even so, the Assistant Secretary in his response to my inquiry on current testing programs, assured me that my amendment, in the context of this new regulatory bill, stands as an important statement of national policy that such

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test methods shall be considered, wherever feasible, for use in place of whole animal tests. The presence of grant and contract authority may yet prove significant for the purposes of this legislation. I am presenting the text of this letter for inclusion in the Record :

Department of Health, Education, and Welfare,

Washington, D.C., August 19, 1976.

Hon. Andrew Maguire,
House of Representatives,
Washington, D.C.

Dear Mr. Maguire : Thank you for your letter of July 27 concerning the current status of research in the development and validation of short-term toxicity tests in the Department of Health, Education, and Welfare laboratories. We share your view that establishing the reliability of rapid bioassay tests is very likely to have far-reaching impact on future regulatory decisions.

In addition to a wide variety of ongoing research activities in this area, the Department is presently developing a document on methods for determining mutagenic properties of chemicals which addresses the current utility of short-term tests for the identification of mutagens in the environment. This activity is under the direction of the Department's Committee to Coordinate Toxicology and Related Programs, chaired by the Director of the National Institute of Environmental Health Sciences (NIEHS).

As indicated by your letter, within the Department the NIEHS and the National Cancer Institute (NCI) are conducting and supporting most of the research and development in this area. These Institutes, beginning in the mid-to-late 1960's, pioneered in the development of short-term tests as a means of rapidly identifying chemicals having potential to cause either cancer or genetic defects. Since 1974 there has been considerable expansion of both Institutes' programs in this area utilizing grants, contracts, and, of course, intramural research to develop and evaluate inexpensive and efficient methods for assessing the health and environmental effects of chemicals.

As you may know, the Committee on Appropriations for the Department of Labor and the Department of Health, Education, and Welfare in its Report on the FY 1977 Appropriation directed that an additional \$3 million be included in the budget for NIEHS to expand short-term testing and for collaborative activities with NCI concerning the carcinogenesis bioassay program. As pointed out in that report, a very close working relationship exists between these two Institutes for developing short-term tests and establishing their acceptability as prescreens and possible alternatives to studies requiring years to conduct.

There are ongoing, continuous program activities at both NCI and NIEHS which seek to establish a matrix of procedures which can serve as an effective prescreen, and to establish priorities for further in-depth testing.

In our view the Public Health Service Act currently contains ample authority for our current and projected activities in this area. We would have no objection to additional language being included in the Toxic Substances Act as a statement of National policy.

In any event we agree with you that this is a vitally important area to the future health of the American people and we will continue to stress our efforts in this area.

Sincerely yours,

Theodore Cooper, M.D.,
Assistant Secretary for Health.

With the Toxic Substances Control Act now being considered by the full House I will be proposing; a further amendment to give the Administrator of EPA the authority to make grants to selected States,

with severe problems related to toxic chemicals, like New Jersey, to cover up to 75 percent of the costs of establishing and operating programs to prevent or eliminate unreasonable risks in the States to health or the environment associated with chemical substances or mixtures. The grant money is earmarked for use in ways which will complement the activities already underway or being planned by EPA for the implementation of this act and for activities which the Admin-

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istrator is unable to undertake because of inadequate resources or other higher priorities. It is not intended to, and will not replace, EPA's authority to require reporting, testing or any other of the authorities given in this act.

The need for strong provisions to begin reversing the deterioration of public health caused by toxic substances which is so evident in my own State of New Jersey is clear. The same is true of other States - New York, Pennsylvania, Ohio, and Texas, for example.

There can be no doubt that the chemical industry has brought great benefits to the people of this country through continuing advances in the manufacturing, agricultural, and service sectors of the economy. But we have paid a high price for that progress. For far too long the chemical industry has proceeded to conduct business without giving adequate attention to the health and environmental dangers of the substances which they produce. At last we have before us legislation which will take significant steps toward insuring that the industry assumes full responsibility in protecting the public from those chemical products which are hazardous.

As a representative from the State of New Jersey I am all too familiar with the serious health problems in my State and the relationship of these problems to the heavy concentration of industrial activity there. New Jersey is host to nearly one-fourth of the chemical companies in this country. Evidence mounts that some of this chemical manufacturing and processing activity may pose a genuine threat to the public health. The major study on cancer mortality by counties, conducted by the National Cancer Institute, found a high correlation between cancer deaths and densely concentrated industry. New Jersey's 21 counties were found to be in the top 10 percent of all counties in the Nation for the rate of cancer deaths. In Salem County, N.J., where 25 percent of the male population works in the chemical industry, the Nation's highest rate of bladder cancer deaths was recorded. This

alarming rate of bladder cancer mortality, an occupational disease associated with exposure to various chemical substances, emphasizes the suspected relationship of chemicals in the workplace and the environment and the excessive cancer incidence and mortality in our State.

On May 28 of this year I chaired an official hearing in Newark, N.J., of the Commerce (committee's Oversight and Investigations Subcommittee. The subject of the hearing was "Cancer in the Environment" and the testimony of experts pointed to the fact that indeed the chemical population in New Jersey is extensive and that EPA does not yet know what chemical, toxic pollutants are present in our State. As a result of that hearing EPA granted a request from the commissioner of the New Jersey Department of Environmental Protection to conduct air monitoring, especially for nitrosamines known to be carcinogenic to humans. Not only were nitrosamines found in the atmosphere in our State but they were also present in significant concentrations in our soil and water along with significant amounts of other organic chemicals. Monitoring to establish the quantities of chemical substances must be continued and expanded ; especially multimedia monitoring which would give a comprehensive evaluation of the passage of chemical substances from one medium to another. It is to problems such as exist in New Jersey, and for State programs such as this, which would augment EPA efforts, that the funds from another amendment

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I will be offering would apply. I will discuss the particulars of that amendment when I offer it later today.

In conclusion, let me stress that New Jersey is actively working to evaluate the extent of these serious threats to the public health. Gov. Brendan Byrne has established a cabinet committee on cancer in an effort to coordinate New Jersey's programs at the highest level of government. The department of environmental protection in our State, an agency whose programs have earned the respect of EPA, is presently drawing u]) plans to expand its programs for measuring the extent of exposure to and the presence of carcinogens, and other environmental contaminants, in the environment.

Specifically the department would like to undertake an inventory of toxic chemicals in use in the State which would record their amounts, forms, and sources of emission, and their ultimate pathw^ays through the environment. Ilaving identified types of substances and pinpointed

the serious risks, monitoring programs would be refined to go beyond measuring the overall pollution of various media and take in more detailed information on organic and inorganic materials, concentrations of which may not be evident from general sampling techniques. Additionally much remains to be learned about the safe handling and disposal of toxic wastes and the department of environmental protection is presently drawing up plans to study and develop safer methods of disposal.

I enclose for the Record, a recent article "The War on Cancer", by Glenn Paulson and Peter W. Preuss of the New Jersey State Department of Environmental Protection.

[From the New York Times, Aug. 15, 1976]
War on Cancer: The Deadly Fight
(By Glenn Paulson and Peter W. Preuss)

The Cancer Atlas[^] published in 1975 by the National Cancer Institute, showed that for a large number of different cancers the State of New Jersey as a whole and many counties within the state ranked significantly above the national average over the 20-year period from 1950 to 1970.

Cancer rates vary significantly between regions in the United States. In general, states with high rates are the Industrial states, such as New Jersey.

We cannot precisely estimate, for New Jersey or for the nation, the extent to which observed cancer rates and changes in those rates are caused by chemicals. Some cancer undoubtedly arises from natural sources, such as cosmic or solar radiation ; our best judgment is that this is a small fraction.

However, there are many examples of cancer directly traceable to industrial or other human activities that involve chemical or other cancer-producing agents.

Liver cancer caused by vinyl chloride, mesothelioma caused by asbestos fibers, lung cancer caused by arsenic compounds, uranium dust, and other agents, a particularly debilitating lung cancer caused by beryllium, and bladder cancer caused by dye and chemical intermediates such as beta-naphthylamine are a few of the well-understood examples. Unfortunately, even the primitive knowledge available at this time leads us to conclude that more such examples will be found in future years.

Exposure to carcinogenic materials is not confined to the industrial work place. In a preliminary assessment of drinking water carried out by the United States Environmental Protection Agency, known and suspected carcinogens (cancer-causing agents) were found in the two New Jersey sources of drinking water that were tested, the Passaic Valley Water Commission and Toms River Water Company. The significance of the levels that were found is not clear, however. This was a preliminary assessment ; E.P.A. made no attempt to measure other

families of known or suspected carcinogenic agents.

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The Department of Environmental Protection should devote more effort to determining and defining the dangers New Jersey residents face as a result of exposure to carcinogens and other environmental contaminants. One important step would be to begin to inventory the presence and patterns of use of toxic chemicals in the environment. Another need is to expand efforts in measuring the concentrations of carcinogenic and other exotic pollutants that may be present in the air, drinking water supplies, fish and other wildlife, surface and ground waters, and sediments.

At present, the department has permit systems that collect data on the emissions of certain relatively common pollutants into the air and water. These existing systems should be expanded to provide information on the emissions of all potentially carcinogenic and other toxic substances. The Solid Waste Administration is developing an equivalent system that would allow it to collect information at a level of detail similar to that obtainable through the air and water permit systems ; this system will allow collection of data regarding emissions, treatment and disposal of solid and liquid toxic wastes.

A department-wide inventory would provide information about the toxic chemicals currently in use in New Jersey, their amounts, and their emissions, as well as their ultimate pathways into the environment. This information will allow priorities to be established for monitoring and regulation. It will also help establish the criteria upon which regulations may be based, including, for example, toxicity, persistence in the environment, and amounts used in the state.

To avoid creating more problems in the future, a program should be established for the environmentally safe treatment and disposal of solid wastes. Such a program would logically be a part of the overall solid waste management program being developed by the Solid Waste Administration. One of the first steps is to determine what kind of wastes are produced, how they are transported, and where they are treated and disposed.

There are a number of toxic substances for which sufficient information is available now, so that a determination may be made as to the unsuitability of their disposal on land. In order for these wastes to be disposed of properly, however, alternative treatment or disposal methods must be made available. This will require the development of criteria to define environmentally sound disposal procedures.

The first priority in this area is the development of performance criteria for incinerators that are or may be used to dispose of toxic and hazardous organic materials. These criteria must insure that the materials are burned completely, and that no toxic substances enter the air through the stack or into the water via water used for cleaning ("scrubbing") the exhaust gases.

The presence of one or more such facilities in New Jersey would provide a necessary alternative to help insure that environmentally dangerous chemicals may be safely treated.

Another problem is the disposal of sludge produced in sewage-treatment facilities. Sludge often contains toxic substances from the effluents of industrial facilities that feed into the sewage plant ; sludge is presently disposed of in the ocean. The Federal policy for disposal of such sludges calls for the phasing out of ocean dumping by 1981 ; as a result, alternative methods will have to be found.

It will be necessary to monitor carefully the development of alternative programs, as well as the facilities themselves to insure that toxic substances present in sludge are not inadvertently released into the environment.

The Department of Environmental Protection, by building on its existing legal authorities and regulatory programs, can take sound steps toward minimizing the threat that cancer-causing agents and other toxic and hazardous pollutants pose to human health in New Jersey.

Mr. Otting?:r. Mr. Chairman, I would like to congratulate the subcommittee chairman and the gentleman from Nebraska for bringing this vitally important legislation before us, this legislation which is vitally important to the health of the Nation, and particularly to complement, as they did, the gentleman from Texas (Mr. Eckhardt) and the gentleman from North Carolina (Mr. Broyhill) for the adept manner in which they were able to work out with the chemical industry the very complicated, complex, economically significant, and controversial items in this bill. I think they did a superlative job and

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a meaningful bill through the committee which obtained the support of the chemical industry. I think that is an attribute to both their efforts and the chemical industry.

The February 13, 1976 issue of Science Magazine had an article titled "Control of Toxic Substances : an idea whose time has nearly come." I dearly hope the time is now, for this legislation has been

stalled for too long as the cancer rates of the country continue to soar. AMien medical authorities seem to agree that between 60 and 90 percent of all cancers have an environmental cause, surely the place to test new chemicals for their potential hazard is not after they have reached the environment, but in the laboratory.

The Toxic Substances bill, H.R. 14032, is not a perfect panacea for the frightening statistics mentioned above but it is a most important beginning and I commend my colleagues on the Interstate and Foreign Commerce Committee who have worked so hard to bring this legislation forward.

The issues dealt with in the legislation are of overwhelming importance; we are sadly more and more aware of the significance as we read of horrendous instances of either chemical pollution or of "mysterious fatal diseases" - all of which might have been prevented if legislation such as this had been in operation sooner. I want also to congratulate both the environmental and consumer groups who have worked together in support of the bill before us.

While I very strongly support the bill, I believe it needs to be improved with respect to the use of nonanimal tests where they are adequate and accurate.

TOXIC SUBSTANCES BILL

At the appropriate time, I will offer an amendment to H.R. 14032, the Toxic Substances Control Act, to prevent the unnecessary use of animals in laboratory experiments.

My amendment to section 4(2) (A) states that "* * * in prescribing tests the Administrator in his discretion shall give preference to available tests which do not involve the use of animals if such tests provide an adequate and accurate means for ascertaining the effect of a chemical substance or mixture on humans and the environment."

This amendment does not ban the use of animal tests, nor does it make it more difficult for the Administrator to prescribe animal tests if he feels they are" necessary. Quite simply, it is meant to require the Administrator to consider alternative testing methods and direct him to use them when, in his discretion, he finds they are adequate and accurate.

Two nonanimal tests presently exist, and have been used to test the toxic effects of known and unknown carcinogens. One such test uses bacteria ; the other laboratory-grown mammal cells. Both are cheaper, easier, faster, and as effective as their whole animal counterparts. I think we should promote their use where feasible and thus minimize

the pain and suffering administered to laboratory animals.

I strongly support adoption of the bill and hope this improving amendment will be adopted.

^ Mr. Collins of Texas. Mr. Chairman, we have heard much discussion about the compromises that were reached between the two sides.

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I could not help but think as I kept sitting there and listening, I wish we would compromise all the facts so we did not have any bill at all. The people that advocated these compromises represented big companies, because big industries can send a lawyer down here. They can send technicians down here to express the views of big industry ; but Avhat we are faced with is the fact that the little businessman, who runs a small Business with 40 or 50 people in it, does not have 10 people in his legal section. He does not have specialized chemists that can fight this thing. So what happens when we pass a bill of this typo is that there is no way a small businessman can live under it. The bureaucracy, the paperwork, the complications, make it overbearing on the manager of small business. The least, I think, that anyone could process for approval would be about \$50,000. That will be the least cost and he cannot put up that much or maybe \$100,000. He cannot afford that sort of thing. So it is going to be the end of the line for all but the giants. i

Mr. Chairman, I would like to further discuss some of the other features of this bill. One group that is probably going to be hurt thei most of all is agriculture. We have in this country the greatest agricultural system that has ever been developed. I come from a city. I del not have over 20 farmers in my district, but the thing that always impressed me was that the American farmers make up only about 4 percent of our population; yet we produce more food than anybody. We really do produce. Over in China, I think it is 80 percent of the people woi'k on farms. In order to produce, they need chemicals and they need these materials to help them.

Mr. EckHARDT. Mr. Chairman, is the gentleman under the impres- sion that this bill would do anything at all with respect t^ pesticides?

Mr. Collins of Texas. I just think in general that anything could be involved through lawsuits. I understand pesticides are out; but we could say anything is a chemical. How do we define "a chemical"?

I thought any combination of elements became a chemical.

Mr. Eckhardt. Mr. Chairman, if the gentleman Avill yield further, that is right; but there are exceptions in the bill. The principal thing this bill purports to do is require that those chemicals put on the market be reported and tested ; but Ave have absolutely nothing in the bill that prevents them from flowing to the marketplace after a maximum of 180 days, unless court action has been taken and that court action has to be based on a determination that they pose a danger.

NoAv, how is the farmer affected by this bill ? I cannot see it.

Mr. Collins of Texas. Well, it has been my experience Avith the courts that as they reach out on their interpretation of any and every subject, that they can go a long way to determine Avhat is terminology. When they determine something to be a pesticide or not is whatever the court determines it to be.

T can give an example, not on this bill, but on busing. There is nothing on the books that says Congress has permitted busing, but courts over the country are defining busing to meet their vicAvs. When { AA'e raise the question that there is nothing here that says pesticides, T Avould remind my friend, the gentleman from Texas, that the lawyers, the judges on the benches, Avill read into this anything they want to.

When we set up the mechanism for EPA to develop it, then Ave have set up the toxic subject for full bureaucratic intervention.

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We have so many bureaucratic rules now that EPA can get into anything they choose. What disturbed me especially in this bill was the fact that we have two sections in here that are going to make it possible for any employee who sees that he is about to be fired to take some action that should give him permanent employment. I am referring to sections 23 and 24. It not only protects him, but it seems that it would almost encourage lawyers to represent him.

Section 23 says:

No employer may discharge any employee or otherwise discriminate against any employee with respect to the employee's compensation, terms, conditions, or privileges of employment because the employee (or any person acting pursuant to a request of the employee) has -

(1) commenced, caused to be commenced, or is about to commence or cause to be commenced a proceeding under this Act ;

(2) testified or is about to testify in any such proceeding; or

(3) assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes of this Act.

What that will do, for instance, is to have this complaint go to the Secretary of Labor. Anybody who is a deadhead on the job, lazy, comes in drunk, tears up the whole place, can now file some kind of complaint on the grounds that something is wrong with the company's products, and from then on he has got built-in job protection. To carry that a step further, when they get through the company has to reinstate the complainant to his former condition as far as compensation goes, and also may include compensatory damages and exemplary damages.

I want to go to section 24, because we seem to be encouraging labor unrest in this bill. In section 24, they say :

The Administrator shall evaluate on a continuing basis the potential effects on employment (including reductions in employment or loss of employment from threatened plant closures) of -

(1) the issuance of a rule or order under section 4, 5, or 6, or

(2) a requirement of section 5.

(b) (1) Investigations. - Any employee (or any representative of an employee) may request the Administrator to make an investigation of -

(A) a discharge or layoff or threatened discharge or layoff of the employee, or

(B) adverse or threatened adverse effects on the employee's employment, allegedly resulting from a rule or order under section 4, 5, or 6 or a requirement of section 5. Any such request shall be made in writing, shall set forth with reasonable particularity the grounds for the request, and shall be signed by the employee, or representative of such employee, making the request.

We have a provision in this bill and in the terminology, of the report as written up to provide for any interested civic group to enter into this intervention action. The lawyer of this civic group is paid by the court on a full fee scale above his regular salary level. It seems to encourage these foundations and civic groups to have their salaried

people enter into legal proceedings, because they are going to draw even more in compensation.

If I ever saw a mumbo-jumbo bill encouraging an employee to do a bad job for a company, this it it. It encourages lawyers, if they are not fully occupied, to stir up one of these lawsuits under this bill.

We have passed more laws in this session of Congress than in any session of the Congress. Yet, when we go home to talk to the folks back home, they will tell us that this is a poor Congress. The reason is that

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we are passing more bills than the public needs, more than it wants, and certainly more than it can afford. The only ones I can see who are going to benefit from this particular piece of legislation are lawyers.

At this time I would like to include the minority views that were filed with this bill where I was joined by my colleague, the gentleman from Ohio (Mr. Devine).

Mr. Chairman, the bill, H.R. 14032, which was reported by the Committee on Interstate and Foreign Commerce on June 9, would give the Administrator of the Environmental Protection Agency broad new powers over this country's chemical industry. In its barest form, the bill authorizes the EPA to require that manufacturers perform tests prescribed by the Agency, and give the Agency advance notification of its intent to market new chemicals or existing chemicals for new uses. Further, EPA is authorized to issue rules regulating the manufacturing processing, use or disposal of a chemical as well as require that the company maintain records and submit reports as required by the EPA.

The House has passed toxic substances legislation in both the 92d and 93d Congresses, but this bill goes far beyond anything we have ever voted on. We are especially disappointed that the committee abandoned the approach adopted in the 93d Congress with respect to premarket notification and screening - section 5. In earlier bills, the Administrator of EPA was authorized to compile a list of those chemicals which he finds pose a danger to health or the environment and the manufacturer of a listed chemical must then provide EPA with notice prior to marketing. In this manner the Administrator's attention would be focused on those potentially dangerous chemicals. The bill reported by the committee, on the other hand, would require that

manufacturers of all new chemicals and new uses of existing chemicals notify and supply EPA with specified information 90 days prior to manufacture or marketing. EPA could extend that period another 90 days. This approach is objectionable because EPA will have to draw upon already limited staff and resources to give each reported substance or use thorough scrutiny within the time allotted. Further, we fear that EPA will be able to hold up the manufacturing of a chemical for up to 6 months for no better reason than administrative backlog.

We fear that this legislation will prove ruinous for the small companies which make up much of this country's chemical industry. Industry estimates put the cost of this legislation at between \$358 million and \$1.3 billion annually. Even the General Accounting Office estimated an annual cost of as much as \$200 million. Further, it can cost as much as \$800,000 to test a single chemical. Although we hope that EPA would not be so unreasonable as to routinely require testing of this magnitude, the costs of testing could be considerable, and the costs of testing will fall heaviest on smaller companies.

Further, in the more than 100 pages making up this legislation, there is set out an incredibly complicated regulatory maze which is guaranteed to completely baffle any layman attempting to pick his way through it. And the bill will be augmented by more rules and regulations issued by the EPA. As we add these increased layers of bureaucracy, it will become more and more difficult to develop and process new chemical compounds. This will not present a great problem to the large chemical companies with their vast legal staffs. But for the small

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company, the time and expense of fighting the bureaucratic machine, as well as the significant costs of testing, may serve to discourage him from undertaking the project at all. This is especially true when he is not able to predict the market a particular chemical may have.

We fear that the end result of this bill will be a long-range and insidious effect on inventiveness and innovation in the American chemical industry. Faced with extensive testing, the burden of pre-market screening, and the rigors of regulation under this bill, development and innovation in the chemical industry will inevitably be curtailed.

Although the above observations are of a general nature, we are specifically concerned about sections 20, 21, 23, and 24, and recom-

I mend that they be deleted from the legislation. We do not believe that these provisions do anything to improve the legislation but, in fact, could be used to harass companies i-egulated by P]PA.

Section 20 provides that any person may bring a civil action against a company regulated under this act or against the EPA in order to enforce the act. Fui-ther, tlie bill specifies that complete costs of the suit, plus attorneys' and expert witnesses' fees, will be paid. If any individual has any idea about suing, he will find an eager lawyer who will bring this case to the already overcrowded judicial docket.

Section 21 provides that any person may petition EPA to issue a rule re(juiring testing or regidating of a substance. If EPA denies the petition and if the petitioner can show, by a preponderance of the ('N'idence in a de novo proceeding in ILS. district court, that the substance may cause or contribute to an unreasonable risk, the court must oi'dei' EPA to begin the i'e(]uested proceeding. The citizen petition }rovision, with its requirement for a trial de novo, will force the ; FedoT-al courts to hear complex, scientific testimony and make technical decisions more appropriately left to an expert regulatory agency. ; In essence, the court will l>e called upon to second-guess the judgment of the EPA in areas in which it has no expertise. Requiring that ; courts consider ami decide technical and scientific factual questions I rather than questions of law, not only places an undue burden on the Federal courts but also destroys the purpose for creating EPA as an K expert agency. Further, this provision substantially diminishes the ' agency's ability to determine its priorities and channel its resources. Section 23 is entitled "Employee Protection" and would prohibit an employer from disciplining an employee because that employee may rl have or is about to issue a complaint with the EPA. Of course, this V means that any time there is an incompetent employee who has been i[put on notice that he is doing a poor job, one can anticipate that he I will commence a proceeding against the company. He will, thereby, j have the Secretary of Labor and the Administrator of the EPA pro- ' tectinj r him until the case is disposed of - possibly years in the future.

This section, along Avith section 24. which authorizes EPA to t conduct investigations, issue subpoenas and hold hearings to determine ' the effects on employment from threatened plant closintr which might be brouirht about by this act, provide so much potential for harassment that we strenuously object to their inclusion in any final legislation.

Finally, we note that section li(e) of the bill provides that infor- ? mation i-eported or obtained by the Administrator under this bill shall be marie available upon written request of any duly authorized

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committee of Congress. We firmly believe that such a provision is needed in that both courts and Attorne3's General of the United States have traditionally taken the position that disclosure to Congress of ''trade secret'' infonnation which was statutorily obtained by agencies of the U.S. Government would be a breach of confidentiality. A clear example of this position is enunciated in the case of Hearst v. Blacky 87 F. 2d 68 (D.C. 1936). In this case, the Federal Communications Commission was enjoined from turning over to a Senate committee certain material which the agency was statutorily required to treat as confidential. In the Hearst case there was no provision similar to section 14(e) ; if there had been Hearst Avould liaA^e had no case. Our position then is that Congress does have the power to acquire information of this sort, but not without the benefit of legislation that specifies that Congress can acquire it. The question of inherent authority is a matter for the courts to determine.

This provision in the bill raises an equally important question which the committee chose not to address. That question is : What is Congress obligation to keep ''trade secret'' material confidential? This bill recognizes that there is certain information that should be kept confidential by the executive branch, but then Congress grants itself access to tliis information with no restrictions on disclosure. We believe that if Congress grants itself access to this type of material then Congress should establish the internal mechanism that would insure that ''trade secrets'' be kept confidential. Bear in mind that Congress is continually requiring the business community to turn over highly valuable and sometimes sensitive material to Federal agencies, and the business community is complying. They are complying because they understand that their trade secret and proprietary data will not be disclosed. If it becomes painfully apparent to the business community that these valuable materials will not be safeguarded, we believe that this climate of cooperation will seriously deteriorate.

Mr. Chairman, I recommend that we vote against this bill.

Mr. Stagoers. Mr. Chairman, members of the Committee, this bill has been considered in the 92d, 93d, and now^ the 94th Congress. The House has passed it twice, and s*^ has the Senate. We have never been able to come to agreement in conference.

I would be remiss if I did not say that this is not a perfect bill. I do not know of a perfect bill that has passed this House. There are some flaws in it, but we will try to w^ork them out in conference. This bill

should be passed.

This bill principally is intended to have new chemicals coming on the market regularly tested to see that they are not going to harm people or the environment.

Mr. Chairman, as I said, it is not a perfect bill. We all know that. There are some imperfections, and there may be some amendments made to it. I am sure that if we find some things that are wrong with it, we can try to correct them. But this is legislation which has been needed for a great many years.

Mr. McCORTNER. Mr. Chairman, I want to say that we are at the point where we are because a great many difficult issues have been compromised and agreed upon, and I would hope we would not go further in our conference with the Senate than we have gone here: that we have a very delicate balance now, and I am just cautioning the Members that that balance can be destroyed rather readily.

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Mr. Staggers. Mr. Chairman, I can agree with the gentleman. The gentleman remembers that is one of the reasons the first bill did not pass. The Senate insisted upon theirs, and we said, "We have to be reasonable to the business people of America," and we did not compromise on what we thought was right for business in the land.

Mr. Chairman I want to compliment the gentleman from Nebraska on his part through the years in working on this legislation and for his interest. He has done a great job. As well as the chairman, the ranking member on the other side, and the gentleman from Texas (Mr. Eckhardt). They have all been very interested in these 4 or 5 years that we have been working on this bill and they have done an excellent job.

Mr. Hicks. Mr. Chairman, the action the Congress takes in considering the Toxic Substances Control Act is a test of our concern for the American people. It is also a test of our consistency. My special concern with this legislation stems from hearings that the subcommittee and Housing subcommittee of the Government Operations Committee held on controlling toxic substances in the workplace. We all know that controlling hazardous materials is important in the marketplace and on the farm, but those who must handle potentially dangerous chemicals every day they earn their bread are at even greater hazard. They

can neither select the chemicals to which they will be exposed, nor avoid such exposure except at the cost of their job.

The vote on this legislation will show where we strike the balance between imposing more requirements on those who produce and market chemicals – a fact we must recognize – and providing protection to many who cannot by any means provide it for themselves. I think this balance has to be struck by placing more responsibility on those who manufacture and formulate chemicals. A recent study by the National Institute for Occupational Safety and Health disclosed that almost half the exposures to identified cancer-causing chemicals was attributable to the use of products that were identified only by trade-names. The composition of these was treated as a secret by their formulators. Our hearings showed that we are way behind in our ability to identify chemicals that can destroy the health of workers who are exposed to them daily. We are even further behind in developing standards for the labeling and control of those chemicals that we already know are hazardous. Presently, complete standards exist for fewer than 2 dozen chemicals. Even here, the fact of exposure to these chemicals is unknown in close to half the cases because the ingredients of the products used are not disclosed. Surely this is a situation that AAT can no longer tolerate.

I said that our vote will also be a test of our consistency. In 1970, we passed the Occupational Safety and Health Act. As we all know, the Act has been the subject of much controversy. That controversy, however, has centered on some of the standards and the way they are applied; it has not swirled around the requirement in the act that an employer tell his employees whenever they are exposed to a dangerous concentration of hazardous chemicals. Since the passage of this act, employers have had a legal requirement to inform employees about dangerously high levels of exposure. Such a requirement is certainly warranted in these days when thousands of new chemical products are flowing into the workplace every year. Yet, in our hearings this year.

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the Assistant Secretary of Labor for Occupational Safety and Health agreed that employers could not comply with the law because they did not know the composition of products that they use in their plants.

Look at the size of the problem – the NIOSH Registry of Toxic Chemicals lists over 19,000 unique chemical substances. The Council on Environmental Quality estimates that 700 new chemicals enter com-

mercial production each year. Yet, the Occupational Safety and Health Administration has been able to issue standards at a rate of only three per year. Both the Assistant Secretary for Occupational Safety and Health and the Director for the Institute of Occupational Safety and Health testified at our hearings that without a toxic substances control act, federal regulatory machinery will never catch up. Unless we require testing of chemicals before they are marketed, how are we to know the toxic effects of new chemicals? Regulation after the fact not only uses our workers as experimental groups without their consent, but also fails to protect them even after damage to their co-workers establishes that a chemical is dangerous.

It can be contended that the burden should be put on the employer – that he should refuse to purchase products unless the manufacturer discloses their composition. This approach is used by some large companies today, with varying degrees of success. In our hearings, we looked at the practices of the Federal Government – the Nation's largest employer – to determine how successfully the Government itself was complying with the law that this Congress passed 6 years ago. For the past 5 of these years, there has been a Federal standard that required Government purchasers to obtain hazardous material data sheets that disclosed the hazardous substances in any product. Despite this, the large purchasing agencies of the Government have obtained these sheets only in a few scattered instances, and Government hygienists, safety professionals, and doctors in the field installations we visited often had never received any data sheets on the hundreds of chemicals that these installations use daily. If the Federal Government cannot tell its employees what they are exposed to, what chance does the owner of a small establishment have of demanding and receiving this information from suppliers who have been effectively denying it to the Federal Government in the face of existing regulations ?

Mr. Chairman, our hearings have shown that the 1970 law is not being obeyed. Employers are not telling employees when they are using hazardous substances, and it seems doubtful that they will be able to unless they are able to find out the contents of the products that they purchase for their businesses.

It would be vastly more effective and less expensive, to identify these substances from the initial manufacturing process onward. Detective work to identify the ingredients of individual formulated products come only after they are already in American marketplaces and factories. The initial producer knows, or can find out, what chemicals he is using. In the chain of marketing, the level at which a substance is first introduced is the most effective and cheapest place to identify it. At this level, it is nearly always known, or can readily be determined. Without the requirement of disclosure by those who develop chemicals

or blend them into products, millions of American workers will continue to be exposed to substances that can cause disease and death.

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For some of these substances, there may not be an acceptable substitute, but there are protective measures available to reduce or eliminate the hazards to health. These protective measures will not be taken unless the employer and the workers are aware that they are needed. In 1970, the Congress said that American workers should not have to pay for their jobs with their health. In this legislation, we have the opportunity to fulfill the promise of that legislation. The toll of occupationally caused diseases and deaths in our workplaces today makes using that opportunity an obligation.

Mr. Staggers. With what I have said, Mr. Chairman, I would conclude. I believe the time has come when we must do something to protect the health of the people of America with regard to the new chemicals which are coming on the market, and this is about the only way we can do it.

I would hope that the EPA, in the administration of the bill, will use discretion. I think the committee will look into EPA's activities and see that they administer the bill fairly while protecting the people of this country.

Mr. Broyhill. Mr. Chairman, I rise in support of this bill. As has been documented, there are chemicals which have been coming on the market, new chemicals, by the thousands. Studies have shown that many of these chemicals, in many cases, are harmful to the health of humans and the environment. Facts have been presented to the committee which indicate that streams have been polluted as a result of dangerous chemicals having been dumped in the streams. The health of humans is directly affected by their coming in direct contact with these dangerous chemicals.

There is no legal authority to deal with testing of dangerous chemicals or those that may pose danger to the health or the environment. We do have laws which regulate disposal of chemicals, but we do not have any laws relating to the testing of chemicals, that is, to assess the safety of these chemicals before they are marketed or before exposure does occur.

So what this bill would do would be to require that the manufac-

turers who bring new chemicals onto the market, or find any new uses for old chemicals, test them to assure that they are safe for use. This testing would be done by uniform regulations of EPA and the test results would be submitted to the EPA in advance of marketing.

Mr. Chairman, .as has been stated, a number of amendments and compromises have been agreed to in this bill. I think that as a result of that we have made it a workable bill. I urge that the House adopt it in its present form.

As a cosponsor of the bill, I want to commend the gentleman from Texas (Mr. Eckhardt) and the gentleman from New York, (Mr. Murphy) , the chairman of the subcommittee, and the ranking minority member of the subcommittee, the gentleman from Nebraska, (Mr. McCollister) for their hard work and cooperation in working out this compromise bill. This is balanced legislation. A balance has been reached between the need to protect health of humans and protection of the environment, and the concerns of small businesses and other industrial and marketing problems that give concern.

Mr. Eckhardt. Mr. Chairman, I heard the expressed hope of the gentleman from Nebraska (Mr. McCollister) that this bill, which is

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well balanced, be retained in its present form in conference. Of course, in conference there is always a certain give and take which must take place.

As to this Member's feelings, I would hope that the considerations and resulting accommodations that I think have made this bill generally acceptable both to industry and to those concerned with the environment will in large measure be kept, and I would certainly attempt to keep them. I believe we have a good bill.

We stated out with two deep and somewhat conflicting concerns. One was the deep concern of .those primarily concerned with health and the environment that no new[^] chemical that is in development stages will in effect sneak up on us before we have time to do something about it. On the other side was the concern of industry that we

not adopt such a busybody policy as to interminably investigate, thus inordinately delaying the final decision so that chemicals could not flow to the marketplace. Industry insisted that innovation must be given some freedom of movement.

I believe that initially the Senate's approach was too tight in this respect. It came very close to embracing premarket screening [Sec. 5]. Under premarket screening no chemical could go into the market unless it had gone through the governmental screen.

We cannot be 100 percent sure that no danger will exist, no matter what legislation we pass. On the other hand, the environmentalists and those primarily concerned with health simply were not satisfied with an attempt to identify all dangerous chemicals and then let anything we had not thought of before go onto the market without notice.

I believe we have resolved the differences between these two groups in this act. Within the general parameters of this concept, I feel we should try to hold the bill to the position of the House. I think we can do that because I believe we have a good bill. It satisfies those two legitimate objectives.

Mr. McCoLLISTER. Mr. Chairman, as we proceed to the reading of the bill for amendment – and there will be amendments – I would simply like to add to what the gentleman from Texas (Mr. Eckhardt) so kindly referred to earlier in regard to my interest in small business. I am very concerned about the impact of this legislation on small business. I hope that we have drafted a bill that will protect the interests of small business as well as the interest of the public.

Whether we have done that or not will, I think, probably be determined by the attitude of the EPA in administering the law. I would urge my colleagues to watch very carefully to see how that is done in order that some remedy can be fashioned, if it is necessary, so that we will not further concentrate our economic powers in fewer and fewer companies. I am very much concerned about the impact of this legislation on small business.

Mr. Metcalfe. Mr. Chairman, I rise in strong support of H.R. 14032, the Toxic Substance Control Act. While the bill before us differs to some extent from the bill reported out of the Consumer Protection Subcommittee on which I serve, I nonetheless support the objectives of this legislation.

Testimony before our subcommittee clearly indicated the need for this type of legislation.

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In April 1971, the Council on Environmental Quality released a report entitled "Toxic Substances." The Council reached the following startling conclusion : Several thousand new chemicals are discovered each year and we do not know which chemicals and at which level each chemical causes cancer, genetic mutation, or physical or chemical defects in offspring.

The Council on Environmental Quality as early as 1971 stated that :

We should no longer be limited to repairing the damage after it has been done ; nor should we continue to allow the entire population or the entire environment to be used as a laboratory.

Five years after this report was issued, the Congress is still grappling with a legislative response to this problem. We are still permitting our planet to be used as a giant laboratory and our population to be used as little more than passive participants in the experiments.

The inadequacy of current law is already documented in the hearing record established by the subcommittee. The point to be stressed is that we must have control of these chemicals before they are produced and entered into commerce. For all too long we have directed our attention to the effect of these toxic substances after the chemical is in the mass-production stage. We now propose to establish a schema whereby we can test and monitor these chemicals before they endanger our fellow man, the environment, and the very planet itself.

Recent studies of cancer mortality conducted by Drs. Robert Hoover I and Joseph F. Fraumeni of the epidemiology branch of the National Cancer Institute show rates of cancer which are far in excess of the normal rate in 139 counties where there is a high concentration of chemical production facilities. The National Cancer Institute estimates that as high as 90 percent of all human cancer is environmentally caused. The World Health Organization estimates are as high as 85 percent.

Mr. Chairman, we either learn to control those products which are having a deleterious effect on the environment and on our fellow

human beings or we will continue to endanger the health and well-being of generations to come.

The committee report clearly indicates that this bill is a major step

forward. It does this primarily "through its testing and premarket notification provisions." Thus, the bill "provides for the evaluation of

I the hazard-causing potential of new chemicals before commercial
' production begins."

Mr. Slack. Mr. Chairman, due to the particular problems of small business, the costs of testing are critical. The "basis for the legislation" section of the "report" accompanying TSCxi - page 5 - mentions that there are significant new methods which reduce the time required and the costs of testing for the cancer-causing properties of chemicals. The Ames test is specifically noted. Can we assume that the Ames test will be accepted as an effective indication of the carcinogenicity of new compounds ?

Section 8(a)-(1)(A)&(B) generally exempts the small manufacturer from the reporting provisions of the bill. However later paragraphs (8(a)-(3)(A) (i) and (ii)) detail broad instances where this exemption may be canceled by the Administrator. Due to the general

li financial inability of small businesses to resist in court, they are anx-

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ious to be protected from arbitrary administration. Are there any assurances that can be given that real justification will be present before reporting will be required by small manufacturers ?

In the same vein, section 3(2)(B)(i) excludes mixtures from jurisdiction, however later sections- 4, 6, and 7 - give the Administrator authority to include mixtures where deemed necessary. Since most small chemical manufacturers produce primarily mixtures, the exemption is critical. What assurances can be offered against arbitrary action on the case of: being required to report and test due to supposed "indications" that a hazard may exist? And being required to report and test due to supposedly "insufficient" data on a mixture?

Can some instances be hypothesized where a mixture might be required to comply as above?

Section 2(b)(3) states that there is no intention to impede or create unnecessary economic barriers to technical innovation. There are a group of specialized small companies who are engaged in the manu-

facture of highly sophisticated intermediate compounds which are marketed to other chemical concerns, universities^{Sj^} et cetera, who use these compounds as starting points in wide-ranging research. The demand for these chemicals is such that very small amounts of a large number of substances are produced annually. Since revenues from the sale of substances produced in such small quantities could not reasonably be expected to be sufficient to defray the costs involved in reporting and testing as could be required under the act, it is conceivable that these manufacturers might be forced to stop making these important items. Is there any way that these chemicals are exempted under the act as it now reads ?

Section 5 establishes the 90-day period by the end of which the Administrator must take action on a substance of which he has been notified. A 90-day extension is also provided where deemed necessary. It seems possible that an agency deluged with newly reported chemicals might be tempted to require testing, on the basis of insufficient data, rather than take a chance on not objecting to a substance which they have not been able to find time or manpower to properly review. Are there assurances that this will not be the case?

Mr. MuRPJiY of New York. Mr. Chairman, the Ames test is certainly an exciting new testing method, and I would expect the Administrator to make considerable use of it. Especially with respect to organic chemicals, the Ames test should be particularly useful in determining if a chemical should be regarded as a carcinogen.

The bill requires specific justifications before reporting [Sec. 8] can be required of small companies. I assure you that my subcommittee will exercise careful oversight to see that the standards in the bill are adhered to.

Likewise, the bill sets out careful standards before mixtures can be subjected to testing or before reporting can be required. In addition to judicial review to strike down action by the Administration acting outside the bounds of the bill, my subcommittee will exercise very careful oversight to protect against abuses.

These chemicals are not exempted per se. However, before they can be subject to regulation, there must be a finding by the Administrator that the chemical may be hazardous. In making such a determination, the Administrator obviously will have to consider the quantities

and the use of the chemical. The risk must be unreasonable in light of the use and amount produced or likely to be produced.

The language of the bill does not permit this result. Only in situations where there is insufficient information and the possibility of an unreasonable risk can production be stopped.

Mr. ASHBROOK. Mr. Chairman, I rise in opposition to H.R. 14032, the toxic substance control bill. This legislation would have severe repercussions on the Nation's chemical industry, pushing up prices, impeding research and development of new products that would aid the public and driving small firms out of business.

I want to make it clear that I support reasonable legislation to strengthen the control of toxic substances. The Government has a responsibility to protect the public from harmful chemicals and substances. We must not neglect matters of human health and environmental safety^

I cannot support H.E. 14032, however, because of its overburdensome regulations. These regulations would result in massive reporting requirements, yards of redtape and high costs.

Most disturbing is the part of the bill requiring premarket notification and screening of new chemical substances [Sec. 5]. The Environmental Protection Agency would be empowered to require manufacturers to give the Agency advance notification of their intent to market new chemicals. The Agency could also require manufacturers to conduct tests prescribed by the EPA. In addition, the EPA would be authorized to promulgate rules on the manufacture, processing, use and disposal of a chemical.

Under the provisions of H.R. 14032, manufacturers of all new chemicals as well as existing chemicals with new uses would have to notify EPA 90 days in advance of manufacturing or marketing. At that time they would also have to furnish EPA with specified information.

This may look good on the surface. The problem, however, is that there are approximately 2 million known chemical compounds with about 25,000 new ones added each year. Although most of these are confined to the laboratory, there are roughly 30,000 chemicals in commercial production. And that number is growing by 700 to 1,000 each year.

Consequently, it would be very difficult for EPA to give its approval in the time allowed. Manufacturing of a new chemical could be delayed for as much as 6 months simply because of administrative

backlog.

Furthermore, the potential cost of this legislation is staggering. According to industry estimates, the cost could range between \$358 million and \$1.3 billion annually. The testing of a single chemical alone could run into the hundreds of thousands of dollars.

These regulations would be bad enough for large companies, resulting in higher product costs and less development of new products. For small companies, however, the impact would be even more disastrous. The expensive reporting requirements, filing fees and testing procedures would place a severe strain on their financial resources.

Small chemical companies play an important role in the economy of our Nation. Of the 11,000 chemical companies now operating, over 10,000 of them are small. It would be tragic if the Congress passed legislation pushing these small companies into oblivion. It would be tragic to create a situation where only the large companies can survive.

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The Chairman. Pursuant to the rule, the Clerk will read the committee amendment in the nature of a substitute recommended by the Committee on Interstate and Foreign Commerce, now printed in the reported bill as ' an original bill for the purpose of amendment.

The Clerk read as follows:

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

Section 1. This Act may be cited as the "Toxic Substances Control Act".

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Sec. 1. Short title.

Sec. 2. Findings, policy, and intent.

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Sec. 7. Imminent hazards.

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Sec. 22. National defense waiver.

Sec. 23. Employee protection.

Sec. 24. Employment effects.

Sec. 25. Studies.

Sec. 26. Administration of Act.

Sec. 27. Development and evaluation of test methods.

Sec. 28. Authorization for appropriations.

Sec. 29. Annual report.

Sec. 30. Effective date.

Mr. ALURPHY of New York (during the reading). Mr. Chairman,
I ask unanimous consent that section 1 be considered as read, printed

in the Record, and open to amendment at any point.

The Chairman. Is there objection to the request of the gentleman from New York?

There was no objection.

The Chairman. Are there any amendments to section 1? If not, the clerk will read.

The clerk read as follows:

FINDINGS, POLICY, AND INTENT

Sec. 2. (a) Findings. – The Congress finds that –

(1) humans and the environment are being exposed to a large number of chemical substances and mixtures each year;

(2) among the many chemical substances and mixtures constantly being developed and produced are some whose manufacture, processing, distribution in commerce, use, or disposal may cause or significantly contribute to an unreasonable risk to health or the environment ; and

(3) the effective regulation of interstate commerce in such chemical substances and mixtures also necessitates the regulation of intrastate commerce in such chemical substances and mixtures.

(b) Policy. – It is the policy of the United States that –

(1) hazardous and potentially hazardous chemical substances and mixtures should be adequately tested with respect to their effect on health and the environment and that such testing should be the responsibility of

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those who manufacture and those who process such chemical substances and mixtures ;

(2) adequate authority should exist to regulate chemical substances and mixtures which cause or significantly contribute to an unreasonable risk to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards ; and

(3) authority over chemical substances and mixtures should be exercised in such a manner as not unduly to impede, or to create unnecessary economic barriers to, technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not cause or significantly contribute to an unreasonable risk to health or the environment.

(c) Intent of Congress. – It is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator proposes to take under this Act.

The Chairman. Are there any amendments to section 2? If not, the Clerk will read.

The Clerk read as follows:

DEFINITIONS

Sec. 3. As used in this Act :

(1) The term "Administrator" means the Administrator of the Environmental Protection Agency.

(2) (A) Except as provided in subparagraph (B), the term "chemical substance" means –

(i) any organic or inorganic substance of a particular molecular identity including a combination of such substances occurring (I) in whole or in part as a result of a chemical reaction or (II) in nature, or

(ii) any element or uncombined radical.

(B) Such term does not include –

(i) any mixture,

(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide,

(iii) tobacco or any tobacco product,

(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act) ,

(v) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any

l0ther provision of such Code) , and

(vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

The term "food" as \ised in clause (vi) of this subparagraph includes poultry and poultry products (as defined in sections 4(e) and 4(f) of the Poultry Products Inspection Act), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act) .

(3) The term "commerce" means trade, traffllc, or transportation (A) between a place in a State and any place outside of such State, or (B) which affects trade, traffic, or transportation described in clause (A).

(4) The term "distribute in commerce" or "distribution in commerce" when used to describe an action taken with respect to a chemical substance or mixture or article containing a substance or mixture means to sell, or the sale of, the substance, mixture, or article in commerce; to introduce or deliver for introduction into commerce, or the introducing or delivery for introduction into commerce of, the substance, mixture, or article ; or to hold, or the holding of, the substance, mixture or article after its introduction into commerce.

(5) The term "environment" includes water, air, and land and the interrelationship which exist among and between water, air, and land and all living things.

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(6) The term "health and safety study" means any study of any effect of a chemical substance or mixture on health or the environment, including epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act.

(7) The term "'manufacture" means to import, produce, or manufacture.

(8) The term "mixture" means any combination of two or mare chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction ; except that such term does include combination which occurs, in whole or in part, as a result of a chemical reaction if each of the chemical substances comprising the combination is not a new

chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.

(9) The term "new chemical substance" means any chemical substance not included in the chemical substance list compiled and published under section 8(b).

(10) The term "process" means the preparation of a chemical substance or mixture for distribution in commerce –

(A) in the same form or physical state, or in a different form or physical state from that, in which it was received by the person making such preparation, or

(B) as part of an article containing the chemical substance or mixture.

(11) The term "processor" means any person who processes a chemical substance or mixture.

(12) The term "standards for the development of test data" means a prescription of –

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(i) health and environmental effects, and

(ii) information relating to toxicity, persistence, and other characteristics which affect health and the environment, for which test data for a chemical substance or mixture are to be developed and any analysis that is to be performed on such data, and

(B) to the extent necessary to assure that such data are reliable and adequate, the manner in which such data are to be developed, the specification of any test protocol or methodology to be employed in the development of such data, and such other requirements as are necessary to provide such assurance.

(13) The term "State" means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, or the Trust Territory of the Pacific Islands.

(14) The term "United States", when used in the geographic sense, means all the States.

AMENDMENT OFFERED BY MR. HAGEDORN

Mr. Hagedorn. Mr. Chairman, I offer an amendment.

The Clerk read as follows :

Amendment offered by Mr. Hagedorn: On page 105, line 15. [Sec 3(2)(B)(i)]

insert the following after the comma "including those combinations which would be mixtures but for the exclusion of all their component substances from the list drawn up by the Administrator pursuant to section 5(c)(2)(A)(i),". On page 108, line 5, [Sec. 3(8)] substitute a comma for the period and add the following "provided that the combination contains component substances listed by the Administrator pursuant to section 5(c) (2) (A) (i)."

Mr. Hagedorn. Mr. Chairman, the purpose of my amendment is to exempt from the act mixtures which contain no chemicals contained on the section 5(c) (2) (A) (i) list. This list is to be compiled by the Administrator of EPA and is to contain chemical substances which might significantly contribute to an unreasonable.- risk to health or the environment.

Although "mixtures" are explicitly excluded from the definition of "chemical substance" on page 105, the effect of this is only to exclude them from the operations of section 5 premarket notification pro-

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cedures. They remain potentially subject to the entire n^tJvfork of regulations and recordkeeping contemplated by the rest of the act.

Mixtures are unlike other chemical formulations in the respect that the component elements do not have their chemical properties altered. Generally, they are as safe or unsafe as their components. While mixtures may result in the alteration of the physical properties of the components, as in shampoos or dish detergents, they retain the same chemical qualities as the substances which comprise them. There is no reason to burden chemical companies Avith the retesting of mixtures which simply partake of the qualities of their components, which have already been admitted to the marketplace. If they have not been, then the premarket notification requirements could be applied to the individual components, rather than requiring the entire mixture to be tested.

The great majority of the smaller chemical companies in this country make nothing but formulations of chemicals that are accepted as safe. If they are not, the Administrator always has the option, under any amendment, to place them on his section 5 list. If they are safe. I see no reason to subject these manufacturers to the extremely heavy testing and paperwork burdens of the bill. I believe

that my amendment would markedly streamline the bill by requiring EPA to concentrate its focus on those chemicals which he considers harmful.

Most of the larger chemical companies say that they can live with this bill ; that may be. The smaller chemical companies, however – the ones that produce 100 formulations and employ 50 to 100 people – they cannot live with this quite so easily. They cannot afford to hire new bookkeepers and paper-shufflers to comply with EPA regulations, they cannot afford the high-power legal staffs to challenge abuses of EPA authority, and they cannot afford legislative liaisons to work hand in hand with Congress in drafting and amending legislation to suit their needs. The Small Business Administration has already estimated that the average small chemical company spends approximately 10 percent of their pretax profits to comply with existing EPA rules. One small company in my district, employing less than 100 persons, claims that it is spending well over 25 percent of their time of Government compliance activities, nearly six times the amount spent only 3 years ago.

There has got to be some recognition of cost-benefit relationships by Congress. The smaller the company, the greater is the ratio of time spent testing and conforming to EPA edict to the volume of chemicals produced. There is no alternative for the small formulator but to hire new personnel that he cannot afford.

Finally, I am aware of the provisions in this bill that either give lip service to the small manufacturer, or distinguish between the treatment given chemical substances and mixtures. I have yet to speak to a small manufacturer, however, who feels comfortable with these. As one of them said to me –

The people who drew up this bill seem to assume EPA will act reasonably. On the basis of past experience, I have to assume otherwise.

I read section 4(a)(2) as imposing that section's testing requirements upon all mixtures unless the Administrator makes certain find-

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ings that such testing will be duplicative or wasteful. To do this, undoubtedly he will have to overcome the presumption that the testing of chemical components is insufficient to enable conclusions about the mixture. Hearings may be required, rules necessitated, and civil suits,

by those groups assuming that man is an intruder upon his environment, may have to be overcome.

Opponents of eliminating mixtures from the act argue that they may sometimes result in a synergistic effect, whereby the mixture takes on additional qualities beyond the qualities of the components. Although a detrimental synergistic effect may occur in one in a million mixtures, this bill may end up requiring the testing of the million in order to uncover the exception. Chemical producers rarely test their chemicals for every conceivable purpose to which they might be put. The Administrator would have extremely broad discretion under the act to contend that a chemical had not been tested for a particular application; hence, requiring additional testing for that application. Once the Administrator argues - correctly - that the hazard is always in the application of a chemical, the exemptions in this bill are effectively rendered meaningless.

The committee states that it has limited the Administrator to taking action only against unreasonable risks because to do otherwise assumes that a risk-free society is attainable, an assumption that the committee does not make. The inclusion of mixtures in this bill does not comport with that premise. Either than requiring EPA to take affirmative action to exclude a mixture from testing, the resources of EPA - and the chemical industry - could far more properly be used if affirmative action was required prior to inclusion. Neither my amendment, nor the bill will do anything about the basic problem involved - abuse and misuse of chemicals ; where, however, the chemical itself is the problem, I believe that my amendment strikes a far more reasonable balance between environmental and economic concerns.

Mr. McCoLLiSTER. Mr. Chairman, I would like to have some clarification of the gentleman's amendment. Is it the gentleman's intent that the Administrator of EPA should be able to exempt the testing of mixtures if the component parts of that mixture can be tested?

Mr. Hagedorx. Yes, if they have been tested.

Mr. McCoLLiSTER. If they have been tested.

Mr. Hagedorx. If they are listed as a priority or a section 5 chemical, then certainly they ought to be tested. If they are not included in the EPA list, then it is my feeling that they ought to be excluded, unless the EPA Director can show good cause for inclusion, which is still his discretion.

Mr. McCoLLiSTER. In section 4, the testing section, at the bottom of page 110, line 21, it says:

[Sec. 4(a)] (2) in the case of a mixture, the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal or any combination of such actions may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture ; '

In other words, the Administrator has the options ?

Mr. Hagedorn. Yes.

Mr. McCoLLiSTER. It is not mandatory ?

Mr. Hagedorn. Right.

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Mr. McCoLLiSTER. He has the option of exempting the mixture from tests if the component parts have been tested ?

Mr. Hagedorn. That is true, but the presumption of innocence always has to be found on that chemical where we are reversing a finding of fault or of possible harm, and putting that burden on the EPA Director to evaluate the mixture as to its potential harmful effects.

Mr. McCoT.LiSTER. And the gentleman's testing of the components would be limited to only those chemicals that are on the list, that have a hazardous chemicals listing?

Mr. Hagedorn. If the gentleman will yield further, certainly any of those lists can be expanded. If the EPA Director so chooses to include them, then my amendment would have no effect. I am not arguing that point. I am only talking about the unlisted chemicals not on the priority list or section 5 list as being included.

Mr. McCoLLTSTER. I thank the gentleman.

Mr. EckHARDT. Mr. Chairman, I rise in opposition to the amendment.

Mr. Chairman, I must say at the outset that I had great difficulty in understanding what this amendment means. It is an addition that is sought to be added after the term "mixture" on line 15 [Sec, 3(2) (B)

(1)], providing including those combinations which would be mixtures, but providing for the exclusion of all their component substances from the list drawn up by the Administrator pursuant to section 5(c)

(2) (A)(i).

I do not see where section 5(c)(2)(A) (i) which is contained on page . 127 of the act, excludes things from the definition of "mixture" at all. I simply do not understand what the gentleman is trying to do. In the bill we provided that wherever possible, and unless a rule were made by the Administrator, testing of the ingredients of the mixture would be enough, and only in the event that that was not enough and found not to be, and positive action taken by the Administrator would a mixture have to be tested separately.

In the argument in favor of the amendment it seems to me that the author seems to reach much further and go to the proposition of excluding everything that has not previously been identified on the list provided for in [Sec. 5(c)] (2) (A) (i). I, frankly, do not understand what the amendment is attempting to get at. It seems to me that, if the , amendment is trying to force the Administrator to leave alone a mixture that is properly tested because its ingredients are tested, the bill already takes care of that proposition. If it goes further than that, I do not agree that we should go further than that. I think it would be in opposition to the major thrust of the bill.

Mr. Hagedorn. I think what we are doing here, Mr. Chairman, is reversing the finding of fault. In other words, the chemical is presumed to be noncarcinogenic and nontoxic, unless the EPA Director, looking at the components involved in that mixture, concludes that it could be harmful.

Mr. Eckhardt. We do not create any presumption of danger in the bill as it stands. "We required in every instance that the EPA take the laboring oar in identifying the danger or else the chemical flows to the market. And even when the EPA does identify a potential danger, and says. "We cannot determine positively whether it is safe or it is

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not safe and, therefore, we cannot act finally," the EPA cannot make a ruling and keep the chemical off of the market. It flows right into the market just the same, unless an order by a court determines that, because of the great quantity of the substance going into the market-

place – and potentially into the environment – or because of the great risk involved that cannot be positively ascertained, harm would be done unless an injunction is issued.

We have tried to avoid the evil that the gentleman very properly points out, the evil of creating a presumption of risk without any proof of it, the evil of making the defendant prove himself not guilty with respect to the chemical. We put the burden on the EPA to identify the danger in every respect. I cannot see how the language of this amendment improves the bill and I think it might do mischief which might be inadvertent as far as the author is concerned.

I would urge that the committee vote against the amendment.

Mr. Hagedorn. Mr. Chairman, if the gentleman would yield further, we are not trying to be mischievous, that is for sure, with this legislation. What we are attempting to do is to insure we will not put undue burdens on the small businessmen as far as testing, the small businessmen who will be manufacturing the vast majority of chemical substances. But with my amendment we will not give EPA any additional powers unless they act in a positive manner indicating that certain mixtures may have a potential of being toxic or carcinogenic agents and will be taken off. Otherwise there will not be testing requirements placed on that small manufacturer. That is my intent.

Mr. McCoLLiSTER. Mr. Chairman, if I might have the attention of the gentleman, as far as the comment he just made, I want to repeat that is my understanding of the bill the way it is now, that testing is required only when there is an unreasonable risk imposed and if there is no such risk no testing is required. Further the Administrator is told both by the language of the bill and by the comment of the gentleman from Texas a moment ago, that with the testing of the basic components, if that has been accomplished, then the testing of the mixture ought not to be required since the testing of the components has been made.

Mr. Hagedorn. But the intent, Mr. Chairman, if the gentleman will yield, would be to exempt those chemicals not under section 5 or the list, they would be eliminated unless they are added in an affirmative manner to the required testing.

Mr. McCoLLiSTER. As far as the required testing.

Mr. Hagedorn. Yes.

Mr. Smith of Iowa. Mr. Chairman, if the gentleman will yield, how will the manufacturer know what is required to be tested?

Mr. McCoLLISTER. He will know because it will be on the list and because there is a rulemaking process by which a potentially dangerous chemical is judged to be a dangerous chemical, and then there follows the testing of it and all other requirements associated with it, and the manufacturer will have notice through the usual processes and in the Federal Register, and in the lists.

Mr. Eckhardt. Mr. Chairman, if the gentleman will yield, actually I think the author of the amendment may be under the misconception that merely by identifying a chemical the EPA may require testing. Actually of course there is a rulemaking process which must determine

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that the chemical poses the risk and should be tested in order to determine whether or not the risk is in actuality.

I am inclined to think that the terms of the act may be even stricter than the gentleman may conceive in his amendment because we do not permit the EPA merely by putting the chemical on the list to require its testing. The EPA must identify the chemical and by rule direct testing in the case.

Mr. McCoLLISTER. Mr. Chairman, if the gentleman will yield back to me, that rulemaking process is a good deal more different and more stringent and more formal, Avith cross-examination and substantial evidence and so forth, than the rulemaking processes we usually associate with what the earlier legislation provided.

Mr. Eckhardt. Mr. Chairman, if the gentleman will yield further, it is not quite so with respect to the testing rulemaking, because we do not want to overload an intermediate process to identify danger or to show that it does not exist. Where we put in the complete cross-examination rights is with respect to keeping the chemical ultimately off the market or limiting its entry into the market.

Mr. Smith of Iowa. Mr. Chairman, I am concerned about this kind of legislation. I know the committee did its best to try to work out something acceptable and that the overriding reason for the legislation is to protect people. But, I think we have gone too far in running small business out of business in this country. Even if all they have to do is watch the Federal Register, it is too much for many small businessmen that are in this business.

Mr. Chairman, take for example a small business. One of them tells me he last year sold 300 formulations. He may only sell 1 ton of a certain product. He cannot afford to watch the Federal Register. He does not have time to watch the Federal Register all the time.

Mr. Ottixger. Mr. Chairman, the gentleman does not want to say that we want small business to be permitted to poison the populace? There has to be some protection here.

Mr. Smith of Iowa. No. If the gentleman will listen. I am saying that it is not enough to work out an agreement with the big companies as to what will satisfy them and forget small business. That is what the committee did in this bill. It does something for companies like Du Pont but forgets all about small business. They did not even know this bill was under consideration until it was out of the full committee. How are they going to know how to protect themselves ?

Mr. ECKHARDT. Will the gentleman please heed me on this? This bill has been before the Congress, or this concept has been before the Congress in a series of bills, for 5 years. There were full hearings in both the Senate and in the House in at least two terms of Congress. There was full opportunity and notice to everyone involved.

Mr. Smith of Iowa. How do you give notice to all these manufacturers out there working 40, 50, and 60 hours a week in their plants making a livinor? How do they know what you are doing?

Mr. ECKHARDT. Mr. Chairman, if the gentleman will yield further, are they going to manufacture poisons in their plants?
I Mr. Smith of Iowa. Oh, no, it is not poison.

- ^ I just want to give this example. This manufacturer mixes coconut oil with some other reactants to form a wetting agent for washing floors. If he buys that from Du Pont, it costs twice as much as if he

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mixes it in his own plant. That is what this legislation does to small business. That is what it does to people who buy the product. It makes them buy it at a much higher price than they would have to. This legislation does for large companies what they are not allowed to do under the antitrust laws. It runs small business out of business by making it so expensive. They are subject to \$2,500 fee or they have to come to Washington to see the EPA. Or they may have to get the Congress-

sional liecord and watch it every day and to hire legal help. Many small businesses cannot operate that way, but the big companies can and after running their small business competition out of business, they can triple and quadruple their prices. That is what happens under too much of this kind of legislation.

Mr. ECKHARDT. Mr. Chairman, if the gentleman will yield further the gentleman gave an example of a company mixing coconut oil with a compound for cleaning floors. Xo. 1, tlie chances are there is no rule made with respect to testing either product.

Mr. Smith of Iowa. How is this small businessman going to know there is a rule for that ?

Mr. ECKHARDT. If there were a rule on that, the person producing the active ingredients in the product would be the one to give notice, not the man mixing the two compounds, because if the basic components had been tested he is under no responsibility.

Mr. Smith of Iowa. We are forcing him to go to see a "Philadelphia lawyer". He would have to watch the Congressional Record and he would be afraid to be in business at all. If they catch one of them in some violation, if one slips up, he will be out of business and then others are afraid.

I think we have passed too much of this kind of legislation. I know it is worked out so big companies will be satisfied, but I think we ought to work it out for small business in this country. I understand tlie need to protect people, but we have gone too far. This is not the only bill in which we have been doing this. Month after month, we pass additional legislation. The importance of it and the intent of it is good, but it goes too far.

I think we have got to come to the time when we, as Members of Congress, are watching out for these people who are not here for the hearings, who are not here to have their side of the story heard. In fact, many of them do not even know what is about to be done to them, and they will not know until they find out in the newspaper, about a month or 2 months from now, that this bill has passed.

What I am saying is that it is too burdensome to make the little manufacturer pay up to \$2,500 in fees, to come to Washington and get permission from the EPA, and file numerous papers. There are too many legalities, and somehow we have to work it out better than what has been done in this bill.

Mr. Ottinger. Fii*st of all, small chemical manufacturers do have an association, and they were heard. We did make provision for the

small manufacturers in the bill.

Mr. Smith of Iowa. The "gentleman gave some discretion to the agency to make exemptions. That is not the same thing.

Mr. Ottinger. It is my understanding that the committee is going to waive the fees for small business, even further aiding small business, in an amendment that is going to be offered. I do think we have con-

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sidered small businesses and their problems, but their inclusion is vitally important because the incidence of cancer has grown so rapidly from environmental causes.

Mr. Smith of Iowa. What we are doing here primarily is running small businesses out of business, and helping big companies to take more business and do what they could not do under the antitrust laws to run the small businesses competitors out of business.

Mr. Ottinger. There is nothing in this bill which forces a man to buy from Du Pont if he is using a mixture of two chemicals that have already been tested.

Mr. Smith of Iowa. If the people buying a few[^] tons from this little manufacturer cannot buy it from him because he is no longer in business because fees are too high, they are going to have to buy it from a big company at a much higher cost.

Mr. Ottinger. We are not going to drive him out of business unless his business is introducing toxic substances into the environment.

Mr. Smith of Iowa. He gets driven out if he does not have a place to sell his product.

Mr. McCOLLISTER. Would the gentleman consider transferring from the Budget Committee to the Committee on Interstate and Foreign Commerce, where we need him badly ?

Mr. Smith of Iowa. I appreciate the compliment but I doubt that it would make that much difference.

Mr. Hagedorn. I want to commend the gentleman from Iowa for his very appropriate remarks as to what the impact of this legislation can

be on the small businessman, because this is where new compounds are coming out. When we talk about poisons in our society today, it is true that there are a few that are mishandled and misused; but there are hundreds, literally thousands, of different compounds that are safe for society in a very positive way. I think we ought to look at it from that basis as well.

Mr. Smith of Iowa. There is surely some way we can protect society without running out competition and running up the price.

Mr. Murphy of New York. Mr. Chairman, I can understand the concern of my colleague from Minnesota in offering this language, but I think the needed protection is already provided. Throughout the hearings and throughout the markup session, the committee carefully considered and evaluated the effects on small business, and built safeguards into this legislation for the small businessman.

The committee does not feel and I do not feel that we can exempt certain mixtures and substances. We have so carefully considered and responded to small businesses. We have responded to the small business associations and representative groups which are here in Washington and across the country. This is the type of response that we have received in committee from their inquiries and from our reaction to those inquiries, and this is an example of one such from a small company in Iowa. It says :

Dear Mr. Murphy : Thank you for your very comprehensive reply to our inquiry into the Toxic Substance Control legislation. In all of the replies from other members of Congress, we were not granted such a detailed and clear cut understanding of this bill. The other replies were vague or down-right pro T.S.C.A.

Since we first became aware of this bill, April of this year, our future plans have been in a state of limbo. Now, with the receipt of your letter we feel that we can get back to business without the threat of the second shoe hanging over our head.

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By design, we are a very small regional company that has been successful through' quality, rather than quantity. We do not subscribe to the theory that "bigger is better", and have been extremely careful to maintain a close personal contact with our clienas. The information we received on this bill convinced us that our days were numbered. Now, we will proceed with business as usual based upon the information which you have supplied.

We have carefully considered small business. We have other amendments that the Members have been kind enough to furnish us with that we will accept, which further consider small business. But I think in a consideration of balance and the health of the Nation, we cannot accept this amendment.

]Mr. McCOLLISTER. Mr. Chairman, many of those comments which all of us received I think were directed to the original bill, H.R. 10318. The work of the gentleman from Texas and the gentleman from North Carolina to produce H.R. 14032 made it quite different from the original bill. I think many small chemical companies were concerned, and justifiably so, about the original bill. I have not heard from any small chemical companies on H.R. 14032 and the changes we have made in it.

Mr. Broyhill. Mr. Chairman, I think the key word that was used by the gentleman from New York (Mr. Murphy) is the word "balance." We have achieved balance in this bill, and we have taken into consideration the needs to protect the environment and at the same time we make sure that we do not do undue harm to the small business interests or any other commercial interests.

Mr. Hagedorn. Mr. Chairman, I want to thank the gentleman from New York for his input, and the gentleman from Texas, as well. It can give reassurance to the small company about the rule-making process.

If the gentleman will yield further, I think this has been worthwhile from that standpoint alone. When we talk about the rule-making process, that is another matter, where the small company must come in and bring in his attorneys and legal counsel to fight this, as well, so that is an added burden, in addition to all the other problems of increasing costs that they face.

The Chairman. The question is on the amendment offered by the gentleman from Minnesota (Mr. Hagedorn).

The question was taken; and on a division (demanded by Mr. Hagedorn) there were – ayes 10, noes 15.

So the amendment was rejected.

AMENDMENTS OFFERED BY MR. FUQUA

Mr. FuQUA. Mr. Chairman, I offer amendments.
The Clerk read as follows:

Amendments offered by Mr. Fuqua : Page 106, line 5 [Sec. 3(2) (B)] strike out

"and" ; at the end of line 10 strike out the period and insert and " ; and after line 10 insert the following :

"(vii) any chemical substance manufactured or processed in small quantities (as defined by the Administrator by rule) solely for scientific experimentation or analysis or chemical research or analysis on such substance or another substance."

Page 141, strike out lines 6 through 21 [Sec. 5(i)(3)i and redesignate the succeeding paragraphs accordingly.

Page 159 beginning in line 1 [Sec 8(a)(1)(A)], strike out "(other than a chemical substance described in subparagraph (B) (ii))".

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Page 159, strike out lines 8 through 15 [Sec. 8(a)(1)(B)] and insert in lieu thereof the following: to manufacture or process a mixture,"

Mr. FuQUA. ;Mr. Chainian, I ask unanimous consent that the amendments be considered en bloc.

The Chairmax. Is there objection to the request of the gentleman from Florida ?

There was no objection.

Mr, FuQUA. Mv. Chairman, I wish to thank the committee for offering some conciliatory concern about the effects of this legislation on small business, but what I am concerned about is research chemicals, those chemicals specifically used for research processes.

I have in my district a small business employing approximately 60 persons, and that business deals solely in research chemicals. These are not chemicals that one may buy in a drug store; they are not chemicals that any individual could purchase from another person. These chemicals are in most cases purchased in very small quantities, sometimes as small an amount as 1 gram and in other cases perhaps a hundred grams.

This company offers a catalogue that contains several thousand chemical formulations that it has the capability of making. They transport the chemical in public commerce, and it is treated as a toxic substance. It does not get into the hands of, for instance, some 10th

grade chemistry buff.

AVith all of these complex compounds that they offer solely for research purposes to universities, to those in research labs, and perhaps to a few other companies, they provide a short circuit for the researcher so that he can work further down the chain of the chemical compound rather than having to take simple compounds and breaking them down into these other types of compounds.

T^Hiile we have waived the requirement of their having to pay the fee and given other considerations, they should be totally exempt from this because they would then be subject to having to see that every compound is tested and tested until it is proven that it is not toxic. They realize these compounds are toxic.

One can even go into a store today and buy nitric acid and glycerine in separate compounds and then put them together. We know, of course, what we have then : we have nitroglycerine, which is a very danfiferous substance.

Mr. Chairman. I plead with the committee to consider this amendment favorably. However, I think that in this particular case, in dealing with research chemicals, we are certainly going too far.

One of the more toxic substances that is now made in these labs is one that is used in one of the compounds for the treatment of cancer. Here we would be subjecting researchers to spending much more time, and it would probably cost twice as much because of the additional research necessary.

As I pointed out earlier, these substances do not get into the hands of incompetent individuals such as myself or any other lay person. These are research scientists; they are using these substances in universities, and they are used in other products.

^Ir. Chairman, I believe this is a very, very important amendment. This bill will produce voluminous amounts of paperwork for the administration and for the EPA Administrator.

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It would almost be too complicated to handle. There are very few of these companies in business today. As the gentleman from Iowa (Mr. Smith) pointed out, these are very small individuals, not the large companies, even though sometimes they sell research chemicals to many of the large companies. However, these are small operators. They do not have attorneys here in Washington or a Washington staff to be up here every day and to get the permits that would be necessary for the manufacturing of these chemicals.

Mr. Chairman, I would hope that the committee would see fit to accept this amendment. I talked to them about it. I think it is also desirable because of the competitive nature involved, and these are not large amounts, but very small amounts.

Mr. Chairman, I am informed that with the increased cost involved these people may probably be forced to go to some other country in order to produce research chemicals. It is providing jobs in this country and the expertise that we need plus the technology that we need in this country.

Therefore, Mr. Chairman, I would certainly hope that the committee would accept this amendment. I think it goes a long way. It does not do violence to the purpose and intent of what the committee is trying to do.

Again, I say I support the committee's position, but I do think that in this particular instance with respect to research chemicals, those chemicals should be exempted from this requirement.

Mr. ECKHARDT. Mr. Chairman, the provisions for premarket notification are contained in section 5 of the bill.

Chemical substances which are for scientific experimentation or analysis or chemical research or analysis on such substances are presently exempted from the premarket notification requirement.

Mr. Chairman, this is certainly enough. Mind you, no chemical, whether it is research or otherwise, is absolutely required to be tested. Therefore, it would not even come under section 6 providing a ban or limitation on its use unless there were some very good reason that it should not be distributed.

Mr. Chairman, it is perfectly proper not to inject control of EPA with respect to research chemicals for the purpose of notice. In most instances, since no notice is required, no testing would be applied and no ban or limitation would be placed on those chemicals. However, even if a chemical is produced in small quantities and used for analysis,

it may be so dangerous and it may be so unnecessary to be used in that particular analysis as to require some limitation on its distribution.

Mr. Chairman, the Fuqua amendment would not only exempt some chemicals from the notification provisions, but it would also prevent the administrator, when he finds that the chemical causes or significantly contributes to or will cause or significantly contribute to an unreasonable risk to health or the environment from applying any of the remedies contained on page 143 [Sec. 6] and the following pages, a requirement prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture. Nor would it permit limiting the amount of such substance or mixture, or a requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate

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warnings and instructions with respect to its use or disposal, or with respect to both.

Mr. Chairman, it seems to me that in many instances it would be most desirable to notify students, for instance, engaged in analysis, in a university laboratory by having the mixture marked with accompanying clear and adequate warnings and instructions with respect to its use.

I give a lot of credit to the teachers in colleges, high schools, and technical institutions with respect to their expertise but we have some 800 new chemicals coming on the market each year. I think that the analysts and laboratory workers are entitled to know something about the danger^e of those new chemicals. We do not require that those be covered by pre-market notification but we do leave open the door to a situation where EPA has determined that this is a most dangerous chemical, perhaps it is a carcinogen. Why in those instances should we exempt it, so that we do not extend protection of persons working in laboratories? I do not think this is going to be abused. We do not require notification in advance. We cannot require any limitation until there is a full scale hearing and a ruling as required in section 6 of the act.

I Mr. FuQUA. Mr. Chairman, I certainly appreciate the concern that

I the gentleman from Texas (ISIr. Eckhardt) is making and I support that, but the point the gentleman is missing is that these are research

chemists. They take it at face value that they are toxic and that they are not to breathe them. But research scientists know how to handle very highly toxic materials, and they can be handled. In addition, they are using these materials so as to break down other materials, if you please, to prove their acceptability or toxicity in the open market. So these materials are not available to just any person. They are available only to research people and they treat them as highly toxic and as

; something that should not be handled without due care. They are toxic but they are being handled by people who know chemicals and who

I know how to handle them. I think without that we will be stifling the very purpose of evaluating many products that later will be sold and that it impedes, really, what the purpose of the act is.

Mr. Eckhardt. Reading from the proposed bill [Sec. 5(i)(3)], it says :

. . . any chemical substance which is manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for -

' Let us take one of these bases :
. . . for scientific analysis ...

Chemicals may be used for scientific analysis in a laboratory by not very well trained people and if that is done why should not the Administrator do what he can do under section 6 and, incidentally, he is not going to limit it at all unless he does something under section 6.

Why should he not have the authority to say what the dangers are?

This is a requirement that says any substances, mixtures, or any mixture thereof is supposed to be marked and accompanied by clear and adequate analysis and instruction. That is not too heavy a burden.

Mr. FrqrA. 'Mr. Chairman, some of the things that they use in chemical analysis are exotic chemicals that are used to check other chemicals

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for toxic material and to secure a true analysis. We are only talking about research chemists, people who know what they are doing, not a 10th grade chemistry buff, or children playing with chemicals they buy at a toy store ; we are talking about universities, research laboratories, professional people trained in this area so that they can use these chemicals or their components to break other materials down, so that they can shortcut the work that would otherwise be necessary, so by

using these chemicals they can break these compounds down.

Mr. ECKHARDT. I do not think that the Administrator is going to restrict that kind of use anyway. In the first place, they are not required to give notice ; therefore, he is not going to issue a rule requiring testing. But even if he did, the only limitation he would ultimately place on some such chemicals is the requirement that instructions be given concerning their danger. It seems to me that the bill is perfectly adequate, as written, and there is no reason to alter it in this way.

Mr. T.xURPiiY of New York. Mr. Chairman, I reluctantly oppose the Fuqua amendment which would exempt chemicals manufactured in small quantities for scientific experimentation or analysis, or chemical research or analysis, from the legislation. The reason is that the Fuqua amendment would create a dangerous loophole in the protection provided by the legislation, and it is not necessary to protect chemical research and innovation.

TL^ bill already makes special provisions for research chemicals in order to insure that chemical research and innovation is not unduly impeded. Research chemicals are exempted from the premarket notification provisions of the bill. Thus there will be no slowdown in researchers obtaining chemicals they need to conduct their research.

During the subcommittee hearings on the legislation, representatives of the American Chemical Society, a professional organization comprised of more than 110,000 chemists, recommended that research chemicals be exempted from the premarket notification provisions of the bill. This the committee has done. The American Chemical Society, however, did not recommend that research chemicals be exempted from the other regulatory provisions. When questioned about the need for such an exemption, the chairman of the American Chemical Society Board of Directors specifically recommended against it. He pointed out that chemicals which find their way into supply houses for sale to anyone who wishes to purchase them are often purchased by high school students or people Avho have home laboratories. Such people may need protection from hazardous chemicals.

For example, if Mr. Fuqua's amendment is agreed to, the EPA could not require a manufacturer of a particularly hazardous research chemical to place warnings on the chemical, so that high school students using the chemical will be informed of the dangers of the chemical.

Before EPA could take regulatory action against a research chemical under the bill, the agency would have to find an unreasonable risk associated with the chemical. This requires that EPA weigh the risks against the benefits presented by the chemical. The risks would have

to outweigh the research benefits before EPA could take regulatory action. If EPA can make the requisite showing that even considering the benefits of the research chemical, the dangers are so great that the public needs protection, should EPA not be authorized to take such

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necessary protective action? This does not necessarily mean that the chemical will be banned. All that may be necessary are warning labels. Or it may be necessary to prescribe disposal techniques.

It is instructive to note that other existing laws which regulate chemicals do not provide total exemptions for research chemicals. For example, the Food, Drug, and Cosmetic Act does not exempt chemicals used for research for drugs. Like the toxic substances bill, research drugs are exempted from the premarket clearance provisions. However, if FDA determined that a research drug were unreasonably endangering public health, it could act to protect against it.

Thus the Fuqua amendment is totally unnecessary to protect against chemical research and development. Further, it creates a gap in the protections provided by the bill. Therefore, it should be defeated.

Mr. Broyitt. I want to compliment the gentleman for giving a very adequate explanation of the many provisions in a bill that do exempt research chemicals from provisions of this bill. But would the gentleman not agree with me that striking the reporting requirements altogether would not be wise, because there is one thing the EPA should have, and that is adequate knowledge of the new chemicals that are being developed?

Mr. IrRPHY of New York. That is one of the thrusts of this bill.

!Mr. Broytill. That is not certainly an onerous burden to know the formulas of new chemicals that are being developed, is it?

Mr. MuRPiiY of New York. It is not.

The Chairman. The question is on the amendments offered by the gentleman from Florida (Mr. Fuqua).
The amendments were rejected.

The Chairmax. There being no further amendments to section 3,
the Clerk will read.

The Clerk read as follows :

TESTING OF CHEMICAL SUBSTANCES AND MIXTURES

Sec. 4. (a) Testing Requirements. - If the Administrator finds that -
(1)(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture or any combination of such actions may cause or significantly contribute to an unreasonable risk to health or the environment.

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal or combination of such actions on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data ; or

(B) (i) a chemical substance or mixture is or will be produced in substantial quantities, and it enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to such substance or mixture.

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or any combination of such actions on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data ; and

(2) in the case of a mixture, the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal or any combination of such actions may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture ;

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the Administrator shall by rule require that testing be conducted on such substance or mixture to develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience and which are relevant to a determination that the manufacture, distribution in commerce,

processing, use, or disposal of such substance or mixture or any combination of such actions does or does not cause or significantly contribute to an unreasonable risk to health or the environment.

(b)(1) Testing Requirement Rule. – A rule under subsection (a) requiring the testing of a chemical substance or mixture shall include –

(A) identification of the substance or mixture for which testing is required.

(B) standards for the development of test data for such substance or mixture, and

(C) a specification of the period (which period may not be unreasonable) within which the persons required to conduct the testing shall submit to the Administrator data developed in accordance with the standards referred to in subparagraph (E).

In determining the standards and period to be included, pursuant to subparagraphs (B) and (C), in a rule under subsection (a), the Administrator shall consider the relative costs of the various test protocols and methodologies which may be required under the rule and the reasonably foreseeable availability of facilities and personnel for performing testing under the rule. Such a rule may require the submission of preliminary data during the period prescribed under subparagraph (C).

(2) (A) The health and environmental effects for which standards for the development of test data may be prescribed include carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may cause or significantly contribute to an unreasonable risk to health or the environment, and the characteristics of chemical substances and mixtures for which such standards may be prescribed include persistence, acute toxicity, subacute toxicity, chronic toxicity, and any other characteristics which may cause or significantly contribute to such a risk. The methodologies that may be prescribed in such standards include epidemiology, serial, or hierarchical tests ; in vitro tests ; and whole animal tests. Before prescribing epidemiology tests in such standards, the Administrator shall consult with the Director of the National Institute for Occupational Safety and Health.

(B) From time to time, but not less than once each twelve month, the Administrator shall review the adequacy of the standards for development of data prescribed in rules under subsection (a) and shall, if necessary, institute proceedings to make appropriate revisions of such standards.

(3) (A) A rule under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph (B) to conduct tests and submit data on such substance or mixture, except that the Administrator may permit two or more of such persons to designate one such person or a qualified third party to conduct such tests and submit such data on behalf of the persons

making the designation.

(B) The following persons shall be required to conduct tests and submit data on a chemical substance or mixture subject to a rule under subsection (a) :

(i) Each person who manufactures or intends to manufacture such substance or mixture if the Administrator makes a finding described in subsection (a) (1) (A) (ii) or (a) (1) (B) (ii) with respect to the manufacture of such substance or mixture.

(ii) Each person who processes or intends to process such substance or mixture if the Administrator makes a finding described in subsection (a) (1) (A) (ii) or (a) (1) (B) (ii) with respect to the processing of such substance or mixture.

(iii) Each person who manufactures or processes or intends to manufacture or process such substance or mixture for distribution in commerce if with respect to the distribution in commerce of such substance or mixture the Administrator makes a finding described in subsection (a) (1) (A) (ii) or (a)(1)(B)(ii).

(iv) Each person who manufactures or processes or intends to manufacture or process such substance of mixture if with respect to the disposal of such substance or mixture the Administrator makes a finding described in subsection (a) (1) (A) (ii) or (a) (1) (B) (ii).

(v) Each person who manufactures or processes or intends to manufacture or process such chemical substance or mixture for a use with respect to which

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the Administrator makes a finding described in subsection (a) (1) (A) (ii) or (a)(1)(B)(ii).

(4) A rule under subsection (a) requiring the testing of a chemical substance or mixture shall expire at the end of the reimbursement period (as defined in subsection (c) (3) (B)) applicable to test data for such substance or mixture, unless the Administrator repeals the rule before such date.

(5) Rules issued under subsection (a) (and any amendment thereto or repeal thereof) shall be promulgated pursuant to section 553 of title 5, United States Code, except that in promulgating, amending, or repealing any such rule (A) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written

submissions; and (B) a transcript shall be made of any oral presentation. The Administrator may not promulgate a rule under subsection (a) respecting a substance or mixture unless the Administrator makes and publishes with the rule the findings described in paragraph (1) (A) or (1) (B) of such subsection and, in the case of a rule respecting a mixture, the finding described in paragraph (2) of such subsection.

(c) ExEMPTION. – (1) Any person required by a rule under subsection (a) to conduct tests and submit data on a chemical substance or mixture may apply to the Administrator (in such form and manner as the Administrator shall prescribe) for an exemption from such requirement.

(2) If, upon receipt of an application under paragraph (1), the Administrator determines that –

(A) the chemical substance or mixture (including any contaminant present in such substance or mixture) with respect to which such application was submitted is equivalent to a chemical substance or mixture for which data has been submitted to the Administrator in accordance with a rule under subsection (a) or for which data is being developed pursuant to such a rule, and

(B) submission of data by the applicant on such substance or mixture would be duplicative of data which has been submitted to the Administrator in accordance with such rule or which is being developed pursuant to such rule.

the Administrator shall exempt, in accordance with paragraph (3) or (4), the applicant from conducting tests and submitting data on such substance or mixture.

(3) (A) If the exemption of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the existence of previously submitted test data and if such exemption is granted during the reimbursement period for such test data (as prescribed by subparagraph (B)), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator) –

(i) to the person who previously submitted such test data, for a portion of the costs incurred by such person in complying with the requirement to submit such data, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) For purposes of subparagraph (A), the reimbursement period for any test data for a chemical substance or mixture is a period -

(i) beginning on the date such data was submitted in accordance with a rule promulgated under subsection (a), and

(ii) ending -

(I) five years after the date referred to in clause (i), or

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(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such data, whichever is later.

(4) (A) If the exemption of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the fact that test data is being developed by one or more persons pursuant to a rule promulgated under subsection (a), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules by the Administrator) -

(i) to each such person who is developing such test data, for a portion of the costs incurred by each such person in complying with such rule, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to the costs of complying with such rule, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall consider the factors described in the second sentence of paragraph (3) (A). An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) If an exemption is granted on the basis of the fact that one or more persons are developing test data pursuant to a rule promulgated under subsection (a) and if after such exemption is granted the Administrator determines that no such person has complied with such rule, the Administrator shall (i) after providing written notice to the person who holds such exemption and an opportunity for a hearing, by order terminate such exemption, and (ii) notify in writing such person of the requirements of the rule with respect to which such exemption was granted.

(d) Notice. – Upon the receipt of any test data pursuant to a rule under subsection (a), the Administrator shall, subject to section 14, promptly publish a notice of the receipt of such data in the Federal Register. Each such notice shall (1) identify the chemical substance or mixture for which data have been received; (2) list the uses or intended uses of such substance or mixture and the information required by the applicable standards for the development of test data; and (3) describe the nature of the test data developed. Except as otherwise provided in section 14, such data shall be made available by the Administrator for examination by any person.

(e) Priority List. – (1) (A) There is established a committee to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of a rule under subsection (a). In making such a recommendation with respect to any chemical substance or mixture, the committee shall consider all relevant factors, including –

(i) the quantities in which the substance or mixture is or will be manufactured,

(ii) the quantities in which the substance or mixture enters the environment,

(iii) the number of persons who will be exposed to the substance or mixture in their places of employment and the duration of such exposure,

(iv) the extent of human exposure to the substance or mixture,

(v) the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to cause or significantly contribute to an unreasonable risk to health or the environment,

(vi) the existence of data concerning the effects of the substance or mixture on health or the environment,

(vii) the extent to which testing of the substance or mixture may result in the development of data upon which the effects of the substance or mixture on health or the environment can reasonably be determined or predicted, and

(viii) the reasonably foreseeable availability of facilities and personnel for performing testing on the substance or mixture.

The recommendations of the committee shall be in the form of a list of chemical substances and mixtures which shall be listed, either by individual substance or

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mixture or by groups of substances or mixtures, in the order in which the committee determines the Administrator should take action under subsection (a) with respect to the substances and mixtures.

(B) Not later than twelve months after the effective date of this Act, the committee shall transmit to the Administrator the list required by subparagraph (A) together with the reasons for the committee's inclusion of each chemical substance or mixture on the lists. At least every six months after the transmission to the Administrator of the list pursuant to the preceding sentence, the committee shall make such revisions in the list as it determines to be necessary and shall transmit them to the Administrator together with the committee's reasons for the revisions. The Administrator shall make available to the public the list transmitted by the committee, any revision by the committee in such list (including the date on which such revision was transmitted to the Administrator), and the reasons of the committee for inclusion of a chemical substance or mixture on the list and for any revision in the list. The Administrator shall provide reasonable opportunity to any interested person to file with the Administrator written comments on the committee's list or any revision of the committee of such list and shall make such comments available to the public.

(C) The Administrator may promulgate a rule under subsection (a) with respect to a chemical substance or mixture which is not contained on a list published under this subsection.

(2) (A) The committee established by paragraph (1) (A) shall consist of eight members as follows :

(i) One member (or designee of the member) appointed from the Environ-

mental Protection Agency by the Administrator.

(ii) One member (or designee of the member) appointed by the Secretary of Labor from officers of the Department of Labor engaged in the Secretary's activities under the Occupational Safety and Health Act of 1970.

(iii) One member (or designee of the member) appointed from the Council on Environmental Quality by the Chairman of the Council.

(iv) One member (or designee of the member) appointed from the National Institute for Occupational Safety and Health by the Director of the Institute.

(v) One member (or the designee of the member) appointed from the National Institute of Environmental Health Sciences by the Director of the Institute.

(vi) One member (or designee of the member) appointed from the National Cancer Institute by the Director of the Institute.

(vii) One member (or designee of the member) appointed from the National Science Foundation by the Director of the Foundation.

(viii) One member (or designee of the member) appointed from the Department of Commerce by the Secretary of Commerce.

A member may designate an individual to serve on the member's behalf only with the approval of the applicable appointing authority and only if the individual is from the entity from which the member was appointed. A vacancy in the committee shall be filled in the same manner in which the original appointment was made.

(B) (i) The term of office of a member of the committee is four years, except that of the members- first appointed, four members shall have initial terms of two years. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of such term. If any member of the committee leaves the office or entity from which the member was appointed, such member may not continue as a member of the committee, and, for purposes of the preceding sentence, the member's position shall be considered as being vacant. A member may serve after the expiration of the member's term of office until a successor has taken office.

(ii) Initial appointments to the committee shall be made not later than the sixtieth day after the effective date of this Act. Not later than the ninetieth day after such date the members of the committee shall hold a meeting for the selection of a chairman from among their number and to determine, by lot, the four members who shall have initial terms of two years.

(C) The Administrator shall provide the committee such administrative support services as may be necessary for the committee to carry out its function under this subsection.

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AMENDMENT OFFERED BY MR. OTTINGER

Mr. Ottinger. Mr. Chairman, I offer an amendment.
The Clerk read as follows :

Amendment offered by Mr. Ottinger : Page 112, strike out the period in line 20 [Sec. 4(b)(2)(A)] and insert in lieu thereof a semicolon and the following: "except that in prescribing tests the Administrator in his or her discretion shall give preference to available tests which do not involve the use of animals if such tests provide an adequate and accurate means for ascertaining the effect of a chemical substance or mixture on humans and the environment."

Mr. Ottinger. Mr. Chairman, as I have stated previously, I strongly support the Toxic Substances Control Act and I am proud to be one of its cosponsors. I believe it needs to be improved, however, with respect to use of nonanimal tests where they are adequate and accurate. Therefore, I offer now the amendment which I previously offered in committee and which was not adopted there, but I think it is a tremendously important amendment because there is a history of abuse of laboratory animals, and the use of animals where they are not necessary, and it results in pain and cruelty to animals which is totally unnecessary and which this amendment seeks to avoid.

The amendment requires the Administrator of the EPA to give preference to tests which do not involve the use of animals but which are found by him in his sole discretion to be accurate and adequate for testing the toxicity of any chemicals to be tested.

In committee it was argued that this would subject the enforcement of the act to possible litigation, but we did provide in the amendment that the Administrator will have sole discretion in making testing determination ; all he has to do is to consider the use of nonanimal tests where they are available and make a determination that they are adequate and accurate, and if he does make that determination he is to give preference to those tests.

It seems to me that is a reasonable requirement which does not sub-

ject the implementation of the act to interference. Again the amendment does not ban the use of animals, but it requires the Administrator to use nonanimal tests where, in his sole discretion, he finds them to be adequate and accurate.

The intent of the amendment is to require the Administrator to consider tests which do not involve the use of animals, and thus prevent unnecessary pain and suffering to which laboratory animals are often subjected - and provide much cheaper and equally accurate testing in many instances.

Two alternative testing methodologies presently exist and are used for testing possible carcinogenic substances. One test uses Salmonella bacteria grown upon animal tissues instead of animals themselves. It has been determined that the mutation of the bacteria catches between 80 to 90 percent of all cancer-causing chemicals. It has roughly the same accuracy as is found in animal tests.

The other test, a new laboratory procedure, involves the growth of mammal cancer cells or primary cells, and their exposure to a potentially carcinogenic chemical. These nonanimal tests achieve striking savings in time and dollars. To illustrate, the average animal test for carcinogenic substances costs \$150,000 and uses 400 animals over a period averaging 3 years. The nonanimal Ames Salmonella test costs

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\$500 to \$750 and can be completed in 2 days. The mammal cell tests I referred to cost between \$1,000 and \$3,000 and take 3 to 6 weeks.

Nobel prize-winning biologist, Dr. Renato Dulbecco, in his prize-winning lecture printed in Science Magazine of April 1976, said :

Identification by conventional (animal) tests is difficult because they are costly and laborious, but they can now be replaced by the bacterial tests for promutagens. Since these tests are easy and inexpensive, it should be possible to investigate many normal constituents of the environment, and every compound before it is offered to the public.

Similarly, Friends of the Earth conducted research which demonstrates that these bacterial tests achieve the same 85 to 90 percent accuracy as animal tests, at considerably less cost.

In addition, the Salem Research Institute of Germany recently pub-

lished a bibliography of the many already published experiments using tissue culture to solve scientific problems. It published this compendium in an effort to spur researchers into using nonanimal experiments. The bibliography lists 286 selected tissue cultures used solely for cancer research ; 626 such experiments for for pharmacological research.

Congress involved itself in protecting animals in laboratory experimentation when it passed the Animal Welfare Act. We were responsible for changing existing attitudes about the treatment of laboratory animals, and these changes have been positive. We must continue what we have started and I believe my amendment is one more step in the direction.

In their book entitled, "The Principles of Humane Experimental Techniques," Russel and Rurch presented a formula for alleviating suffering of laboratory animals, stating three criteria:

First. Redefinement of experimental techniques.

Second. Reduction of animals used.

Third. Replacement by less or nonsentient material.

My amendment is fashioned around this formula. It has the support of the Society for Animal Protective Legislation, which sent a "Dear Colleague" letter to all offices to support the amendment ; the Humane Society of the United States; Defenders of Wildlife; Friends of the Earth ; and Fund for Animals.

Mr. Chairman, at the appropriate time, I will ask unanimous consent to have these statements of support put in the Record.

I just want to read briefly from the Fund for Animals :

Reducing the unnecessary use of animals in experimentation is a subject that is of deep concern to the Fund for Animals and our 60,000 members across the country. Congressman Ottinger's amendment is an excellent step in the right direction which sets a valuable precedent in protecting animals without detracting one iota from the public's right to be safeguarded from toxic substances.

Mr. Chairman, I urge my colleagues to support the amendment and to support this important legislation.

Mr. WmTETirKST. Mr. Chairman, I rise in support of the amendment offered by the gentleman from Xew Yoi'k which would prevent the unnecessary use of animals in laboratory experiments. This amendment would direct the Administrator to utilize available tests which do not involve the use of animals and which provide an adequate and

accurate means of ascertaining the effects of chemical substances on humans and the environment.

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It is important to note that this amendment does not ban the use of animal tests nor does it make it more difficult for the Administrator to prescribe animal tests if he feels they are necessary. The amendment simply requires the Administrator to consider alternate testing methods and directs him to use them when he finds they are adequate and accurate.

Fortunately, technology now exists to test the impact of chemicals on humans without the use of animals. These tests have the same 85 to 90 percent accuracy of animal tests and are actually much cheaper to perform. Current tests using animals to determine the cancer-causing potential of a chemical are expensive and lengthy, costing as much as \$150,000 a test for 400 animals and 3 years of work. One alternative test using bacteria costs approximately \$500 to \$700 per test for a 2-day experiment. Another test involving lab-grown mammal cells costs about \$1,000 to \$3,000 a test and takes 3 to 6 weeks. Consequently, these newly developed tests are cheaper, easier, faster, and equally, effective as the tests involving animals.

While it is true that we probably cannot eliminate the use of animals altogether, I believe that we have a responsibility to limit the pain and suffering of animals used in laboratory experiments to the maximum feasible extent. Since realistic and proven alternatives to the use of animals exist, I feel the Congress should make clear its desire to have these sound alternatives used whenever feasible. Once again, I urge the adoption of this humane amendment offered by the gentleman from New York.

Mr. ECKHARDT. Mr. Chairman, I rise in opposition to the amendment.

Now, Mr. Chairman, I recognize that it is always with some trepidation that one should take the floor opposing a fund for animals or a fund for anything else, because all these funds have behind them the people with long memories and they have an intense interest in the particular subject matter. Yet it seems to me inadvisable to direct the Administrator with respect to the manner in which he determines a danger to exist. In the first place, some of the dangers involve dangers to the lower species themselves. For instance, in the case of PCB there

is danger to fish and in many instances new chemicals affect the environment by affecting animals.

Now, it is true, of course, that the amendment only applies if tests which do not involve the use of animals provide an adequate and accurate means for ascertaining the effect of a chemical substance or mixture on humans and the environment.

But actually, the Administrator usually does not come into the game early enough to determine what kind of tests are to be used, whether they are on animals or not on animals, because the Administrator ordinarily merely requires testing. He does not determine the precise nature of the tests in most instances. He only prescribes the tests to be applied to the extent necessary to assure that such data are reliable and adequate, the manner in which such data are to be developed, the specification of any test protocol or methodology to be employed in the development of such data, and such other requirements as are necessary to provide such assurance.

Of course, this amendment only goes to the Administrator's choice of the use of tests. Ordinarily, the choice of use of tests is with the

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person producing the chemical. He is conducting the tests, he is presenting the data, and the Administrator may either accept the data or may prescribe additional testing.

Now I suggest, Mr. Chairman, that we are ill advised to place in the law itself this kind of directive. If we do, we are going to have people meddling with the Administrator's process, with all good intention, and thus holding up the ultimate result of the tests for inordinately long periods of time.

Mr. Ottinger. On page 112, section 4(b)(2)(A), it says that the Administrator can prescribe the standards for the development of test data, and says specifically, starting on line 18, "The methodologies that may be prescribed in such standards include * * *" and names the various kinds of tests.

So that there is provision here for the Secretary to prescribe the kinds of tests, and where there are nonanimal tests that are adequate, he should prefer those. I do not think that does any mischief, and I think it will help prevent some of the unnecessary carnage to animals

that does unfortunately occur in some laboratories today.

Mr. ECKHARDT. It is true that he may prescribe the standards, and he may ultimately prescribe the tests in certain instances, but it seems to me that we would do great mischief to permit anyone who wants to, to come in and make an objection to the nature of these tests on the grounds of some particular preference or some particular kind of test or some particular prejudice against the use of a kind of testing.

For instance, concerning PCB's, I have a very interesting little document here that was sent to me by the gentleman from Michigan (Mr. Dingell). One of the statements is with reference to rhesus monkeys:

Rhesus monkeys exposed to dietary levels as low as 2.5 and 5.0 ppm of PCB (lower than Lake Michigan fish) developed facial acne, subcutaneous edema and loss of eyelashes.

Why not use those tests, and why should it be available for anyone who has a particular love for rhesus monkeys, to come in and try to hold up the testing and get some kind of a court determination as to whether or not there is an adequate and accurate means of ascertaining whether a poison would cause injury to people by some other means?

Mr. OXINGER. I just want to say that the gentleman is playing monkeyshines with my amendment.

Mr. BROYILL. Mr. Chairman, just briefly, I want to say that I can understand the gentleman's concern, but our concern, of course, is that this amendment could do undue harm to testing of chemicals that might be dangerous to the health of mankind and to the environment. For these reasons, I oppose the amendment.

Mr. KOCH. Mr. Chairman, I rise in support of the amendment. I think it is a good one, and let me tell the Members why I think it is a good amendment. I am not someone who is an antivivisectionist. I believe that there is appropriate experimentation on animals to be done. That includes basic research; that includes matters which would relate to the welfare and the health of humankind as well as animals that are not human. But, obviously there are limitations, and wherever it is possible to use nonanimal substances for experimentation, surely that is to be preferred instead of the use of animals.

I do not think anyone would want to quarrel with that. But even those who would not want to quarrel with it are always reluctant, so to speak.

to enter the battle because in some way or other we think we are going to limit the scope of experimentation and impose restraints on those who "know better" than we do.

Mr. ECKHARDT. Who is to determine whether other experimentation is adequate? Is it going to be the court, or is it going to be a scientist?

Mr. Koch. I will read the amendment. The amendment says:

. . . except that in prescribing tests the Administrator in his or her discretion shall give preference to available tests which do not involve the use of animals if such tests provide an adequate and accurate means for ascertaining the effect of a chemical substance or mixture on humans and the environment.

It seems to me the amendment is very carefully drawn so as to allow that discretion to the Administrator, who certainly should know whether or not there are adequate substitutes.

Why would the gentleman not want to use a nonanimal substitute, if one is available, in the discretion of the Administrator?

Mr. ECKHARDT. If the gentleman will yield to permit me to answer the question, I would say he would have the discretion, clearly, if we did not put this in the bill. I would hope he would lean in the direction of humaneness.

Mr. Koch. Let me tell the gentleman why it does not always happen.

Mr. ECKHARDT. The thing is that this discretion, as I understand it, is limited to a situation where there is not an adequate or an accurate means for ascertaining the effects of a chemical substance.

Mr. Koch. Let me tell the gentleman a story, which happens to be true and which happens to be current.

In the city of New York today, the Museum of Natural History is engaging, quite properly, in experimentation with respect to basic research. But there are those who believe – and I am one of them – that the experimentation that they are undertaking with respect to cats is unwarranted.

That is a layman's opinion, and I have asked the National Institutes of Health for its opinion on it. I happen to have a lay opinion which will not decide for me what I will ultimately do without getting a more expert opinion, but it is a gut reaction.

I want to tell the Members what happened when I went to the Museum of Natural History, at the request of constituents who were distressed that the museum had received a grant from the Federal Government, NIH, to engage in an experimentation on cats relating to hyper- and hyposexuality. My constituents were told, based on the grant application, that this museum was going to engage in the following experimentation :

One, it was going to blind the cats. The fact is that they never did that. I want to make that very clear. But it was one of the programs that it was allowed to engage in under the grant that it received. And, second, it was going to surgically affect the penises of kittens to ascertain what effect that would have on sexuality, in addition to other experimentation. So I went to the museum and I asked them to tell me what it is that they were actually doing, and they asked me if I would like to go in and see the cats in their cages, I said yes, and I went there, and there were about 35 cats. They appeared well treated, in the sense that they were in clean cages, and they did not seem to be in any pain. So I said to the doctor who was explaining what was happening, "What do you do here? What is the purpose of this experiment?" And

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she said, "Well, the purpose is to look at the effect of hyper- and hyposexuality in cats. We find," said she, "that if you take a normal male cat and you place that cat in a room with a female cat that is in heat," said the professor, "the male cat would mount the female cat." I said, "That sounds very reasonable to me."

Then she said, "Xow, if you take a cat, a male cat, and you put lesions in its brain - "

I interrupted and asked, "'\`niat are lesions?"

She said. "Well, you destroy part of the brain cells."

I asked, "What happens then?"

She said. "Well, if you take that male cat that has lesions in its brain and you place it in a room with a female cat and a female rabbit, the cat will mount the rabbit."

I said to her, "How does the rabbit feel about all this?"

There was no response.

Then I said to this professor, "Now tell me, after you have taken a deranged male cat with brain lesions and you place it in a room and you find that it is going to mount a rabbit instead of a female cat, what have you got?"

There was no response.

Then I ask, "How long, by the way, have you been doing this?"
She said, "\$435,000."

I said, "How much has this cost the Government?"
She said. "^35,000."

Mr. Chairman, I tell this story, not because I am prepared to say that experimentation on cats is wrong. I repeat I am not an anti-vivisectionist. I am simply saying that there is a role here for lay persons and an opportunity for people to be interested in what is taking place in this field, and where we can explore any of these basic problems with nonanimal substitutes, if that is possible, then we should. "Where it is not possible and if the project is scientifically worthwhile – and I am not the one to suggest which projects are worthwhile; I am going to leave that to the Administrator – then obviously it should proceed.

All the amendment offered by the gentleman from New York (Mr. Ottinger) does is it says that the Administrator in his discretion shall give preference to nonanimal tests wherever those are available, and that is on the basis of the facts as I have outlined them.

Mr. Chairman, on that basis would the gentleman not wish to support this Ottinger amendment?

Mr. ECKHARDT. Mr. Chairman, I think that the cat and rabbit situation may be most interesting, and it would be more interesting if they used a male rabbit and a female cat. However, it seems to me it is far beside the point. This is an experiment for the sake of experimentation.

What we are talking about is experimentation with respect to a poison. If it affects a cat or a rabbit, it will probably, or may possibly, affect a person.

Mr. Koch. Mr. Chairman, if the gentleman will bear with me, I repeat if there is no other way, if there is no nonanimal substitute available, the gentleman from New York (Mr. Ottinger) and I do not disagree with the gentleman from Texas. What we are saying is that

there ought to be consideration given to the use of nonanimal substitutes when they are available.

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Mr. Chairman, I think this is a very reasonable amendment, and I urge the Committee to accept it.

Mr. Murphy of New York. Mr. Chairman, I regretfully oppose the amendment offered by my colleague, the gentleman from New York (Mr. Ottinger). The Ottinger amendment on its face directs the Administrator in his or her discretion to give preference to tests which do not involve the use of animals if such tests provide an adequate and accurate means of ascertaining the health and the environmental effects of a chemical.

This amendment could result in undermining the protection of human health which can be achieved under this bill. The amendment could result in EPA's not receiving the use of the most reliable and effective means of determining the effect that a chemical might have on a human being.

Although a nonanimal test may be adequate and accurate, a test using animals may be more acceptable and more reliable. When the objective is to protect human health, EPA should not be discouraged from using the best means available of determining whether a chemical is safe.

The gentleman from New York (Mr. Ottinger) argues that the amendment will result in reducing testing costs to manufacturers because nonanimal tests are less expensive to perform. The bill already fully protects manufacturers from being subjected to unnecessarily expensive testing.

What it does do is that it permits a scientific evaluation by the Environmental Protection Administrator as to whether to use photomicrography or necessary animal testing, if that is required to protect human health and human life.

Mr. Chairman, I think we should respect the various test protocols

and methodologies and the discretion of scientists within the tight guidelines that we have in this bill.

Mr. Ottinger. Mr. Chairman, my good colleague, the gentleman from Tennessee (Mr. Allen) points out that we could even insulate this further from the courts if, before the word "discretion," we put "sole," so that it would read: "The Administrator, in his sole discretion, shall give preference * *

Mr. Chairman, I have no objection to that.

Mr. Chairman, I ask unanimous consent that the word "sole" be inserted before the word "discretion."

The Chairman. Is there objection to the request of the gentleman from New York (Mr. Ottinger) ?

There was no objection.

The Chairman. The amendment is modified accordingly.

Mr. Murphy of New York. Mr. Chairman, if I might close, my colleague, the gentleman from New York (Mr. Ottinger) and I have supported legislation with respect to the slaughtering of animals in laboratory animal testing, and our committee put strict Federal guidelines on animal testing in laboratories.

We also worked very closely on humane slaughtering in the slaughterhouses of America.

Mr. Chairman, with respect to the fact that certain societies have written and have said that they support this amendment on the basis

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of humane conditions for animals, I certainly can understand their feelings; but I think we should underscore the philosophy here that we are trying to protect humans as well as animals and that we should use the most effective and reliable methods. If animal testing is needed, the discretion should be with the scientists at EPA to make that determination.

Mr. McCOLLISTER. Mr. Chairman, I wish to associate myself with the remarks of the gentleman from New York (Mr. Murphy).

As I said, the sole basis for determining what tests are to be run ought to be : What is best to preserve and protect human life ?

;Mr. Chairman, I think the amendment of the gentleman from New York (Mr. Ottinger) provides additional criteria that might well interfere with that objective.

Mr. Murphy of New York. Mr. Chairman, I urge my colleagues to reject the Ottinger amendment.

The C II AIRMAN. The question is on the amendment offered by the gentleman from New York (Mr. Ottinger) , as modified.

The question was taken; and on a division (demanded by Mr. Ottinger) there were - ayes 14, noes 19.

Mr. Ottixger. Mr. Chairman, I demand a recorded vote, and pending that, I make the point of order that a quorum is not present.

The Chairman. Evidently a quorum is not present. Members will record their presence by electronic device.

The call was taken by electronic device.

QUORUM CALL VACATED

The Chairman. One hundred Members have appeared. A quorum of the Committee of the Whole is present. Pursuant to rule XXIII, clause 2, further proceedings under the call shall be considered as vacated.

The Committee will resume its business.

The Chairman. The pending business is the demand of the gentleman from New York (Mr. Ottinger) for a recorded vote. A recorded vote was refused. So the amendment, as modified, was rejected.

The Chairman. Are there further amendments to section 4? If not, the Clerk will read.

The Clerk read as follows :

MANUFACTURING AND PROCESSING NOTICES

Sec. 5 (a) Notification for Manufacture of New Chemical Substances. - On and after the date on which the Administrator first publishes under section 8(b)

a list of chemical substances manufactured or processed in the United States, no person may manufacture a new chemical substance unless (except as provided in subsection (i) (relating to exemptions)) such person -

(1) has, at least ninety days before such manufacture, submitted to the Administrator, in accordance with subsection (f) (relating to notice content), a notice of such person's intention to manufacture such substance, and

(2) has complied with any applicable requirement of subsection (d) (relating to submission of test data).

(b) Notification for the Manufacture or Processing of a Chemical Substance for a Significant New Use. - (1) No person may manufacture or process a chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use of such substance unless (except as provided in subsection (i)) such person -

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(A) has, at least ninety days before such manufacture or processing, submitted to the Administrator, in accordance with subsection (f), a notice of such person's intention to manufacture or process such substance for such use, and

(B) has complied with any applicable requirement of subsection (d).

(2) A determination by the Administrator that a new use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) or subsection (c)(1)(ii) shall be made by a rule promulgated after a consideration of all relevant factors, including -

(A) the projected volume of manufacturing and processing of such substance for such use,

(B) the extent to which such use changes the type or form of exposure of humans or the environment to such substance, and

(C) the extent to which such use increases the magnitude and duration of exposure of humans or the environment to such substance.

The last sentence of section 19(c) (1) shall not apply to judicial review of any rule

promulgated under this paragraph.

(c) Notification for the Manufacture of Processing of Listed Chemical Substances. – (1) (A) No person may manufacture a chemical substance – (i) which is listed under paragraph (2), and

(,ii) which was a new chemical substance at the time of publication of the earliest proposed rule under paragraph (2) listing such substance, unless (except as provided in subsection (i)) such person has, at least ninety days before such manufacture, submitted to the Administrator, in accordance with subsection (f), a notice of such person's intention to manufacture such substance and has complied with the requirement of subsection (d).

(B) No person may manufacture or process a chemical substance, listed under paragraph (2), for a use which the Administrator has determined, in accordance with subsection (b) (2), is a significant new use of such substance unless (except as provided in subsection (i)) such person –

(i) has, at least ninety days before such manufacture or processing, submitted to the Administrator, in accordance with subsection (f), a notice of such person's intention to manufacture or process such substance for such use, and

(ii) has complied with the requirement of subsection (d) .

(2)(A)(i) Within twelve months after the effective date of this Act, the Administrator shall, by rule, compile, and from time to time thereafter revise, a list of chemical substances the manufacture, processing, distribution in commerce, use, or disposal of which, or any combination of such actions respecting which, the Administrator finds causes or significantly contributes to or may cause or significantly contribute to an unreasonable risk to health or the environment.

(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such actions causes or significantly contributes to or may cause or significantly contribute to an unreasonable risk to health or the environment, the Administrator shall consider all relevant factors, including –

(I) the effects of the chemical substance on health and the magnitude of human exposure to it ; and

(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to it.

(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, in accordance with subsection (b)(2), would constitute a significant new use of such substance. The last sentence of section 11)(c) (1) shall

not apply to judicial review of any provision of a rule under subparagraph (A) which provision is prescribed pursuant to this subparagraph.

(C) Any rule under subparagraph (A), and any amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of title 5, United States Code, except that (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, and (ii) a transcript shall be kept of any oral presentation. The Administrator may not promulgate under subparagraph (A) a rule listing a chemical substance unless the Administrator makes and publishes with the rule the finding described in such subparagraph.

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(d) Requirement Respecting Submission of Test Data. – (1) (A) If –

(i) a person is required by subsection (a), (b), or (c) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and

(ii) such person is required to submit test data for such substance pursuant to a rule promulgated under section 4 before the submission of such notice or such person has been granted an exemption under section 4(c) from the requirement of such rule.

such person may not, before the expiration of the period prescribed by subparagraph (B), manufacture such substance if the person is subject to subsection (a) or (c)(1)(A) or manufacture of process such substance for a significant new use if the person is subject to subsection (b) or (c) (1) (B).

(B) The period referred to in subparagraph (A) is –

(i) in the case of a person required to submit test data pursuant to a rule promulgated under section 4(a) a period of ninety days which begins on the date on which such person submits to the Administrator such data in accordance with such rule, and

(ii) in the case of a person who under section 4(c) is exempt from a requirement to submit test data pursuant to a rule promulgated under section 4(a), a period of ninety days which begins on the date of the submission in accordance with such rule of the test data the submission or the development of which was the basis for the exemption.

(2) (A) If–

(i) a person is required by subsection (c) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and

(ii) (I) a rule promulgated under section 4 before the submission of such notice requiring the submission of test data for such substance does not require such person to submit such data, or

(II) the Administrator has not promulgated such a rule for such substance before the submission of such notice, such person may not, before the expiration of the ninety-day period which begins on the date such person submits to the Administrator data prescribed by subparagraph (B), manufacture such substance if such person is subject to subsection (c)(1)(A) or manufacture or process such substance for a significant new use if such person is subject to subsection (c) (1) (B).

(B) Data submitted pursuant to subparagraph (A) shall be data which the person submitting the data believes show that -

(i) in the case of a substance for which notice is required under subsection (c) (1) (A), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such actions would not cause or significantly contribute to an unreasonable risk to health or the environment, or

(ii) in the case of a chemical substance for which notice is required under subsection (c) (1) (B), the intended significant new use of the chemical substance would not cause or significantly contribute to an unreasonable risk to health or the environment.

(3) Data submitted under paragraph (1) or (2) shall be made available, subject to section 14, for examination by interested persons.

(e) Extension of Notice Period. - The Administrator may for good cause extend for one additional period of not to exceed ninety days the period, prescribed by subsection (a), (b); (c), or (d), before which the manufacturing or processing of a chemical substance subject to such subsection may begin. Subject to section 14, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

(f) Content of Notice; Publication in the Federal Register. - (1) The notice required by subsections (a), (b), and (c) respecting a chemical substance shall include -

(A) the name of the chemical substance;

(B) the chemical identity and molecular structure of the substance, insofar

as such are reasonably ascertainable ;

(C) the proposed categories of use of such substance, insofar as such are reasonably ascertainable ;

(D) a reasonable estimate of the amount of the substance to be manufactured or processed and, insofar as reasonably ascertainable, a reasonable

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estimate of the amount of the substance to be manufactured or processed for each proposed category of use of the substance ;

('E) a description of the byproducts, if any, resulting from the manufacture, processing, use, or disposal of the substance, insofar as such are reasonably ascertainable; and

(F) any test data in the possession or control of the person giving such notice which are related to the effect on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the substance or any article containing such substance.

Such a notice shall be made available, subject to section 14, for examination by interested persons.

(2) Subject to section 14, not later than five days (excluding Saturday's, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a), (b), or (c) or data under subsection (d) the Administrator shall publish in the Federal Register a notice which -

(A) identifies the chemical substance for which notice or data has been received ;

(B) lists the uses or intended uses of such substance; and

(C) in the case of the receipt of data under subsection (d), describes the nature of tests performed on such substance and any data which was developed pursuant to subsection (d) or a rule under section 4.

Notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

(g) Regulation Pending Development of Information. - (1) (A) The district courts of the United States shall, upon application of the Administrator made through attorneys of the Environmental Protection Agency, have jurisdiction to enjoin in accordance with subparagraph (B), the manufacture, processing, or distribution in commerce of a chemical substance subject to a notification requirement of subsection (a), (b), or (c) if the court finds that -

(i) information available to the Administrator is insufficient to permit a reasoned evaluation of the effects on health or the environment of the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance or any combination of such actions, and

(ii) in the absence of such information, the manufacture, processing, distribution in commerce, use, or disposal of such substance or an[^] combination of such actions may cause or significantly contribute to an unreasonable risk to health or the environment.

(B) An injunction issued under subparagraph (A) with respect to a chemical substance subject to a notification requirement under subsection (b) or (c) (1) (B) respecting a significant new use of such substance shall apply only to the manufacture, processing, or distribution in commerce, as the case may be, of the substance for such use.

(C) An injunction issued under subparagraph (A) with respect to a chemical substance shall expire -

(i) upon the expiration of the five-day period beginning on the day after the issuance of the injunction, if the Administrator does not within such period publish the notice required by paragraph (2), or

(ii) if the Administrator publishes such notice within such period, upon the completion or termination of the proceeding begun by publication of such notice.

(2) (A) Within five days after the issuance of an injunction under paragraph (1) with respect to a chemical substance, the Administrator shall publish, in accordance with section 553(b) of title 5, United States Code, a general notice of proposed rulemaking to begin proceedings for the promulgation of a rule to apply to such substance one or more of the requirements described in section 6(a) as is necessary to adequately protect against the risk to health or the environment found by the court under paragraph (1) (A) (ii).

(B) Upon publication of such a notice the Administrator shall, as expeditiously as possible, provide reasonable opportunity for a hearing (in accordance with paragraphs (2) and (3) of section 6(c)) on such proposed rule, and either adopt such rule (as proposed or with modifications) or by notice published in the Federal Register terminate the proceeding for the promulgation of the rule. If such a hearing is requested, the Administrator shall commence the hearing within

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fifteen days from the date such request is made unless the Administrator and each person making the request agree upon a later date for the hearing to begin, and after the hearing is concluded the Administrator shall, within thirty days of the conclusion of the hearing, either adopt such rule (as proposed or with modifications) or terminate the proceeding (as prescribed in the preceding sentence).

(3) After a rule promulgated under paragraph (2) has taken effect any person may petition the Administrator to initiate a proceeding to amend or repeal such rule. Within thirty days of the receipt of such a petition, the Administrator shall by order either grant or deny the petition. If the Administrator grants such petition, the Administrator shall promptly initiate a proceeding for the amendment or repeal, as the case may be, of such rule. Such a proceeding shall be conducted in accordance with paragraphs (2) and (3) of section 6(c).

(h) Petition for Standards for the Development of Test Data. – A person intending to manufacture or process a chemical substance for which notice is required under subsection (a), (b), or (c) and who is not required under a rule under section 4 to conduct tests and submit data on such substance may petition the Administrator to prescribe standards for the development of test data for such substance. The Administrator shall either grant or deny any such petition within sixty days of its receipt. If the petition is granted, the Administrator shall prescribe such standards for such substance within seventy-five days of the date the petition is granted. If the petition is denied, the Administrator shall publish in the Federal Register the reasons for such denial.

(i) Exemption. – (1) The Administrator may, upon application (made in such form and manner as the Administrator may prescribe) exempt any person from the requirement of subsection (a), (b), (c), or (d) or of any combination of such subsections to enable such person to manufacture or process a chemical substance for test marketing purposes –

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance for such purposes would not cause or significantly contribute to any unreasonable risk to health or the environment, and

(B) under such restrictions as the Administrator considers appropriate. Within forty-five days of the receipt of an application under this paragraph the Administrator shall either approve or deny such application.

(2) (A) The Administrator may upon application (made in such form and manner as the Administrator may prescribe) exempt any person from the requirement of subsection (d) (2) to submit data for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that—

(i) the chemical substance (including any contaminant present in such substance) with respect to which such application was submitted is equivalent to a chemical substance for which data has been submitted to the Administrator in accordance with subsection (d) (2), and

(ii) submission of data by the applicant on such substance would be duplicative of data which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from submitting such data on such substance. No exemption granted under this subparagraph with respect to the submission of data for a chemical substance may take effect before the beginning of the reimbursement period applicable to such data.

(B) If the Administrator, under subparagraph (A), exempts any person from submitting under subsection (d) (2) data for a chemical substance because of the existence of previously submitted data and if such exemption is granted during the reimbursement period for such data, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator) —

(i) to the person who previously submitted the data on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (d) (2) to submit such data, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

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In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall consider all relevant factors, including the effect on the competitive position of the person required to pro-

vide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph shall be considered final agency action, for purposes of judicial review.

(C) For purposes of this paragraph, the reimbursement period for any previously submitted data for a chemical substance is a period -

(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such data to the Administrator, and

(ii) ending -

(I) five years after the date referred to in clause (1), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later.

(3) The requirements of subsections (a), (b), (c), and (d) do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for -

(A) scientific experimentation or analysis, or

(B) chemical research or analysis on such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer or processor has reason to believe may be associated with such chemical substance.

(4) (A) The requirements of subsections (a) and (e)(1)(A) do not apply with respect to the manufacturing or processing of any chemical substance which is the same as a listed chemical substance.

(B) For purposes of subparagraph (A), a chemical substance shall not be considered as different from a listed chemical substance solely because -

(i) the proportion of the inert chemical substances which are present in the listed chemical substance is different from the proportion of such sub-

stances present in the chemical substance being compared to the listed chemical substance ; or

(ii) an inert listed chemical substance has been added to or deleted from the chemical substance being compared.

(C) For purposes of this paragraph -

(i) the term "inert chemical substance" means a chemical substance which when combined with other chemical substances to produce another chemical substance does not react chemically with such other chemical substances ; and

(ii) the term "listed chemical substance" means a chemical substance included in the list compiled and published under section 8(b).

(5) The Administrator may, upon application, by rule exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that such chemical substance will not cause or significantly contribute to an unreasonable risk to health or the environment. A rule under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with paragraphs (2) and (3) of section 6(e).

(j) Definition. - For purposes of this section, the terms "manufacture" and "process" mean to manufacture or to process for commercial purposes.

Mr. Murphy of New York. . . . Mr. Chairman, I think it is important to point out to my colleagues that research chemicals are exempted from the requirements of section 5. It has come to my* attention that some people have interpreted this exemption as applying only to research chemicals which are manufactured and used in-

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house by a company. While the exemption does include such research chemicals, it is not limited to them. If a chemical is manufactured by one person in small quantities for use as a research chemical and sold to another person to use for research purposes, then the exemption covers such a chemical. In other words, one company can make chemicals to be used for research by another company or by another person and the exemption covers that chemical.

I would like to ask the authors of the legislation, the gentleman from

Texas (Mr. Eckhardt) and the gentleman from North Carolina (Mr. Broyhill), if that is their understanding of the exemption?

Mr. Eckhardt. Mr. Chairman, that is my understanding of the exemption.

Mr. Broyhill. Mr. Chairman, I agree with the gentleman from New York.

Mr. Murphy of New York. Mr. Chairman, I would also like to note that there are requirements in section 5 and elsewhere in the bill that the Administrator publish information in the Federal Register within a set number of days. The committee recognizes, of course, that the Administrator does not have control over the printing schedule of the Federal Register. Thus, the requirement should be construed as imposing on the Administrator the duty to submit the information to the Federal Register for publication within the requisite time period.

One further point on section 5. A small manufacturer told me the other day that he interpreted section 5 as permitting the Administrator to stop manufacture of a new chemical solely on the basis that the new chemical would not be effective for its proposed use. Mr. Chairman, I just want to clarify that this is totally untrue. Section 5 does not permit the Administrator to stop manufacture on the grounds that a chemical will not be effective.

The Clerk. Are there amendments to section 5? If not, the Clerk will read.

The Clerk read as follows :

REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND MIXTURES

Sec. 6 (a) Scope of Regulation. - If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture or any combination of such actions causes or significantly contributes to or will cause or significantly contribute to an unreasonable risk to health or the environment, the Administrator shall by rule apply to such substance or mixture one or more of the following requirements as is necessary to adequately protect against such risk :

(1) A requirement prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture or limiting the amount of such substance or mixture which may be manufactured processed or distributed in commerce.

(2) A requirement -

(A) prohibiting the manufacture, processing or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement or

(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

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(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use or disposal or with respect to both. The form and content of such warnings and instructions shall be prescribed by the Administrator.

(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture,

(5) (A) A requirement regulating the manner or method of disposal of such substance or mixture or article containing such substance or mixture by its manufacturer or processor or any other person who uses it for commercial purposes.

(B) A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law of a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such requirement.

(6) If the rule imposes on a chemical substance or mixture a requirement described in paragraph (1) or (2), a requirement directing the manufacturer, processor, or distributor in commerce of such substance or mixture or article containing such substance or mixture or directing any combination of such person (A) to give notice of such risk to processors or distributors in commerce of such substance, mixture, or article, or to both, and, to the extent reasonably ascertainable, to any other person in possession of or exposed to such substance mixture, or article; (B) to give public notice of such risk; or (C) to give both such notices.

A requirement imposed under this subsection shall be the least burdensome requirement necessary to adequately protect against the risk with respect to which the requirement was imposed and may be limited in application to specified geographic areas.

(b) Protection Against Adulteration or Contamination of Substances AND Mixtures. – If the Administrator has good cause to believe that a particular manufacturer or processor is manufacturing or processing a chemical substance or mixture in a manner which unintentionally causes the chemical substance or mixture to cause or significantly contribute to or to be likely to cause or significantly contribute to an unreasonable risk to health or the environment –

(1) the Administrator may by order require such manufacturer or processor to submit a description of the relevant quality control procedures followed in the manufacturing or processing of such chemical substance or mixture; and

(2) if the Administrator determines after the issuance of an order described in paragraph (1) –

(A) that such quality control procedures are inadequate to prevent the chemical substance or mixture from causing or significantly contributing to such risk, the Administrator may order the manufacturer or processor to revise such quality control procedures to the extent necessary to remedy such inadequacy ; or

(B) that the use of such quality control procedures has resulted in the distribution in commerce of chemical substances or mixtures which cause or significantly contribute to an unreasonable risk to health or the environment, the Administrator may order the manufacturer or processor to (i) give notice of such risk to processors or distributors in commerce of any such substance or mixture, or to both, and, to the extent reasonably ascertainable to any other person in possession of or exposed to any such substance, (ii) to give public notice of such risk, and (iii) to provide such replacement or repurchase of any such substance or mixture as is necessary to adequately protect health or the environment.

A determination under subparagraph (A) or (B) of paragraph (2) shall be made on the record after opportunity for hearing in accordance with section 554 of title 5, United States Code. The manufacturer or processor subject to a requirement to replace or repurchase a chemical substance or mixture may decide whether to replace or repurchase the substance or mixture and shall take either such action in the manner prescribed by the Administrator.

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(c) Promulgation of Subsection (a) Rules. – (1) In promulgating any rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider all relevant factors and make findings with respect to–

(A) the effects of such substance or mixture on health and the magnitude of human exposure to such substance or mixture,

(B) the effects of such substance or mixture on the environment and the magnitude of environmental exposure to such substance or mixture,

(C) the benefits of such substance or mixture for various uses and the availability of other substances or mixtures for such uses, and

(D) the reasonably ascertainable economic consequences of such rule taking into account the impact on small business.

If the Administrator determines that a risk to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not promulgate a rule under subsection (a) to protect against such risk unless the Administrator makes a finding that it is in the public interest to protect against such risk under such rule taking into consideration all aspects of the risk, the authorities under this Act and such other law (or laws) to enforce actions taken under this Act or such law (or laws) to protect against such risk, a comparison of the estimated costs of complying with actions taken under such law (or laws), and the relative efficiency of actions under this Act and under such law (or laws). In the judicial review of a rule under subsection (a) the last sentence of section 19(c) (1) shall not apply with respect to the determinations and findings required to be made by this paragraph.

(2) (A) Rules under subsection (a) shall be promulgated pursuant to section 553 of title 5 of the United States Code ; except that in promulgating any such rule (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions; (ii) a transcript shall be kept of any oral presentation ; and (iii) during any such oral presentation, the Administrator shall include an opportunity for cross-examination as provided in subparagraph (B). The Administrator may not promulgate a rule under subsection (a) respecting a chemical substance or mixture unless the Administrator makes and publishes with the rule the finding described in such subsection.

(B) An interested person is entitled, if the Administrator determines that it is

necessary to resolve disputed issues of material fact, to conduct or have conducted by the Administrator such cross-examination of persons as the Administrator determines (i) to be appropriate in view of any need for expedition, the nature of the issues involved, and the number of participants and the nature of their interests, and (ii) to be required for a full and true disclosure with respect to such issues.

(C) (i) If the Administrator determines that a group of persons, each of whom would but for this subparagraph be entitled to conduct (or have conducted) cross-examination, has the same or similar interests in a proceeding, the Administrator may (I) conduct cross-examination on behalf of such group, or (II) require such group to designate a single representative of such interests for purposes of conducting cross-examination in such proceeding and such representative shall, except as provided in clause (ii), conduct such cross-examination. If such group cannot agree upon a single representative for such purposes, the Administrator may limit the representation of such interests for such purposes.

(ii) When any person who is a member of a group with respect to which the Administrator has made a determination under clause (i) is unable to agree upon group representation with the other members of the group, then such person shall not be denied under the authority of such clause the opportunity to conduct (or have conducted) cross-examination as to issues affecting the person's particular interests if (I) the person satisfies the Administrator that the person has made a reasonable and good faith effort to reach agreement upon group representation with the other members of the group and (II) the Administrator determines that there are substantial and relevant issues which are not adequately presented by the group representative.

(D) The Administrator may issue procedural rules for the conduct of any oral presentation (including cross-examination) under this paragraph and may impose such reasonable time limits on each person's oral presentations authorized by this paragraph as may be appropriate in view of any need for expedition, the

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nature of the issues involved, and the number of participants and the nature of their interests.

(E) In the judicial review of a rule under subsection (a) the last sentence of section 19(c)(1) shall not apply to any determination of the Administrator under this paragraph.

(3) (A) The Administrator may, pursuant to rules prescribed by it, provide compensation for reasonable attorneys' fees, expert witness fees, and other costs

of participating in a rulemaking proceeding for the promulgation of a rule under subsection (a) to any person who represents an interest which will substantially contribute to a fair determination of the issues to be resolved in the proceeding taking into account the number and complexity of such issues and whether representation of such interest will contribute to widespread public participation in the proceeding and representation of a fair balance of interests for the resolution of such issues if -

(i) the economic interest of such person is small in comparison to the costs of effective participation in the proceeding by such person, or

(ii) such person demonstrates to the satisfaction of the Administrator that such person does not have sufficient resources adequately to participate in the proceeding in the absence of compensation under this subparagraph.

In determining whether compensation should be provided to a person under this subparagraph and the amount of such compensation, the Administrator shall take into account the financial burden which will be incurred by such person in participating in the rulemaking proceeding.

(B) The aggregate amount of compensation paid under this paragraph in any fiscal year to all persons who, in rulemaking proceedings in which they receive compensation, are persons who either -

(i) would be regulated by the proposed rule, or

(ii) represent persons who would be so regulated, may not exceed 25 per centum of the aggregate amount paid as compensation under this paragraph to all persons in such fiscal year.

(4) Paragraphs (1), (2), and (3) of this subsection apply to the promulgation of a rule repealing, or making a substantive amendment to, a rule promulgated under subsection (a).

(d) Effective Date. - (1) The Administrator shall specify in any rule under subsection (a) the date on which it shall take effect, which date shall be as soon as feasible.

(2) (A) The Administrator may declare a proposed rule under subsection (a) to be effective upon its publication in the Federal Register and until the effective date of final action taken, in accordance with subparagraph (B), respecting such rule if -

(i) the Administrator determines that -

(I) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities is likely to result in an unrea-

sonable risk of serious or widespread harm to health or the environment before such effective date ; and

(II) making such proposed rule so effective is necessary to protect! the public interest ; and

(ii) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under clause (i) (I), a court has in an action under section 7 granted relief with respect to such risk associated with such substance or mixture.

(B) If the Administrator makes a proposed rule effective upon its publication in the Federal Register, the Administrator shall, as expeditiously as possible, give interested persons prompt notice of such action, provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c), for a hearing on such rule, and either affirm such rule (as proposed or with modifications) or revoke it ; and if such a hearing is requested, the Administrator shall commence the hearing within five days from the date such request is made unless the Administrator and the person making the request agree upon a later date for the hearing to begin, and after the hearing is concluded the Administrator shall, within ten days of the conclusion of the hearing, either affirm such rule (as proposed or with modifications) or revoke it.

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AMENDMENT OFFERED BY MR. m'cOLLISTER

Mr. McCoLLiSTER. Mr. Chairman, I offer an amendment.
The Clerk read as follows :

Amendment offered by Mr. McCollister: Page 145, line 6 [Sec. 6(a)(5)(B)], strike out "law of" and insert "law or requirement of or in effect for".

Mr. ^IcCoLLiSTER. Mr. Chairman, this is in the nature of a technical or clarifying amendment. Under the bill, EPA can issue regulations concerning the manner and method of disposal. These regulations must be in conformity with State law. This amendment would make clear that when State regulations are in effect as required by Federal law, such as the Clean Air Act or the proposed Solid Waste Disposal bill - which would require State plans - the EPA disposal regulations would also have to be in conformity with these requirements.

I I have discussed the amendment with the gentleman from New York land the gentleman from Texas, and I believe that they are in agree-

iment on the clarifying intent of it.

Mr. Murphy of New York. Mr. Chairman, the ranking minority member has well stated the case, and I am happy to accept this amendment.

The Chairman. The question is on the amendment offered by the gentleman from Nebraska (Mr. McCollister).
The amendment was agreed to.

Mr. Hagedorn. Mr. Chairman, I have just two points I would like to cover in a colloquy with the gentleman from New York (Mr. Murphy).

On page 148 [Sec. 6(c)(1)] the Administrator is directed to consider various factors before imposing sanctions permitted under section (6) (a). Among these are (C) "the benefits of such substance or mixture for various uses and the availability of other substances or 'mixtures for such uses . .

My question, is this intended to involve the Administrator ruling upon the efficacy of a chemical for its intended purpose in any way?

Mr. Murphy of New York. No. The purpose of this language is to be certain that the benefits of a substance are considered in any determination of whether a risk is an unreasonable one.

Mr. Hagedorn. I thank the gentleman. I have a further question, Mr. Chairman, for the gentleman from New York.

Section (6) (a) permits the Administrator to prohibit the manufacturing, processing or distribution of a chemical substance, or to limit the amount which may be manufactured, processed or distributed in commerce. My question is at this point, what does the term "limit" contemplate? Does it mean quotas or levels of production, or how is that word "limit" to be defined ?

Mr. Murphy of New York. This would in no way mean quotas for individuals. It would mean a limitation on the total manufactured volume. Such limitations would have to apply equally to all companies.

Mr. Hagedorn. Throughout all chemical companies?

Mr. Murphy of New York. On that particular chemical.

Mr. Hagedorn. Would all companies be able to participate in the manufacturing of that chemical, or would it be given possibly to certain companies for that process ?

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Mr. Murphy of New York. No, it would not be limited by companies. It would be limited by volume.

Mr. ECKHARDT. I would think that the bill would envisage the Administrator treating all manufacturers desiring to produce a limited quantity of a substance equitably, and in that way there would have to be a division among companies.

Mr. Hagedorn. Then there is adequate protection for the small businessmen so that they will not be squeezed out ?

Mr. ECKHARDT. I would think not only should it be equitably divided as among companies, but should he in terms of something like equal quantities so as to give small producers something of an advantage.

Mr. Hagedorn. I thank the gentleman.

AMENDMENT OFFERED BY MR. DINGELL

Mr. DINGELL. Mr. Chairman, I offer an amendment.
The Clerk read as follows :

Amendment offered by Mr. Dingell : Page 154, insert after line 21 [Sec 6] the following :

(e) POLYCHLORINATED BIPHENYLS. - (1) Within 6 months after the effective date of this Act the Administrator shall initiate proceedings for the promulgation of rules to -

(A) prescribe methods for the disposal of polychlorinated biphenyls, and

(B) require polychlorinated biphenyls to be marked with clear and adequate warnings and instructions with respect to their processing, distribution in commerce, use, or disposal or with respect to any combination of such activities. Requirements prescribed by rules under this paragraph shall be consistent with the requirements prescribed by or under paragraphs (2) and (3).

(2) (A) Except as provided under subparagraph (B), effective one year after

the effective date of this Act no person may manufacture, process, or distribute in commerce any polychlorinated biphenyl for any use other than a use in a totally enclosed manner.

(B) The Administrator may by rule authorize the manufacture, processing, or distribution in commerce (or any combination of such activities) of any polychlorinated biphenyl for any use other than a use in a totally enclosed manner if the Administrator finds that such manufacture, processing, or distribution in commerce (or combination of such activities) will not cause or significantly contribute to an unreasonable risk to health or the environment.

(C) For the purposes of this paragraph, the term "totally enclosed manner" means any manner which will ensure that any leakage of a polychlorinated biphenyl from its enclosure will be insignificant as determined by the Administrator by rule.

(3) (A) Except as provided in subparagraphs (B) and (C), effective two years after the effective date of this Act no person may manufacture any polychlorinated biphenyl, and effective two and one-half years after such effective date no person may process or distribute in commerce any polychlorinated biphenyl.

(B) Any interested person may petition the Administrator for an exemption from the requirements of subparagraph (A) for a particular use of a polychlorinated biphenyl, and the Administrator may grant by rule such an exemption if the Administrator determines that -

(i) the exemption is necessary for the protection of the health or environment, and , . ,

(ii) good faith efforts have been made to develop a chemical substance which may be substituted for such polychlorinated biphenyl in such use and which does not cause or significantly contribute to an unreasonable risk to health or the environment.

An exemption granted under this subparagraph shall be subject to such terms and conditions as the Administrator may prescribe and shall be in effect for

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such period (but not more than one year from the date it is granted) as the Administrator may prescribe.

(C) Subparagraph (A) shall not apply to the distribution in commerce of any article containing any polychlorinated biphenyl if such article was manufactured before two and one half years after the effective date of this Act.

(4) Any rule under paragraph (1), (2)(B), or (3)(B) shall be promulgated in accordance with paragraphs (2) and (3) of subsection (e).

Mr. DiNGELL. Mr. Chairman, this is a very simple amendment. My colleagues have recently received "Dear Colleague*" letters from both my friend and colleague, the gentleman from Maryland (Mr. Gude), who joins me in the sponsorship of it, and from myself. It has the support of all of the conservation organizations.

The amendment directs itself very clearly and very directly at one substance, polychlorinated biphenyls. Polychlorinated biphenyls have been one of the biggest environmental problems that we have had in the State of Michigan. And PCB's are also one of the biggest problems that most of the States in the Union have, in terms of long-term degradation of the human environment and hazard to human health. They are found in fish, they are found in the flesh of cattle, they are found in fowl, and they are found in the milk of the mothers of the State of Michigan. They are a long-term hazard to human beings. They are not biodegradable. They do not break down. They persist. They accumulate in the food chain. They are in the fish in the Hudson River, they are in the fish in the Great Lakes, and they are one of the reasons that the fish caught in the Great Lakes cannot be marketed commercially, in many instances.

Mr. Chairman, the Toxic Substances Control Act is a good proposal and it provides environmental protection, with urgently needed authority. But there are no clear requirements in the bill mandating action by EPA within a specified period of time to control or to regulate this most persistent and this most hazardous of substances, the polychlorinated biphenyls.

The amendment requires the Environmental Protection Agency to initiate proceedings within 6 months to prescribe methods for the disposal of the polychlorinated biphenyls. There is no such requirement in the bill. It requires them to be marked with warnings and with instructions for disposal, and it requires certain safeguards with regard to rulemaking for the manufacture, processing and distributing in commerce of the polychlorinated biphenyls for any other use except in a totally enclosed container. It also authorizes certain minor exemptions which may become necessary where the requirement is quite clear that there is going to be no hazard to human health.

Mr. Chairman, in a large number of other instances, such as the Federal Water Pollution Control Act, the Administrator has authority to control the discharge of PCB's, but it should be noted that this authority, which was given in 1970, was not exercised by EPA until July 23, 1976, after this amendment had been brought forward.

We must ask : Why did EPA issue proposed regulations that would prohibit discharges of this substance which will not become effective for another 2 years ? Why do we single out PCB's ?

For many reasons. First of all, they are enormously persistent. Second, they are enormously dangerous. Third, they accumulate in the food chain. They flow upward toward human use. As I pointed out.

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they are found not only in fish, the flesh of fowl and animals, but also in the* milk of human mothers concentrating on the feeding of children.

Under section 6 of the bill the Administrator does not have authority during the pendency of administrative decisionmaking to effect the immediate prohibition of manufacture, processing or distribution of any chemical substance. This amendment gives him that authority, and I say that it is desperately needed.

Curiously enough, I spoke, on the way over here, to a representative of one of the major manufacturers of PCB's, and he advised me his company does not object to this amendment. His company felt that it is a good one and it would help his company to be citizens. The amendment does not call, I want my colleagues to know, for immediate prohibition but, rather, a gradual phase out, to assure action within a reasonable period of time.

As previously noted, the history of EPA is not one of vigorous and quick action.

This amendment defines PCB's to be bad, hazardous, and dangerous, and it mandates a program for their gradual removal, beginning with those uses which are outside of enclosed containers.

Mr. McCoLLiSTER. Mr. Chairman, the gentleman describes the risks associated with PCB's. Is the gentleman aware of similar risks with PBB's?

Mr. DixGELL. Mr. Chairman, I am fully aware of those risks, and it would be my hope that some of my colleagues would offer an amendment to apply this same principle to PBB's.

Mr. McCoLLTSTER. Mr. Chairman, I will suggest that we could go on and on and on with these substances, but that is not what this whole

legislation is about.

Mr. DixGELL. Mr. Chairman, if the gentleman wishe« to offer an amendment to add PBB's, I will support it, because I am fully aware of the perils of PBB's. If the gentleman wants to offer such an amendment, I would be happy to support it. I think it might be a meritorious amendment.

I would point out that we have a long history of PCB's. We know of their perils, we know that PCB's are not biodegradable, we know that they accumulate in the food chain, we know they are a hazard, we knew they are universal, and we know that they actually have a longer life than many radioactive substances. For those reasons, I urge my colleagues to support the amendment.

I would point out that PCB's have caused a major cessation of commercial fishinor activities in all the Great Lakes. A \$95 million-a-year industry could be shut down because of PCB's. A similar situation has occurred in the rivers of Xew York, in the rivers of New England, in the Mississippi River, the Missouri, the Ohio, the Columbia River system, and in the Sacramento River. It even extends to the Gulf Stream and to the Yukon in Alaska.

Mr. Ottixger. Mr. Chairman, I rise in support of the gentleman's amendment.

All of the commerecial fishing activities have been very substantially damaged in the Hudson River. Even fishing has been barred because of the presence of PCB's in the Hudson River at the present tim^ and that has caused tremendous damage to the commercial fish-

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mg industry in Xew York. I think the gentlemen's amendment is a v'ery important one.

Mr. DiXGELL. Mr. Chairman, I thank my good friend, the gentleman from Xew York.

There is no assurance unless this amendment is adopted that PCB's will be attacked. Section 6 does not give immediate power to the EPA to get PCB's off the market and out of places where they are a hazard bo humankind.

- Mr. Chairman, I urge my colleagues to support the amendment which my colleague and friend, the gentleman from Maryland (Mr. Grude) , and I have offered to the House at this time.

Mr. McCoLLiSTER. ^Mr. Chairman, I rise in opposition to the amendment.

^ Mr. Chairman. I oppose the amendments for some of the reasons that our brief colloquy suggested.

'■ This legislation that we are considering gives the EPA general authority to regulate hazardous chemicals. I think consequently it is improper in the context of this legisithion to attempt to regulate a specific chemical in a specific fashion. Further, there is no reason why PCB's should be treated in this fashion and other known environmental hazards such as perhaps vinyl chloride or asbestos, for example, 'should be excluded from the same specific treatment.

Second, the amendment would restrict EPA to an inflexible schedule. Under the provisions of the bill EPA could do all of the things that the gentleman from Michigan (Mr. Dingell) would like to do. However, EPA has the authority to establish its own timetable for regulating PCB's. Indeed, the EPA may feel that the 21/^ years the gentleman from Michigan (Mr. Dingell) suggests is too long and that more immediate action might be necessary. Tlie Dingell amendment could in this case actually slow down the regulatory process.

Mr. Russell Train, the Administrator of EPA, has indicated in a press report that I have seen that he would prefer that the bill did not set specific deadlines for phasing out PCB's.

The third reason why I am opposed to the amendment offered by the gentleman from Michigan (Mr. Dingell) is that by mandating a complete phasing out of PCB's in 21^ years the amendment is attempting to legislate technology. Although substitutes with the necessary alectrical characteristics are now being developed, the perfect substitute for PCB's in closed electrical systems does not yet exist.

Banning the use of PCB's in closed electrical systems before a suitable substitute has been developed may result in a cure which is worse than the problem. For example, PCB's are used in capacitors and transformers not only because of their electrical characteristics, but also because the substance is nonflammable. Therefore, any substitute for PCB's must also have the same fire-resistant properties. Such a substitute has not yet been developed.

Mr. Dingell. Mr. Chairman, I would like to point out to my good friend, the gentleman from Nebraska (Mr. McCollister) , that, first

of all, the phaseout is required to take place over a period of time. Second of all, there is provision for an exemption in the amendment which we have offered to allow year-by-year extension where no substitute is available.

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Mr. McCoLLISTER. Fourth, Mr. Chairman, there is no need for the amendment since the EPA has indicated a willingness to proceed expeditiously in this area. For example, in April of this year, EPA published its "Recommended Procedures for Disposal," applicable to wastes containing PCB's. PCB's are found in many small appliances as well as in fluorescent light bulbs, and, consequently, disposal of these items must be closely checked. Further, on July 23 of this year, EPA issued proposed effluent standards for PCB's affecting all PCB manufacturers and transformer and capacitor manufacturers. These standards were issued pursuant to a consent agreement entered into between EPA and the National Resource Defense Council.

Fifth and finally, Mr. Chairman, coverage under the amendment is unclear. It would appear, although it is not certain, that the Dingell amendment would not require that existing equipment containing PCB's must be discarded. That existing equipment could be used for the rest of the useful life should be made clear. Further, it would be helpful if the gentleman from Michigan (Mr. Dingell) would state that the amendment is not intended to curtail the resale or repair of existing equipment.

For all these reasons, Mr. Chairman, I oppose the amendment of the gentleman from Michigan (Mr. Dingell).

Mr. GuDE. Mr. Chairman, I rise in support of the amendment.

Mr. Chairman, this legislation is certainly meritorious and goes a long way to deal with toxic substances in our environment. But, in the case of PCB's, however, we have a problem that is a little different from some of the ones that have been discussed on the floor.

There has been concern about the act injuring small business; but our amendment does not affect small business except in the handling of articles that have PCB's in them; in such cases there is, a provision whereby small firms would be protected.

Mr. Chairman, there is only one company, which is a large manu-

facturer of PCB's in this country; they have already indicated to EPA their interest in phasing out this material.

But, the most important thing about PCB's, as opposed to other materials which are unknown quantities as far as danger is concerned, is that we have identified a mad dog - a known bad actor in the case of PCB. There is no doubt about its toxicity and danger in the environment. It has caused millions of dollars worth of damage in the United States ; the time has arrived to get rid of it.

Mr. Chairman, State governments all across the country, not just the Federal Government, have been concerned.

The States of New Jersey, Georgia, California, Washington, Texas, Michigan, and my own State of Maryland favor this amendment and wish to see the PCB's phased out.

As my colleague, the gentleman from Michigan (Mr. Dingell), has pointed out, this amendment does not specify replacement of PCB's in existing equipment or the equipment itself. Xew language that we have added to the amendment makes it clear that the distribution as well as the resale of PCB-containing equipment manufactured prior to the ban, is not prohibited. This would apply to such everyday products as air conditioners.

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Also, the amendment does have flexibility in it in that it includes exemptions in certain cases if acceptable substitutes are not yet developed.

For example, an electric company must show that continued use of PCB's in transformers is necessary to guarantee safety from fire and that they are making a good faith research effort to find substitutes.

Mr. Chairman, the amendment which has been drawn by the gentleman from Michigan and myself is well thought out.

It provides a timetable which will speedily eliminate the introduction of additional PCB's into the environment without damage to the citizens and industry.

The Japanese people suffered a terrible tragedy from PCB poisoning; probably because of the centralized system of their government

they were able to move swiftly and eliminate this product from the industrial and business technology of their country. Because of the need for conformance of State regulations and requirements that would provide for PCB substitutes the amendment my colleague, the gentleman from Michigan (Mr. Dingell), and I have offered will give a strong impetus to the phasing out of the manufacture and distribution of all PCB's.

This is a bad problem; it has already caused millions of dollars of damages to the fisheries across the Nation. It is a problem that has been identified by the State and Federal governments - let's act before we have another environmental tragedy.

Mr. Chairman, I urge the adoption of the amendment.

Mr. Eckhardt. Mr. Chairman. I rise in opposition to the amendment.

Mr. Chairman, we have today in the legislation of the United States four environmental and safety laws of major significance. We have the Clean Air Act, the Water Pollution Control Act. We have OSHA and we have the Product Safety Act. This would be a fifth major piece of legislation to protect the environment and the safety of the people. But we are now just initiating a new act in an extremely important field and we have not ordinarily, when we enacted legislation in any of these fields, attempted to address; specifically particular scientific questions. I think we have done well not to do so here.

Why should we, in enacting this act, move specifically to deal with PCB'S and not PBB's? We are not attempting to, and of course it is a little too late to deal with vinyl chlorides by preventing their entry into the market. Nor are we attempting to regulate PBB's, a pernicious and persistent toxin that get in the legislative environment. I do not think we should try to anticipate each specific danger to the environment. If we do, we will overly encumber this bill.

Suppose it is discovered that in the entire range of dangerous substances some type of pattern of removing them from the marketplace or limiting their use to control the environment is desirable; then the agency may set up regulations in which the treatment of PCB's is specifically dealt with in a different way than the present pattern of control which may ultimately seem the most desirable. Why carve out one chemical to treat in this manner? There are many other chemicals that presently pose potential danger. I think that we would be well advised to let the agency chart its course in the same manner that we

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have let other agencies with like authority chart their courses, and not foist upon a preconceived manner of control before we find whether they will in due course address the question.

As has been pointed out before, the EPA has already indicated its willingness to move in this direction.

Mr. DixGELL. Mr. Chairman, I would like to ask the gentleman some questions. I would like to ask the gentleman whether under section 6 of the bill the Administrator has not the authority during the pendency of the administrative law making the function of immediately prohibiting the manufacturing or processing of chemical substances such as PCB's ?

Mr. EckHARDT. When he goes through the procedures provided by section 6, he has, yes.

Mr. DiNGELL. But he may not do it during the pendency, even though the peril is as great as it is in PCB's?

Mr. EckHARDT. No. He is required to give due process to the person against whom the rule may be issued, and I think that is most desirable.

Mr. DixGELL. The answer to the question is he may not during the pendency of the rulemaking rule out substances like PCB's?

Mr. EckHARDT. Wait just 1 minute. He can use the imminent hazard technique of stopping PCB's if he can in fact prove they are hazardous.

Mr. DiNGELL. But in that, that action is subject to long and sustained court review which may drag out over a period of years.

Mr. EckHARDT. Not unless a higher court actually stays the action of a lower court. One can easily get the same instant relief that one can get in other cases involving a court's peremptory authority to enjoin.

Mr. DiNGELL. The gentleman is very carefully and I think very prudently, and in a very lawyer-like fashion, pointing out that the failure to rule this out would be dependent upon the prudence of a higher court upon appeal. That is, there is not immediate power in the administrator to move them out except subject to court review ; am I correct in that statement ?

Mr. ECKHARDT. Except subject to court action. I think that the only way that the agency can finally outlaw PCB's or limit them under section 6 is after a rather complete due process-oriented type of hearing.

But if during the pendency of the rulemaking, the continued release of PCB's into the environment would constitute an imminent hazard, the agency may go into court and by proving that such is the case, may get an injunction which would immediately stop the complained of activity.

Mr. DINGELL. This is a matter, though, which is time consuming and which is subject to judicial review and which could take a substantial amount of time.

Mr. ECKHARDT. It is not time consuming from the time the action is brought in court until the time the court has the power to act; it may be time consuming in the long run, but that may work against either the manufacturer of the PCB's or against the public. The question has to be decided by the court as to whether or not a preliminary injunction will be granted, or whether action will be upheld pending the ultimate ruling.

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Mr. DIXGELL. The gentleman is a very able lawyer and valuable Member of the House. The hard fact of the matter is that the committee bill, as opposed to the amendment offered by my friend and colleague, the gentleman from Maryland (Mr. Gude) and me, regarding PCB's which are a proven hazard - this would much more quickly and expeditiously remove them from the environment than would be the situation under the committee bill.

Mr. ECKHARDT. That is right. Of course, we can legislatively do anything to anybody as long as we comply with due process of law. I suppose that is done, but I think judicial process would be preferable in this case.

Mr. DEXT. ^Ir. Chairman, I am not going to take time on the PCB's except to give the Members a related situation which I think many Members - most Members of this Congress- have heard something about.

If this type of legislation had been brought before this House 3

years ago, there would probably be a group of citizens Avho would have some hope of living out their lives in an orderly and normal fashion. Kepone was a chemical. It was known to be a dangerous chemical. It was known to be the kind of chemical that could not be restrained in any given course. It could not be held within any confined area. Yet with warning after warning and appeal after appeal to various State, local, and Federal Government inspection agencies, nothing was done. It took two committees of this House, the gentleman from New Jersey's, Mr. Daniels, and my own, to spend a weekend after a great deal of research at the homesite of the Kepone manufacturer. To the best of our knowledge, this entire family of workers – and I mean family by going into not only the worker himself but the family and the children – was affected. We saw before us children whose eyes flickered constantly. The workers were told that they had some sort of Parkinson's disease.

However, they could not get any evidence in the town from any of the medical authorities or from the Federal or State or local inspection officials that it was the kind of toxic material which ought to be investigated thoroughly and on which work ought to be stopped immediately and that they should not be permitted to continue.

There is no hope for any of the workers who worked in that plant, as far as we know. The people have had to go to the extreme precaution of completely burning down the plant and cleaning that up. Now, there is a suit pending and a plea and an admission of guilt on the part of one of the officers of the company, which may result in hundreds of millions of dollars of damages – but these damages w^ll do no good for the sick people.

This kind of action should have been taken whenever there was any reasonable cause to expect that by stopping and investigating we could avoid that kind of disaster. And it is a disaster. The folks today are nothing but living dead.

Mr. Leggett. Mr. Chairman, I rise in support of the amendment. As chairman of the Subcommittee on Fisheries and Wildlife Conservation and the Environment, this issue has been of particular concern to our Members. The subcommittee held 3 days of oversight hearings in January 1976, to examine the impact of jpolychlorinated biphen-

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yls – PCB's – and similar toxic substances on fisheries and wildlife

resources. Witnesses from the administration and from the industry presented us with startling evidence of the critical levels of PCB residues found in samples of birds and fresh water fish all over the United States. Consequently, the survival of some threatened and endangered species is involved. PCB contamination appears to severely reduce the reproductive success of the bald eagle, along with other waterfowl and mammals, according to the U.S. Fish and Wildlife Service.

The adverse and far-reaching effects of PCB's are most vividly demonstrated in the Great Lakes region. In the past decade, Canada and the United States have invested solidly in restoring the fishery resources of the Great Lakes, and their programs – such as trout restoration – are threatened by PCB levels in Great Lakes fish which now exceed the permissible amount established by the FDA. Many species are close to being considered unmarketable, raising the potential spectre of the closing of the \$95 million commercial fishing industry and the \$300 million sport fishing industry of the Great Lakes. This is no exaggerated speculation, as Lake Michigan and the Hudson River have already been closed for given periods to commercial fishing because of high levels of PCB's.

PC B's are difficult to regulate as they are used in widely different industries for a variety of uses. They contaminate our rivers and waterways through the dumping of waste materials – such as plastic bottles, ink, papers – containing toxic substances. Although the only American manufacturer of PCB's Monsanto, has voluntarily restricted its production to enclosed uses – such as in electrical transformers – such industrial self-regulation and existing laws have failed to prevent the seepage of 10 million pounds of PCB's into the environment, and even greater quantities through sewage treatment systems and imported products. In view of the fact that PCB's cannot be removed from the environment and are not readily biodegradable, it will take years before our contaminated waterways will be ready again for commercial and recreational fishing if PCB's were eliminated now.

The flexibility of the Dingell-Gude amendment is shown by its exemption provisions, which recognize that some uses of PCB's outweigh safety considerations. Feasibility of PCB elimination has been shown by the example of Japan's almost complete PCB ban and its successful use of substitutes.

It is significant that the executive department's involved voice strong support of this amendment. The U.S. Fish and Wildlife Service supports a complete ban of PCB's. Russell Train, Administrator of EPA, told us :

So far as I am concerned, there is absolutely no disagreement whatsoever that PCB's should be eliminated, all uses should be gotten rid of just as rapidly as

we can."

I stress today just the sense of emergency that Russell Train did in January. If PCB's were abolished tomorrow, it would be 100 to 200 years before they would allow a decision on PCB's to undergo the review process of H.R. 14082, PCB's will continue to seep into the environment, endangering human health, our wildlife resources, and our freshwater fishing industries for several years. The Dingell-Gude amendment will give us a program immediately, setting the mandatory deadline for a phase-out of PCB's.

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I trust that my colleagues will recognize the profound detrimental effects this one toxic substance has on our environment, and will realize the need to clarify the phaseout of PCB's as a priority under the Toxic Substances Act of 1976, as this amendment would do.

There is no partisan division in the subcommittee with respect to the urgency and importance of solving this PCB problem. Therefore, I would urge that the House support this amendment.

Mr. Ottixger. Mr. Chairman, I have been told, and I would like to have the gentleman confirm it, that in many places in the United States, mothers' milk is now so contaminated with PCB's that it would not be allowed to be shipped in interstate commerce if it were in any other container. Is that correct ?

Mr. Leggett. I have not heard that, but if the gentleman makes that assertion I am sure it is worthy of review.

Mr. GuDE. ^Ir. Chairman, I want to commend the gentleman for his remarks, particularly in drawing attention to the widespread dispersal of this contaminate in our environment.

To further illustrate, Mr. Chairman, I would like to just quote from a telegram from the Georgia Game and Fish Division:

Serious poly chlorinated biphenyls (PCB) contamination problem just encountered at Lake Hartwell with harsh impact affecting sport fishermen and businesses dependent thereon. PCB ubiquitous in the environment and posing serious threat to human health and all living natural resources.

Mr. Chairman, I think we have ample testimony that we have a

mad dog, in the form of PCB, on our hands. We must pen him up and I urge support of this amendment.

Mr. Dellums. Mr. Chairman, I would like to associate myself with the gentleman's remarks.

. ^Mr. Chairman, I also would like to point out, I think the distinguished gentleman from Pennsylvania (Mr. Dent) made a very telling and important statement, that is, where there is reasonable documentation as to the danger of a snbetanro to life in ireneral and to human life specifically, there is no obligation more important than the human responsibility to protect that life.

It would seem to me almost incredible as I have sat here quietly and patiently listening to the debate for any person to raise the legal argument or the political argument or the economic argument that in any way transcends the important responsibility we have to protect human life under conditions which are injurious or a danger to human life and we have a responsibility, clinical and moral, to protect the citizens.

Mr. Leggett. Mr. Chairman, the gentleman is exactly correct.

Mr. Murphy of Xew York. Mr. Chairman, during the debate in the committee, I supported this amendment. T supported it because polvchlorinated biphenyls have been proven today to be a highly toxic and persistent chemical. It causes skin ailments, liver ailments, and undersized infants. In laboratory animals they have produced skin cancer and genetic effects.

True, the substances are necessary at the present time for use in capacitors and transformers. We have heard the debate on what the Japanese have Hone and what they have been forced to do because of the effects on their environment.

This amendment seems reasonable. It gives at least 2 years to the industn^ to come up with substances other than PCB's. I think 21/^

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years is certainly a reasonable compromise and warning to the industry. The EPA Administrator is given the flexibility to extend, if necessary, that period of time. PCl i s are a highly persistent and toxic chemical. They Imxe caused great damage to the Great Lakes, and

irreparable damage in the Pludson River. The State of New York estimates it will take over \$20 million to correct the damage at the present time to bring back the fisheries areas that have been so harmfully affected.

Mr. Chairman, I hope we adopt this amendment.

The Chairman. The question is on the amendment offered by the gentleman from Michigan (Mr. Dingell).

The amendment was agreed to.

The Chairmax. Are there further nmei-idments to section 6?

Mr. Ottixger. Mr. Chairman, very briefly, I ask the chairman of the committee, since my amendment was not adopted which would require preference be siven to nonanimal tests, it does appear that that is the intent of the committee in the report on page 19 [Sec. 4(b)(2)(A)] which reads as follows:

However, the Committee does not intend that the Administrator needlessly require whole animal tests. The Administrator should consider alternative test methods. With the development of reliable non-animal tests for predicting the long-term effects of chemicals on health, the need for animal test data to determine if a substance or mixture causes or significantly contributes to an unreasonable risk will diminish.

The report also says that the committee opposes the amendment only so as not to put a legal restriction on the Administrator, though it agrees with the thrust of the amendment that nonanimal tests should be preferred where adequate. I take it that the gentleman would stand behind the language of the report ?

Mr. Murphy of New York. The committee did intend that the Administrator not needlessly require animal testing.

Mr. OiTIXGER. I thank the gentleman.

The Chairmax. Are there further amendments to section 6? If not, the Clerk will read.

The Clerk read as follows :

IMMINENT HAZARDS

Sec. 7. (a) Actions Authorized and Required. - (1) The Administrator may file an action in a district court of the United States -

(A) for seizure of an imminently hazardous chemical substance or mixture

or any article containing such a substance or mixture.

(B) for relief (as authorized by subsection (b)) against any person who manufactures, processes, or distributes in commerce an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture, or

(C) for both such seizure and relief.

An action may be filed under this paragraph notwithstanding the existence of a rule under section 4, 5, or 6, and notwithstanding the pendency of any administrative or judicial proceeding under any provision of this Act.

(2) If the Administrator has not made a rule under section 6(a) immediately effective as authorized by subsection 6(d) (2) (A) (i)) with respect to an imminently hazardous chemical substance or mixture, the Administrator shall file in a district court of the United States with respect to such substance or mixture or article containing such substance or mixture an action described in subparagraph (A), (B), or (C) or paragraph (1).

(b) Jurisdiction of Court. - (1) The district court of the United States in which an action under subsection (a) is brought shall have jurisdiction to grant

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such temporary or permanent relief as may be necessary to protect health or the environment from the unreasonable risk associated with the chemical substance, mixture, or article involved in such action.

(2) In the case of an action under subsection (a) brought against a person who manufactures, processes, or distributes in commerce a chemical substance or mixture or an article containing a chemical substance or mixture, the relief authorized by paragraph (1) may include the issuance of a mandatory order requiring (A) in the case of purchasers of such substance, mixture, or article known to the defendant, notification to such purchasers of the risk associated with it; (B) public notice of such risk; (C) recall; (D) the replacement or repurchase of such substance, mixture, or article; or (E) any combination of the actions described in the preceding clauses.

(3) In the case of an action under subsection (a) against a chemical substance, mixture, or article, such substance, mixture, or article may be proceeded against by process of libel for its seizure and condemnation. Proceedings in such an action shall conform as nearly as possible to proceedings in rem in admiralty.

(c) Venue and Consolidation. - (1) (A) An action under subsection (a) against a person who manufactures, processes, or distributes a chemical substance or mixture or an article containing a chemical substances or mixture may be brought in the United States District Court for the District of Columbia or for any judicial district in which any of the defendants is found, resides, or transacts business ; and process in such an action may be served on a defendant in any other district in which such defendant resides or may be found. An action under subsection (a) against a chemical substance, mixture, or article may be brought in any United States district court within the jurisdiction of which the substance, mixture, or article is found.

(B) In determining the judicial district in which an action may be brought under subsection (a) in instances in which such action may be brought in more than one judicial district, the Administrator shall take into account the convenience of the parties.

(C) Subpenas requiring attendance of witnesses in an action brought under subsection (a) may run into any judicial district.

(2) Whenever proceedings under subsection (a) involving identical chemical substances, mixtures, or articles are pending in courts in two or more judicial districts, they shall be consolidated for trial by order of any such court upon application reasonably made by any party in interest, upon notice to all parties in interest.

(d) Action Under Section 6. - Where appropriate, concurrently with the filing of an action under subsection (a) or as soon thereafter as may be practicable, the Administrator shall initiate a proceeding for the promulgation of a rule under section 6(a).

(c) Representation. - Notwithstanding any other provision of law, in any action under subsection (a), the Administrator may direct attorneys of the Environmental Protection Agency to appear and represent the Administrator in such an action.

(f) Definition. - For purposes of subsection (a), the term "imminpntly hazardous chemical substance or mixture" means a chemical substance or mixture which causes or .significantly contributes to an imminent and unreasonable risk of serious or widespread harm to health or the environment. Such a risk to health or the environment. shall be considered imminent if it is shown that the manufacture, processing, distribution in commerce, use. or disposal of the chemical substance or mixture or any combination of such actions is likely to result in such harm to health or the environment before a final rule under section 6 can protect against such risk.

reporting and retention of information

Sec 8. (a) Reports. - (1) The Administrator shall promulgate rules under

which -

(A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B) (ii)) shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require, and

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(B) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process -

(i) a mixture, or

(ii) a chemical substance in small quantities (as defined by the Administrator by rule) solely for scientific experimentation or analysis or for chemical research or analysis on such substance or another substance, including such research or analysis for the development of a product,

shall maintain records and submit to the Administrator reports but only to the extent the Administrator determines the maintenance of records or submission of reports, or both, is necessary for the effective enforcement of this Act.

The Administrator may not require in a rule promulgated under this paragraph the maintenance of records or the submission of reports with respect to changes in the proportions of the components of a mixture unless the Administrator finds that the maintenance of such records or the submission of such reports, or both, is necessary for the effective enforcement of this Act. For purposes of the compilation of the list of chemical substances required under subsection (b), the Administrator shall promulgate rules pursuant to this subsection not later than one hundred and eighty days after the effective date of this Act.

(2) The Administrator may require under paragraph (1) reporting with respect to the following :

(A) The common or trade name, the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required, insofar as known to the person making the report or insofar as reasonably ascertainable.

(B) The categories or proposed categories of use of each such substance

or mixture, insofar as known to the person making the report or insofar as reasonably ascertainable.

(C) Reasonable estimates of the amount of each substance and mixture to be manufactured or processed and, insofar as known to the person making the report or insofar as reasonably ascertainable, a reasonable estimate of the amount of each such substance and mixture to be manufactured or processed for each of its categories or proposed categories of use.

(D) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture, insofar as known to the person making the report or insofar as reasonably ascertainable.

(E) All existing data concerning the adverse environmental and health effects of such substance or mixture, insofar as known to the person making the report.

(F) Estimates of the number of persons who will be exposed to such substance or mixture in their places of employment and the duration of such exposure, insofar as known to the person making the report.

To the extent feasible the Administration shall not require under paragraph (1) unnecessary or duplicate reporting.

(3) (A) (i) The Administrator may by rule require a small manufacturer or processor of a chemical substance to submit to the Administrator such information respecting the chemical substance as the Administrator may require for publication of the first list of chemical substances required by subsection (b).

(ii) The Administrator may by rule require a small manufacturer or processor of a chemical substance or mixture -

(I) subject to a rule proposed or promulgated under section 4, 5(c), 5(g), or 6, or .

(II) with respect to which relief has been granted pursuant to a civil action brought under section 7, to maintain such records on such substance or mixture, and to submit to the Administrator such reports on such substance or mixture, as the Administrator may reasonably require. A rule under this clause requiring reporting may require reporting with respect to the matters referred to in paragraph (2).

(B) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the manufacturers and processors which qualifying as small manufacturers and processors for purposes of this paragraph and paragraph (1).

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(b) Inventory – (1) The Administrator shall compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States. Such list shall at least include each chemical substance which any person reports, under section 5 or subsection (a) of this section, is manufactured or processed in the United States or was manufactured or processed in the United States within three years before the effective date of the rules promulgated pursuant to the last sentence of subsection (a)(1). In the case of a chemical substance for which a notice is submitted in accordance with section 5, such chemical substance shall be included in such list as of the earliest date (as determined by the Administrator) on which such substance was manufactured or processed in the United States. The Administrator shall first publish such a list not later than one year after the effective date of this Act. The Administrator shall not include in such list any chemical substance which is manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for scientific experimentation or analysis or for chemical research or analysis on such substance or another substance, including such research or analysis for the development of a product.

(2) To the extent consistent with the purposes of this Act, the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.

(c) Records. – Any person who manufactures, processes, or distributes in commerce or proposes to manufacture, process, or distribute in commerce any chemical substance or mixture shall, as required by the Administrator by rule, maintain records of adverse reactions to health or the environment alleged to have been caused by the substance or mixture. In such a rule the Administrator may require that –

(1) records of adverse reactions to the health of employees be retained for a period of not more than fifty years from the date such reactions were first reported to or known by the person maintaining such records, and

(2) any other record be retained for a period of not more than five years from the date the information contained in the record was first reported to or known by the person maintaining the record.

Records required to be maintained under this subsection may include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce by indi-

viduals or governmental agencies. Upon request of an officer or employee duly designated by the Administrator, each person who is required to maintain records under this subsection shall permit the inspection of such records and shall submit copies of such records.

(d) Health and Safety Studies. – The Administrator shall promulgate rules under which the Administrator may require any person who manufactures, processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce any chemical substance or mixture (or with respect to paragraph (2), any person who has possession of a study) to submit to the Administrator –

(1) lists of health and safety studies conducted or initiated by or for such person at any time or known to such person; and

(2) copies of any such studies appearing on a list submitted pursuant to paragraph (1) or (2), or otherwise known by such person.

(e) Notice to Administrator of Unreasonable Risks. – Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture causes or significantly contributes to a substantial risk to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

(f) Definitions. – For purposes of this section, the terms "manufacture" and "processes" mean manufacture or process for commercial purposes.

relationship to other federal laws

Sec. 9. (a) Laws Not Administered by the Administrator.– (1) If the Administrator has reason to believe that the manufacture, processing, distribution in commerce, use of, or disposal of a chemical substance or mixture or any

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combination of such actions causes or significantly contributes to or is likely to cause or significantly contribute to an unreasonable risk to health or the environment and determines that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of , the activity or combination of activities which the Administrator

has reason to believe so causes or contributes to such risk. Such report shall also request such agency –

(A) (i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and !

(ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk causes or significantly contributes to such risks ; and

(B) to report such determination and order to the Administrator.

Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be published in the Federal Register. The agency receiving a request under such a report shall make the requested determination, issue the requested order, and make the requested report within such time as the Administrator specifies in the request, but such time specified may not be less than ninety days from the date the request was made. The report of an agency in response to a request of the Administrator shall be accompanied by a detailed statement of the findings and conclusions of the agency respecting the order and determination requested to be made and shall be published in the Federal Register.

(2) If the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which such report was made either –

(A) issues an order declaring that the activity or combination of activities specified in the description of the risk described in the report does not cause or significantly contribute to the risk described in the report, or

(B) initiates, within ninety days of the publication in the Federal Register of the report of the agency under paragraph (1) in response to the Administrator's report, action under the law (or laws) administered by such agency to protect against such risk, the Administrator may not take any action under section 6 or 7 with respect to such risk.

(3) If the Administrator has initiated action under section 6 or 7 with respect to a risk associated with a chemical substance or mixture which was the subject of a report made to an agency under paragraph (1), such agency shall before taking action under the law (or laws) administered by it to protect against such risk consult with the Administrator for the purpose of avoiding duplication of Federal action against such risk.

(b) Laws Administered by the Administrator. – The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If a risk to health

or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines that it is in the public interest to protect against such risk by actions taken under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

(c) Occupational Safety and Health. – In exercising any authority under this Act, the Administrator shall not, for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

(d) Coordination. – In administering this Act, the Administrator shall consult and coordinate with the Secretary of Health, Education, and Welfare and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes. The Administrator

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shall report annually to the Congress on actions taken to coordinate with such other Federal departments, agencies, or instrumentalities, and on actions taken to coordinate the authority under this Act with the authority granted under other Acts referred to in subsection (b) .

RESEARCH, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA

Sec. 10 (a) AUTHORITY. – The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare and with other heads of appropriate departments and agencies, conduct such research and monitoring as is necessary to carry out the purposes of this Act. The Administrator may enter into contracts and may make grants for such research and monitoring. Contracts may be entered into under this subsection without regard to sections 3818 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5).

(b) Data Systems. – (1) The Administrator shall establish, administer, and be responsible for the continuing activities of an interagency committee which will design, establish, and coordinate an efficient and effective system, within the Environmental Protection Agency, for the collection, dissemination to other

Federal departments and agencies, and use of data submitted to the Administrator under this Act.

(2) (A) The Administrator shall, in consultation with the Secretary of Health, Education, and Welfare and other heads of appropriate departments and agencies design, establish, and coordinate an efficient and effective system for the retrieval of toxicological and other scientific data which could be useful to the Administrator in carrying out the purposes of this Act. Systematized retrieval shall be developed for use by all Federal and other departments and agencies with responsibilities in the area of regulation or study of chemical substances and mixtures and their effect on health or the environment.

(B) The Administrator, in consultation with the Secretary of Health, Education, and Welfare, is authorized to make grants and enter into contracts for the development of a data retrieval system described in subparagraph (A). Contracts may be entered into under this subparagraph without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5).

inspections

Sec 11. (a) In General. – For purposes of enforcement of this Act the Administrator, or any representative of the Administrator, duly designated by the Administrator, may inspect any establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce and any conveyance being used to transport chemical substances or mixtures in connection with distribution in commerce. Such an inspection may only be made upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge of the premises or conveyance to be inspected. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness and shall be conducted at reasonable times, within reasonable limits, and in a reasonable manner.

(b) Scope. – (1) Except as provided in paragraph (2), an inspection under subsection (a) shall extend to all things within the premises or conveyance inspected (including records, files, papers, processes, controls, and facilities) bearing on whether the requirements of this Act applicable to the chemical substances or mixtures within such premises or conveyance have been complied with.

(2) No inspection under subsection (a) shall extend to –

(A) financial data,

(B) sales data other than shipment data,

(C) pricing data,

(D) personnel data, or

(E) research data (other than research data required by this Act), unless the nature and extent of such data are described with reasonable specificity in the written notice required by subsection (a) for such inspection.

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E3CPOBTS

Sec. 12. (a) General. - (1) Except as provided in paragraph (2) and subsection (b), this Act (other than section 8) shall not apply to any chemical substance, mixture, or an article containing a chemical substance or mixture if -

(A) it can be shown that such substance, mixture, or article is being manufactured, processed, sold, or held for sale, for export from the United States, unless such substance, mixture, or article was, in fact, manufactured, processed, or distributed in commerce, for use in the United States, and

(B) such substance, mixture, or article when distributed in commerce, or any container in which it is enclosed when so distributed, bears a stamp or label stating that such substance, mixture, or article is intended for export.

(2) Paragraph (1) shall not apply to any chemical substance, mixture, or article if the Administrator finds that the substance, mixture, or article will cause or significantly contribute to an unreasonable risk to health within the United States or to the environment of the United States. The Administrator may require, under section 4, testing of a chemical substance or mixture exempted from this Act by paragraph (1) to determine whether or not such substance or mixture causes or significantly contributes to an unreasonable risk to health within the United States or to the environment of the United States.

(b) Notice. - (1) If any person exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under section 4 or 5(d), such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of the availability of the data submitted to the Administrator under such section for such substance or mixture.

(2) If any person exports or intends to export to a foreign country a chemical

substance or mixture for which a rule has been proposed or promulgated under section 5 or 6, or with respect to which an action is pending, or relief has been granted under section 7, such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of such rule, action, or relief.

ENTRY INTO CUSTOMS TERRITORY OF THE UNITED STATES

Sec 13. (a) In General. – (1) The Secretary of the Treasury shall refuse entry into the customs territory of the United States (as defined in general headnote 2 to the Tariff Schedules of the United States) of any chemical substance, mixture, or article containing a chemical substance or mixture offered for entry if –

(A) it fails to comply with any rule in effect under this Act, or

(B) it is offered for entry in violation of section 5, a rule or order under section 5 or 6, or an order issued in an action brought under section 5 or 7.

(2) If a chemical substance, mixture, or article is refused entry under paragraph (1), the Secretary of the Treasury shall notify the consignee of such entry refusal, shall not release it to the consignee, and shall cause its disposal or storage (under such rules as the Secretary of the Treasury may prescribe) if it has not been exported by the consignee within ninety days from the date of receipt of notice of such refusal, except that the Secretary of the Treasury may, pending a review by the Administrator of the entry refusal, release to the consignee such substance, mixture, or article on execution of bond for the amount of the full invoice of such substance, mixture, or article (as such value is set forth in the customs entry), together with the duty thereon. On failure to return such substance, mixture, or article for any cause to the custody of the Secretary of the Treasury when demanded, such consignee shall be liable to the United States for liquidated damages equal to the full amount of such bond. All charges for storage, cartage, and labor on substances, mixtures, or articles which are refused entry or release under this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future entry made by such owner or consignee.

(b) Rules. – The Secretary of the Treasury, after consultation with the Administrator, shall issue rules for the enforcement of subsection (a) of this section.

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DISCLOSURE OF DATA

Sec. 14. (a) In General. – Except as provided by subsection (b), any information reported to, or otherwise obtained by, the Administrator (or any representative of the Administrator) under this Act, which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b) (4) of such section, shall not be disclosed by the Administrator or by any officer or employee of the United States, except that such information may be disclosed –

(1) to officers and employees of the United States –

(A) in connection with their official duties under laws for the protection of health or the environment, or

(B) for specific law enforcement purposes ;

(2) to contractors with the United States and employees of such contractors if in the opinion of the Administrator such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States entered into on or after the effective date of this Act for the performance of work in connection with this Act; or

(3) when relevant in any proceeding under this Act, except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding.

(b) Data From Health and Safety Studies. – (1) Subsection (a) does not prohibit the disclosure of –

(A) any health and safety study submitted under this Act with respect to–

(i) any chemical substance or mixture which on the date the study is to be disclosed has been offered for commercial distribution, or

(ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5, and

(B) any data reported to, or otherwise obtained by the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

This paragraph does not authorize the release of data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

(2) If a request is made to the Administrator under subsection (a) of section

552 of title 5, United States Code, for information which is described in the first sentence of paragraph (1) and which is not information described in the second sentence of such paragraph, the Administrator may not deny such request on the basis of subsection (b) (3) or (b) (4) of such section.

(c) Designation of Confidential Data; Disputes. - (1) In submitting data under this Act, a person may (A) designate the data which the person believes is entitled to confidential treatment under subsection (a), and (B) submit such designated data separately from other data submitted under this Act.

(2) If the Administrator proposes to release for inspection data which has been designated under paragraph (1)(A), the Administrator shall notify, in writing and by certified mail, the person who submitted such data of the intent to release such data. If the release of such data is to be made pursuant to a request made under section 552(a) of title 5, United States Code, such notice shall be given immediately upon approval of such request by the Administrator. The Administrator may not release such data until the expiration of thirty days after the person submitting such data has received the notice required by this paragraph.

(d) Criminal Penalty for Wrongful Disclosure. - (1) Any officer or employee of the United States or former officer or employee of the United States, who by virtue of such employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a), and who knowing that disclosure of such material is prohibited by such subsection, willfully discloses the material in any manner to any person not entitled to receive it. shall be guilty of a misdemeanor and fined not more than \$5,000 or imprisoned for not more than one year, or both. Section 1905 of title 18, United States Code, does not apply with respect to the publishing, divulging,

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disclosure, or making known of, or making available, information reported or otherwise obtained under this Act.

(2) For the purposes of paragraph (1), any contractor with the United States who is furnished information as authorized by subsection (a)(2), and any employee of any such contractor, shall be considered to be an employee of the United States.

(e) Access by Congress. - Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this Act shall be made available, upon written request of any duly au-

thorized committee of the Congress, to such committee.

PROHIBITED ACTS

Sec. 15. It shall be unlawful for any person to -

(1) fail or refuse to comply with (A) any rule or order promulgated or issued under section 4, (B) any requirement prescribed by section 5, or (C) any rule or order promulgated under section 5 or 6 ;

(2) use for commercial purposes a chemical substance or mixture which such person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5, a rule or order under section 5 or 6, or an order issued in an action brought under section 5 or 7 ;

(3) fail or refuse to (A) establish or maintain records, (B) submit reports, notices, or other information, or (C) permit access to or copying of records, as required by this Act or a rule thereunder ; or

(4) fail or refuse to permit entry or inspection as required by section 11.

PENALTIES

Sec. 16. (a) Civil. - (1) Any person who violates a provision of section 15 of this Act shall be liable to the United States for a civil penalty in an amount not to exceed \$25,000 for each such violation. Each day such violation continues shall for purposes of this subsection constitute a separate violation of section 15.

(2) (A) A civil penalty for a violation of section 15 shall be assessed by the Administrator by an order made on the record after opportunity (provided in accordance with this subparagraph) for a hearing in accordance with section 554 of title 5, United States Code. Before issuing such an order, the Administrator shall give written notice to the person to be assessed a civil penalty under such order of the Administrator's proposal to issue such order and provide such person an opportunity to request, within fifteen days of the date the notice is received by such person, such a hearing on the order.

(B) In determining the amount of a civil penalty, the Administrator shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Administrator may, in the Administrator's discretion, compromise, modify, or remit, with or without conditions, any civil penalty which may be imposed under this subsection. The amount of such i)en'alty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(3) Any person who requested in accordance with paragraph (2) (A) a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the thirty-day period beginning on the date the order making such assessment was issued.

(4) If any person fails to pay an assessment of a civil penalty after it has become a final order and does not file a petition for judicial review of the order in accordance with paragraph (3) or after a court in an action brought under paragraph (3) has entered final judgment in favor of the Administrator, the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from such date) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

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(b) Criminal. – Any person who knowingly or willfully violates any provision of section 15 shall, in addition to or in lieu of a civil penalty which may be imposed under subsection (a) of this section for such violation, be subject, upon conviction, to a fine of not more than \$25,000 for each day of violation, or to imprisonment for not more than one year, or both.

(c) Notice, Repurchase, or Replacement.– If in a proceeding for the issuance of an order under paragraph (1) to assess a civil penalty against a person the Administrator determines that such person manufactured, processed, or distributed in commerce a chemical substance or mixture in violation of a requirement applicable to such substance or mixture under paragraph (1) or (2) of section G(a) or otherwise determines by order made on the record after opportunity for agency hearing that a person has so violated such a requirement, the Administrator may, in such order, require such person (1) to give notice of the risk associated with the chemical substances or mixture subject to such requirement to processors or distributors in commerce of such substance or mixture, or to both, and, to the extent reasonably ascertainable, to any other person in possession of or exposed to such substance or mixture; (2) to give public notice of such risk; (3) to either replace or repurchase such substance or mixture, as determined by the person (or persons) to whom the requirement is directed, in the manner prescribed by the Administrator; or (4) to take any combination of the actions described in the preceding clauses.

SPECIFIC enforcement AND SEIZURE

Sec. 17. (a) Specific Enforcement. – (1) The district courts of the United States shall have jurisdiction over civil actions to –

(A) restrain any violation of section 15,

(B) restrain any person from manufacturing or processing a chemical substance before the expiration of the period before which such manufacturing or processing is prohibited under section 5,

(C) restrain any person from taking any action prohibited by section 5 or by a rule or order under section 5 or 6, or

(D) compel the taking of any action required by or under this Act.

(2) A civil action described in paragraph (1) may be brought –

(A) in the case of a civil action described in subparagraph (A) of such paragraph, in the United States district court for the judicial district wherein any act, omission, or transaction constituting a violation of section 15 occurred or wherein the defendant is found or transacts business, or

(B) in the case of any civil action described in such paragraph, in the United States district court for the judicial district wherein the defendant is found or transacts business.

In any such civil action process may be served on a defendant in any judicial district in which a defendant resides or may be found. Subpenas requiring attendance of witnesses in any such action may run into any judicial district.

(b) Seizure. – Any chemical substance, or mixture which was manufactured, processed, or distributed in commerce in violation of this Act or any rule or order promulgated under this Act or any article containing such a substance or mixture shall be liable to be proceeded against by process of libel for the seizure and condemnation of such substance, mixture, or article, in any district court of the United States within the jurisdiction of which such substance, mixture, or article is found. Such proceedings shall conform as nearly as possible to proceedings in rem in admiralty.

preemption

Sec. 18. (a) Effect on State Law. – (1) Exempt as provided in paragraph (2), nothing in this Act shall affect the authority of any State or political subdivision of a State to establish or continue in effect regulation of any chemical substance, mixture, or article containing a chemical substance or mixture.

(2) Except as provided in subsection (b) –

(A) if the Administrator requires by a rule promulgated under section 4 the testing of a chemical substance or mixture, no State or political sub-

division may, after the effective date of such rule, establish or continue in effect a requirement for the testing of such substance or mixture for purposes similar to those for which testing is required under such rule ; and

(B) if the Administrator prescribes a rule or order under section 5 or 6 of this Act (other than a rule imposing a requirement described in sub-

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section (a) (5) of section 6) which is applicable to a chemical substance or mixture, and which is designed to protect against a risk to health or the environment associated with such substance or mixture, no State or political subdivision of a State may, after the effective date of such requirement, establish or continue in effect a requirement applicable to such substance or mixture, or an article containing such substance or mixture, and designed to protect against such risk unless such requirement is identical to the requirement prescribed by the Administrator or unless such requirement is adopted under the authority of the Clean Air Act or any other Federal law.

(b) Exemption. - Upon application of a State or political subdivision of a State the Administrator may be rule exempt from subsection (a) (2), under such conditions as may be prescribed in such rule, a requirement of such State or political subdivision designed to protect against a risk to health or the environment associated with a chemical substance, mixture, or article containing a chemical substance or mixture if -

(1) compliance with the requirement would not cause the manufacturing, processing distribution in commerce, or use of the substance, mixture, or article to be in violation of the applicable requirement imder this Act described in subsection (a) (2), and

(2) the State or political subdivision requirement (A) provides a significantly higher degree of protection from such risk than the requirement under this Act described in subsection (a) (2) and (B) does not, through diflBculties in marketing distribution, or other factors, unduly burden interstate commerce.

JUDICIAL BEVIEW

Sec. 19. (a) In General. - Not later than sixty days following the promulgation of a rule under section 4, 5, or 6(a) of this Act, any person may file a petition for judicial review of such rule with the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which such person resides or in which such person's principal place of business is located. Copies of the petition shall be forthwith transmitted by the clerk of such court to the

Administrator and to the Attorney General. The Administrator shall transmit to the Attorney General, who shall file in the court, the record of the proceedings on which the Administrator based such rule as provided in section 2112 of title 28, United States Code. For purposes of this section, the term "record" means such rule ; any transcript required of any oral presentation ; any written submission of interested parties ; and any other information which the Administrator considers to be relevant to such rule and with respect to which the Administrator, on or before the date of the promulgation of such rule, publishes a notice in the Federal Register identifying such information.

(b) Additional Data. – If the petitioner applies to the court for leave to adduce additional data, views, or arguments, and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there are reasonable grounds for the petitioner's failure to adduce such data, views, or arguments in the proceeding before the Administrator, the court may order the Administrator to provide additional opportunity for oral presentation of data, views, or arguments and for written submissions. The Administrator may modify findings or determinations upon which the rule subject to review by such court was based, or make new findings or determinations by reason of the additional data, views, or arguments so taken and shall file such modified or new findings or determinations, and the Administrator's recommendation, if any, for the modification or setting aside of such rule, with the return of such additional data, views, or arguments.

(c) Authority and Review Standard. – (1) Upon the filing of a petition under subsection (a), the court shall have jurisdiction (A) to review the rule involved, in accordance with chapter 7 of title 5, United States Code, and (B) to grant appropriate relief, including interim relief, as provided in such chapter. Any rule promulgated by the Administrator under section 4, 5, or 6 of this Act and reviewed under this section shall be affirmed, unless the determination or findings required to be made by the Administrator under the applicable section are not supported by substantial evidence on the record taken as a whole.

(2) The judgment of the court affirming or setting aside, in whole or in part, any rule reviewed in accordance with this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

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(3) The judgment of the court in an action (a) may include an award of costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. The Supreme Court of the United States in its decision on a review of judgment in such an action may

provide for the award of costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(d) Other Remedies. – The remedies provided in this section shall be in addition to and not in lieu of any other remedies provided by law.

citizens' civil actions

Sec. 20. (a) In General. – Except as provided in subsection (b), any person may commence a civil action –

(1) against any person (including (A) the United States, and (B) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution) who is alleged to be in violation of this Act or any rule prescribed under section 4, 5, or 6(a) to restrain such violation, or

(2) against the Administrator to compel the Administrator to perform any act or duty under this Act which is not discretionary.

Any civil action under paragraph (1) shall be brought in the United States district court for the district in which the alleged violation occurred or in which the defendant resides or in which the defendant's principal place of business is located. Any action brought under paragraph (2) shall be brought in the United States District Court for the District of Columbia, or the United States district court for the judicial district in which the plaintiff is domiciled. The district courts shall have jurisdiction over suits brought under this section, without regard to the amount in controversy or the citizenship of the parties. In any civil action under this subsection process may be served on a defendant in any judicial district in which the defendant resides or may be found and subpoenas for witnesses may run into any judicial district.

(b) Limitation. – No civil action may be commenced –

(1) under subsection (a)(1) to restrain a violation of this Act or rule under this Act –

(A) before the expiration of sixty days after the plaintiff has given notice of such violation (i) to the Administrator, and (ii) to the person who is alleged to have committed such violation, or

(B) if the Administrator (or the Attorney General on behalf of the Administrator) has commenced and is diligently prosecuting a civil action in a court of the United States to require compliance with this Act or such rule, but if such action is commenced after the giving of notice, any person giving such notice may intervene as a matter of right in such action ; or y

(2) under subsection (a) (2) before the expiration of sixty days after the plaintiff has given notice to the Administrator of the alleged failure of the Administrator to perform an act or duty which is the basis for such action or, in the case of an action under such subsection for the failure of the Administrator to file an action under section 7. before the expiration of ten days after such notification.

Notice under this subsection shall be given in such manner as the Administrator shall prescribe by rule.

(c) General. - (1) In any action under this section, the Administrator, if not a party, may intervene as a matter of right.

(2) The court, in issuing any final order in any action brought pursuant to subsection (a), may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to re\view such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(3) Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of this Act or any rule under this Act or to seek any other relief.

(d) Consolidation. - When two or more civil actions brought under subsection (a) involving the same defendant and the same issues or violations are pending in two or more judicial districts, such pending actions, upon applica-

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tion of such defendants to such actions which is made to a court in which any such action is brought, may, if such court in its discretion so decides, be consolidated for trial by order (issued after giving all parties reasonable notice and opportunity to be heard) of such court and tried in -

(1) any district which is selected by such defendant and in which one of such actions is pending,

(2) a district which is agreed upon by stipulation between all the parties to such actions and in which one of such actions is pending, or

(3) a district which is selected by the court and in which one of such actions is pending.

The court issuing such an order shall give prompt notification of the order to the other courts in which the civil actions consolidated under the order are pending.

citizens' PETITIQjSrS

Sec. 21. (a) In General. – Any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 4, 5(c), or 6(a).

(b) Procedure. – (1) Such petition shall be filed in the principal office of the Administrator and shall set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule under section 4, 5(c), or 6(a).

(2) The Administrator may hold a public hearing or may conduct such investigation or proceeding as the Administrator deems appropriate in order to determine whether or not such petition should be granted.

(3) Within ninety days after filing of a petition described in paragraph (1), the Administrator shall either grant or deny the petition. If the Administrator grants such petition, the Administrator shall promptly commence an appropriate proceeding in accordance with section 4, 5(c), or 6(a). If the Administrator denies such petition, the Administrator shall publish in the Federal Register the Administrator's reasons for such denial.

(4) (A) If the Administrator denies a petition filed under this section (or if the Administrator fails to grant or deny such petition within the ninety-day period) the petitioner may commence a civil action in a United States district court to compel the Administrator to initiate a rulemaking proceeding to take the action requested. Any such action shall be filed within sixty days after the Administrator's denial of the petition or, if the Administrator fails to grant or deny the petition within ninety days after filing the petition, within sixty days after the expiration of the ninety-day period.

(B) If in an action under subparagraph (A) respecting a petition to initiate a proceeding to issue a rule under section 4, 5(c), or 6(a) the petitioner demonstrates to the satisfaction of the court, by a preponderance of the evidence in a de novo proceeding before the court, that –

(i) in the case of a petition to initiate a proceeding for the issuance of a rule under section 4, that the manufacture, distribution in commerce, processing, use, or disposal of the chemical substance or mixture to be subject to such rule may cause or significantly contribute to an unreasonable risk to health or the environment,

(ii) in the case of a petition to initiate a proceeding for the issuance of a rule under section 5(c), that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance petitioned to be included in a list compiled under such rule causes or significantly contributes to or may cause or significantly contribute to an unreasonable risk to health or the environment, or

(iii) in the case of a petition for the issuance of a rule under section 6(a), that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture to be subject to such rule causes or significantly contributes to or will cause or significantly contribute to an unreasonable risk to health or the environment.

the court shall order the Administrator to initiate the action requested by the petitioner unless the court finds, after considering the extent of the risk to health or the environment alleged by the petitioner in relation to the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act, the resources available to the Administrator to take the action requested by the petitioner, and other relevant factors, the failure of the Administrator to initiate such action was not unreasonable.

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(C) The court in issuing any final order in any action brought pursuant to subparagraph (A) may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(5) The remedies under this section shall be in addition to, and not in lieu of, other remedies provided by law.

NATIONAL DEFENSE WAIVER

Sec. 22. The Administrator shall waive compliance with any provision of this Act upon a request and determination by the President that the requested waiver is necessary in the interest of national defense. The Administrator shall maintain a written record of the basis upon which such waiver was granted and make such record available for in camera examination when relevant in a judicial proceeding under this Act. Upon the issuance of such a waiver, the Administrator shall publish in the Federal Register a notice that the waiver was granted for national defense purposes, unless, upon the request of the President,

the Administrator determines to omit such publication because the publication itself would be contrary to the interests of national defense, in which event the Administrator shall submit notice thereof to the Armed Services Committees of the Senate and the House of Representatives.

EMPLOYEE PROTECTION

Sec. 23. (a) In General, - No employer may discharge any employee or otherwise discriminate against any employee with respect to the employee's compensation, terms, conditions, or privileges of employment because the employee (or any person acting pursuant to a request of the employee) has -

(1) commenced, caused to be commenced, or is about to commence or cause to be commenced a proceeding under this Act ;

(2) testified or is about to testify in any such proceeding; or

(3) assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes of this Act.

(b) Remedy. - (1) Any employee who believes that the employee has been discharged or otherwise discriminated against by any person in violation of subsection (a) of this section may, within thirty days after such alleged violation occurs, file (or have any person file on the employee's behalf), a complaint with the Secretary of Labor (hereinafter in this section referred to as the "Secretary") alleging such discharge or discrimination. Upon receipt of such a complaint, the Secretary shall notify the person named in the complaint of the filing of the complaint.

(2) (A) Upon receipt of a complaint filed under paragraph (1), the Secretary shall conduct an investigation of the violation alleged in the complaint. Within thirty days of the receipt of such complaint, the Secretary shall complete such investigation and shall notify in writing the complainant (and any person acting on behalf of the complainant) and the person alleged to have committed such violation of the results of the investigation conducted pursuant to this paragraph. Within ninety days of the receipt of such complaint the Secretary shall, unless the proceeding on the complaint is terminated by the Secretary on the basis of a settlement entered into by the Secretary and the person alleged to have committed such violation, issue an order either providing the relief prescribed by subparagraph (B) or denying the complaint. An order of the Secretary shall be made on the record after notice and opportunity for agency hearing. The Secretary may not enter into a settlement terminating a proceeding on a complaint without the participation and consent of the complainant.

(B) If in response to a complaint filed under paragraph (1) the Secretary determines that a violation of subsection (a) of this section has occurred, the Secretary shall order (i) the person who committed such violation to take affirmative action

to abate the violation, (ii) such person to reinstate the complainant to the complainant's former position together with the compensation (including back pay), terms, conditions, and privileges of the complainant's employment, (iii) compensatory damages, and (iv) where appropriate, exemplary damages. If such an order is issued, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate

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amount of all costs and expenses (including attorney's fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

(c) Review.— (1) Any person adversely affected or aggrieved by an order issued under subsection (b) may obtain review of the order in the United States Court of Appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred. The petition for review must be filed within sixty days from the issuance of the Secretary's order. Review shall conform to chapter 7 of title 5 of the United States Code.

(2) An order of the Secretary, with respect to which review could have been obtained under paragraph (1), shall not be subject to judicial review in any criminal or other civil proceeding.

(d) Enforcement. — (1) Whenever a person has failed to comply with an order issued under subsection (b)(2), the Secretary shall file a civil action in the United States district court for the district in which the violation was found to occur to enforce such order. In actions brought under this subsection, the district courts shall have jurisdiction to grant all appropriate relief, including injunctive relief and compensatory and exemplary damages. Civil actions brought under this subsection shall be heard and decided expeditiously.

(2) Any nondiscretionary duty imposed by this section is enforceable in mandamus proceeding brought under section 1361 of title 28, United States Code.

(e) Exclusion. — Subsection (a) of this section shall not apply with respect to any employee who, acting without direction from the employee's employer (or any agent of the employer), deliberately causes a violation of any requirement of this Act.

EMPLOYMENT EFFECTS

Sec. 24. (a) In General. — The Administrator shall evaluate on a continuing basis the potential effects on employment (including reductions in employment

or loss of employment from threatened plant closures) of -

(1) the issuance of a rule or order under section 4, 5, or 6, or

(2) a requirement of section 5.

(b) (1) Investigations. - Any employee (or any representative of an employee) may request the Administrator to make an investigation of -

(A) a discharge or layoff or threatened discharge or layoff (of the employee, < or

(B) adverse or threatened adverse effects on the employee's employment, allegedly resulting from a rule or order under section 4, 5, or 6 or a requirement of section 5. Any such request shall be made in writing, shall set forth with reasonable particularity the grounds for the request, and shall be signed by the employee, or representative of such employee, making the request.

(2) (A) Upon receipt of a request made in accordance with paragraph (1) the Administrator shall (i) conduct the investigation requested, and (ii) if requested by any interested person, hold public hearings on any matter involved in the investigation unless the Administrator determines that there are no reasonable grounds for holding such hearings. If the Administrator makes such a determination respecting a request for a hearing, the Administrator shall notify in writing the person requesting the hearing of the determination and the reasons therefor.

(B) If public hearings are to be held on any matter involved in an investigation conducted under this subsection -

(i) at least five days' notice shall be provided the person making the request for the investigation and any person identified in such request,

(ii) a transcript shall be made of the hearings, and

(iii) each employee who made or for whom was made a request for such hearings and the employer of such employee shall be required to present information respecting the applicable matter referred to in paragraph (1) (A) or (1) (B) together with the basis for such information.

(3) Upon completion of an investigation under paragraph (2), the Administrator shall make findings of fact, shall make such recommendations as the Administrator deems appropriate, and shall make available to the public such findings and recommendations.

(4) In connection with any investigation or public hearing conducted under this subsection, the Administrator may issue subpoenas for the attendance and testimony of witnesses and the production of relevant papers, books, and documents,

and the Administrator may administer oaths. Witnesses summoned shall be paid

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the same fees and mileage that are paid witnesses in the courts of the United States. In case of contumacy or refusal to obey a subpoena served upon any person under this paragraph, the United States district court for any district in which such person is found or resides or transacts business, upon application by the United States and after notice to such person, shall have jurisdiction to issue an order requiring such person to appear and give testimony before the Administrator to appear and produce papers, books, and documents before the Administrator, or both, and any failure to obey such order of the court may be punished by such court as a contempt thereof.

STUDIES

Sec. 25. (a) Indemnification Study. – The Administrator shall conduct a study of all Federal laws administered by the Administrator for the purpose of determining whether and under what conditions, if any, indemnification should be accorded any person as a result of any action taken by the Administrator under any such law. The study shall –

(1) include an estimate of the probable cost of any indemnification programs which may be recommended ;

(2) include an examination of all viable means of financing the cost of any recommended indemnification; and

(3) be completed and submitted to Congress not less than two years from the effective date of this Act.

The General Accounting Office shall review the adequacy of the study submitted to Congress pursuant to paragraph (3) and shall report the results of its review to the Congress within six months of the date such study is submitted to Congress.

(b) Classification, Storage, and Retrieval Study. – The Council on Environmental Quality, in consultation with the Administrator, the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate Federal departments or agencies, shall coordinate a study of the feasibility of establishing (1) a standard classification system for chemical substances and related substances, and (2) a standard means for storing and for obtaining rapid access to information respecting such substances, A report on such study shall be completed and submitted to Congress not later than eighteen months

after the effective date of this Act.

administration* of act

Sec. 26. (a) Cooperation of Federal Agencies. – Upon request by the Administrator, each Federal department and agency is authorized –

(1) to make its services, personnel, and facilities available (with or without reimbursement), to the Administrator to assist the Administrator in the administration of this Act ; and

(2) to furnish to the Administrator such information, data, estimates, and statistics, and to allow the Administrator access to all information in its possession as the Administrator may reasonably determine to be necessary for the administration of this Act.

(b) Fees. – The Administrator may, by rule, require the payment of a reasonable fee from any person required to submit data under section 4 or 5 of this Act to defray the cost of administering this Act. Such rules shall not provide for any fee in excess of \$2,500. In setting such a fee, the Administrator shall take into account the ability to pay of the person required to submit the data and the cost to the Administrator of reviewing such data. Such rules may provide for sharing such a fee in any case in which the expenses for testing are shared under section 4 or 5 of this Act.

(c) Action With Respect to Categories. – (1) Any action authorized or required to be taken by the Administrator under any provision of this Act with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the Administrator takes action under a provision

I of this Act with respect to a category of chemical substances or mixtures, any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category.

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(2) For purposes of paragraph (1) : .]

(A) The term "category of chemical substances" means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance] into the human body or into the environment, or the members of which are in] some other way suitable for classification as such for purposes of this Act^ except that such term does not mean a group of chemical substances which

are grouped together solely on the basis of their being new chemical substances.

(B) The term "category of mixtures" means a group of mixtures the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act.

(d) Assistance Office. – The Administrator shall establish in the Environmental Protection Agency an identifiable office to provide technical and other nonfinancial assistance to manufacturers and processors of chemical substances and mixtures respecting the requirements of this Act applicable to such manufacturers and processors, the policy of the Agency respecting the application of such requirements to such manufacturers and processors, and the means and methods by which such manufacturers and processors may comply with such requirements.

DEVELOPMENT AND EVALUATION OF TEST METHODS

Sec. 27. (a) The Secretary of Health, Education, and Welfare, in consultation with the Administrator and acting through the Assistant Secretary for Health, may conduct, and make grants to public and nonprofit private entities and enter into contracts with public and private entities for, projects for the development and evaluation of inexpensive and efficient methods (1) for determining and evaluating the health and environmental effects of chemical substances and mixtures, and their toxicity, persistence, and other characteristics which affect health and the environment, and (2) which may be used for the development of test data to meet the requirements of rules promulgated under section 4. The Administrator shall consider such methods in prescribing under section 4 standards for the development of test data.

(b) No grant may be made or contract entered into under subsection (a) unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be submitted in such form and manner and contain such information as the Secretary may require. The Secretary may apply such conditions to grants and contracts under subsection (a) as the Secretary determines are necessary to carry out the purposes of such subsection. Contracts may be entered into under such subsection without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529 ; 41 U.S.C. 5).

(c) (1) The Secretary shall prepare and submit to the President and the Congress on or before January 1 of each year a report of the number of grants made and contracts entered into under this section and the results of such grants and contracts.

(2) The Secretary shall periodically publish in the Federal Register reports describing the progress and results of any contract entered into or grant made

under this section.

AUTHORIZATION FOB APPROPRIATIONS

Sec. 28. There are authorized to be appropriated to the Administrator for purposes of carrying out this Act (other than section 27 thereof) \$11,100,000 for the fiscal year ending September 30, 1978, \$10,100,000 for the fiscal year ending September 30, 1979, and \$11,100,000 for the fiscal year ending September 30, 1980. No part of the funds appropriated under this section may be used to construct any research laboratories.

ANNUAL REPORT

Sec 29. The Administrator shall prepare and submit to the President and the Congress on or before January 1, 1979, and on or before January 1 of each succeeding year a comprehensive report on the administration of this Act during the preceding fiscal year. Such report shall include -

(1) a list of the testing required under section 4 during the year for which the report is made and an estimate of the costs incurred during such year by the persons required to perform such tests ;

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(2) the number of notices received during such year under section 5, the number of such notices received during such year under such section for chemical substances subject to a section 4 rule, and a summary of any action taken during such year under section 5(g) ;

(3) a list of rules issued during such year under section 6;

(4) a list, with a brief statement of the issues, of completed or pending judicial actions under this Act during such year ;

(5) a summary of major problems encountered in the administration of this Act; and

(6) such recommendations for additional legislation as the Administrator deems necessary to carry out the purposes of this Act.

EFFECTIVE DATE

Sec. 30. This Act shall take effect October 1, 1977.

The Chairman. Are there amendments to the remainder of the bill ?

AMENDMENTS OFFERED BY MR. MOORE

Mr. Moore. Mr. Chairman, I offer amendments.
The Clerk read as follows :

Amendments offered by Mr. Moore ; Page 210, after line 3, add the following new section :

KULE REVIEW

Sec. 30 [Sec. 32, as passed], (a) Any rule prescribed pursuant to this Act by the Administrator may by resolution of either House of Congress be disapproved, in whole or in part, if such resolution of disapproval is adopted not later than the end of the first period of 60 calendar days when Congress is in session (whether or not continuous) which period begins on the date such rule is finally adopted by the Administrator, Secretary of the Treasury, or Secretary of Health, Education, and Welfare, as the case may be. The authority which prescribes a rule pursuant to this Act shall transmit such rule to each House of Congress immediately upon its final adoption. Upon adoption of such a resolution of disapproval by either House of Congress within such 60-day period, such rule, or part thereof, as the case may be, shall cease to be in effect.

(b) Congressional inaction on or rejection of a resolution of disapproval of a rule promulgation under this Act shall not be deemed an expression of approval of such rule.

Redesignate the succeeding section accordingly.

Page 103, insert after the item in the table of contents relating to section 29 the following new item :

Sec 30. Rule Review.

Redesignate the succeeding item accordingly.

Mr. Moore. Mr. Chairman, I ask unanimous consent that the amendments be considered en bloc.

The Chairman. Is there objection to the request of the gentleman from Louisiana ?

There was no objection.

Mr. Moore. Mr. Chairman, one of the biggest problems today in the Federal Government operations is the massive regulatory power of the bureaucracy. Let us not forget that regulations have the full force and effect of law, and often go far beyond what we intend here in

Congress, in the act we passed under which the regulations may be issued.

They are made by bureaucrats who are not elected and cannot even be readily removed, as many of them are employees of independent agencies and actually may well answer to no one, especially the people.

Our Government is an ingenious one of checks and balances. We do

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have checks and balances for the three branches of Government, and we have had it for 200 years. But there has come upon us a fourth branch of Government, one for which we do not have any checks and balances. That fourth branch is the bureaucracy. We have no effective way today to undo an undesirable regulation, as the court will not touch a regulation if it is in fact legal. Congress itself is not going to pass a law to reverse a regulation as it is far too cumbersome to overturn every undesirable or oppressive regulation.

The fourth branch we have today of the bureaucracy was not contemplated by our Founding Fathers. Indeed, the first regulatory agency that appeared in this country did so after this country was well over 100 years old, in 1887, when the ICC was created. Today we have over 105,000 Federal bureaucrats, according to the Office of Management and Budget, cranking out regulations on every aspect of our lives, at a cost, according to the OMB, of \$130 billion a year. But far more important is the cost of our personal freedom infringed upon by the issuance of every regulation. I point out to my colleagues that this is being done without any effective checks or balances of this great power of the rulemaking agencies. I point out to my colleagues that this problem is not just going to go away. It is not one that we can sit here and make speeches about and go home and say, "Yes, bureaucracy is a terrible thing but there is nothing I can do about it." We can do something here and now with the passage of this amendment.

In the last 15 years this Congress created 236 different rulemaking agencies, while disbanding only 21. Today the number of agencies, bureaucrats, rules and regulations are growing at an alarming rate. This problem is becoming more acute. It is not going away. The people, rightfully, want us to do something now to correct this imbalance of power. It is a very real, a very legitimate campaign issue, which we must address.

Some 10,000 people responded so far to my latCvSt questionnaire sent out last month, and 80 percent of the people responding heartily support this proposal. They fear today the very real excessive and unchecked power of regulatory agencies, they feel a loss of personal freedom and they feel a frustration, as they know that nothing is currently being done to check this power. As one of my constituents put it, when he answered the questionnaire, "We often could live better with the problem than we can with the Federal Government's solution to it."

This amendment is not a cure-all solution, but it is a tool with which we can begin to solve this problem. It will help check the imbalance of power by giving either House of Congress at long last, as one of the three legitimate branches of Government, a veto over any rule or regulation issued under this bill by the bureaucracy. It will begin to bring into balance, this out-of-balance power of the bureaucracy.

This House during the 94th Congress has already eight times accented this same amendment to eight other bills. This House has not rejected it once. I will also point out that this is very similar to the Administrative Rulemaking Reform Act (H.R. 12048) which has been reported from the Committee on the Judiciary, and is now pending before the Committee on Rules, which we all hope will soon grant a rule.

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According to the Library of Congress, there are 19 other provisions such as this that are currently existing in law, some going back as far as 1946.

I feel very strongly that this amendment should be adopted, to give protection the awesome powers of this bill and more importantly protection from the rulemaking powers of the bureaucracy. We must protect our people from any further loss of personal freedom and to bring into check this out-of-balance power.

Mr. ECKHARDT. Mr. Chairman, I rise in opposition to the amendment.

Mr. Chairman, we are considering one of the most important issues that has been raised here. I would like to say that if we should vote favorably for this amendment, we would put into this bill precisely the same provision that was the expressed reason and the only rea-

son for the veto of the Pesticide and Rodenticide Act by the President the other day.

There may be many Members who disagree with me with respect to the desirability of attaching a yo-yo string to legislative authority. I have always been against that, and in this respect I agree with the President's objection in his veto message. Indeed the attachment of a yo-yo string which may pull back authority by legislative veto has exactly the opposite effect that many of my colleagues think it has. It tends to make Congress grant more irresponsible authority because we feel we can pull it back when in fact we cannot.

But if Members believe in principle in this type of review, in this type of mixing of legislative with executive authority, if Members believe in this retention of a qualified power to change a law after it is enacted, I believe they should nevertheless vote against this amendment in this particular case, because this amendment requires legislative review of every type of rule that is finally adopted by the Administrator, by the Secretary of the Treasury, or by the Secretary of the Department of Health, Education, and Welfare. This includes a testing rule under which the only thing the Administrator has done is to say that "This chemical poses a threat to humans or to the environment, and we think it ought to be tested", [section 4]

A chemical company that does not want to have it tested, a company that does not want to submit it to testing, then could come up to Congress and lobby before Congress to reject the testing rule. Now, are we not in a fine position to review the question of whether or not testing should be had? And, of course, the EPA has authority in some instances to say that "We want this kind of testing." Should we come in and second-guess the agency and say that we want another kind of testing?

The second review is with respect to a ban under section 6 if ultimately a chemical is found to be dangerous such as PCB. We had this argument, and nearly all the Members voted to ban PCB's legislatively after a given period of time. But would we permit some person or some industry that thinks something similar to PCB's, like PBB's I are not dangerous to come in and lobby before Congress to reverse a ; rule?

1 It seems to me that if we provide for a congressional veto in this instance we are inviting every large chemical manufacturer in the

country to come in and ask us to veto an administrative act. Why should we encumber ourselves with this kind of provision ?

We have been talking here about little business. Who is going to have the money to come up here and lobby for a change, for an amelioration, or for a removal of the limitation with respect to a chemical? Is a little business going to have the money to do that ?

When we delegate authority, we ought to delegate it in restricted fields, as we have done in this bill. When we are dealing with a ban, we ought to give full due process, as we have done in this bill. When we are considering prohibiting a person from putting a product that he manufactures on the market, we should permit him to have the opportunity of cross-examination; he should be allowed to cross-examine with respect to the rule, and we have done that here.

But let us not make this a political matter that can be later raised by anyone who has the clout to change the legislative process,

Mr. Broyhill. Mr. Chairman, I ordinarily agree with amendments that are similar to that offered by the gentleman from Louisiana (Mr. Moore). In fact, I have cosponsored legislation which would require the agencies to submit the rules which subject individuals to criminal penalties and to submit those rules and regulations to Congress for a period of time for review.

However, Mr. Chairman, this amendment actually goes far beyond the terms of that bill. Under this amendment, even nonsubstantial rules, rules of just ordinary procedure of the agency to guide people in their access to the agency, would be subject to this amendment.

I also would point out that there are some very technical rules that are going to come about as a result of section 4. Particularly, these are the rules of the agency which spell out what kind of tests are going to be required on these various chemicals.

Mr. Chairman, I just do not think that the Congress has the expertise to be making these judgments on technical subjects like this.

Furthermore, Mr. Chairman, under this amendment there is no guarantee that the Congress would act. There is no procedure spelled out in this amendment that would require the consideration of these rules by Congress. What I am saying, Mr. Chairman, is that, in considering the way in which this amendment is written, it is reasonable to assume that all of the rules that would be submitted pursuant to this amendment would lie in the committee; and no action will be

taken by the Congress. There is no procedure spelled out in this amendment which gives the right to a Member to discharge a committee, for example, from further consideration of that rule or regulation.

For these reasons, Mr. Chairman, I ask that this amendment be rejected. Let us consider this subject in the bill which has been co-sponsored by close to 200 Members, which I understand is now pending before the Committee on Rules; and let us consider this idea of congressional review of rules and regulations in one bill under which we can debate the merits of the legislation and not do it piecemeal in this way.

Mr. Seiberling. Mr. Chairman, I would like to associate myself with the remarks of the gentleman from North Carolina (Mr. Broyhill), as well as with the remarks of the gentleman from Texas (Mr. Eckhardt).

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It seems to me that this is an abdication of the legislative process when we, on a blanket basis like this and without consideration of distinctions between different types of rules and rulemaking situations, would have every one come back to the Congress. We would soon find that we were utterly incapable of coping with the flood and would have to triple the size of our committee staffs if we were to handle it in a proper manner.

Mr. Broyhill. Mr. Chairman, let me comment. I do not personally go all the way along with the argument of the gentleman from Ohio (Mr. Seiberling). I am just speaking in opposition to this particular amendment.

As I pointed out, Mr. Chairman, I have cosponsored legislation which would apply to those rules which would subject the individual to a criminal penalty. This amendment goes far beyond that. This would apply to any rule.

Mr. Seiberling* Mr. Chairman, if the gentleman will yield further, I thought that was a particularly good distinction which the gentleman from North Carolina (Mr. Broyhill) made, and I simply wanted to commend him and associate myself with his remarks.

Mr. Eckhardt. Mr. Chairman, I think one thing ought to be pointed out : It was said that we never rejected these matters.

I think, as the gentleman has indicated, we need to consider them individually. We have rejected such an amendment on the Coal Leasing Act.

Each bill raises a different question and makes out a different case. I think the gentleman has very clearly distinguished this case from any of the others in which we have adopted such an amendment.

Mr. Martin. Mr. Chairman, I want to commend the gentleman from Louisiana (Mr. Moore) for his timely amendment, the arguments of the gentleman from North Carolina (Mr. Broyhill) and the gentleman from Texas (Mr. Eckhardt) to the contrary notwithstanding.

Mr. Chairman, in 1771, over 200 years ago, a group of North Carolina farmers, ironically calling themselves regulators, set out to oppose excessive control by the King's agents. Today our people resent those I people who are contemporary regulators. It is time, regardless of the opinion of the executive branch, to limit our regulatory agencies, to hold them accountable - in other words, to regulate the regulators.

Congress will respond under this amendment offered by the gentleman from Louisiana (Mr. Moore) only where the cost of the regulators clearly exceeds the benefits.

It seems to me we would reserve the authority to make that judgment. The executive branch should not be allowed to enlarge its power without being subject to elective authority. If we in the Congress are indeed wise enough to judge the necessity to create such an agency as is being proposed here today to regulate the chemical industry, it again seems to me we should need the right to review those regulations and reject them where they exceed our intent.

Mr. RousSELOT. Mr. Chairman, from some of the comments by my colleagues who oppose this amendment they would leave the impression that Congress is mandated to review every single rule issued, and that is not the case. We merely can take up the ones that our appropriate committees think should be taken up, or that we feel are excessive. Is that correct ?

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Mr. Martin. That would be the way it would work out, I can assure the gentleman from California.

Mr. RousSELOT. So that there is no demand that we absolutely take

up every new rule * * * it merely gives us a reviewing procedure. As the gentleman from Louisiana (Mr. Moore) has wisely tried to provide j in his amendment, it gives a veto capability to the Congress that we have needed for some time. Because, unfortunately, so many of our regulatory agencies assume powers by implementing rules which we never intended in original legislation.

I think this would be an excellent practice. I think that 60 days is more than adequate time for our committees to take a hardnosed look at many of these rules and regulations. ,

Again I compliment the gentleman from North Carolina (Mr. Martin) and my colleague, the gentleman from Louisiana (Mr. Moore). We have voted on this amendment many times although I i have noticed that my colleague, the gentleman from Louisiana (Mr. Moore) has very carefully worded this amendment to make sure that it does not create any legal problems. I compliment both of my colleagues for offering this important amendment.

Mr. Martix. Mr. Chairman, I thank the gentleman for his observations. Over the past 15 years it has become the practice of Congress to I create agency after agency and charging it to "Go ye forth into ye j streets and do ye thing." These agencies have proceeded to do just that, without restraint from any elected officials, and they themselves are not elected and are not accountable for their actions. It is high time for j such an amendment as this and other amendments that I have seen to ll enable the Congress to reserve that authority to review the regulators I and give them timely guidance. !

Mr. RousSELOT. I think the amendment is even more important be- j cause this bill affects so many small chemical businesses. The rule- I making power provided in this legislation is very substantial. It is j important that the Congress give itself the chance to review this rulemaking power.

Mr. Murphy of New York. Mr. Chairman, the President vetoed earlier this month the Pesticide Control Act amendments because of an amendment similar to that of the gentleman from Louisiana.

My colleague, the gentleman from Louisiana (Mr. Moore) has offered his amendment in good faith and I can know and understand the reason surrounding it. But I think the way to approach legislating properly is the way we have done in this bill, and that is to get guide- lines for the agency regarding the hearing process.

As a consequence, Mr. Chairman, I would ask that the committee reject this amendment.

Mr. RoussEiX)T. Mr. Chairman, I would ask the gentleman from New York, is there any great harm in the Congress taking the prerogative of review? Does the gentleman see any great damage that would be done to the congressional process for us to assume our responsibilities of reviewing what agencies have done under the rulemaking process ? Is that harmful ? 1

Mr. Murphy of New York. I think we have the resolution and the ! joint resolution route if we want to veto the Administrator's actions. And we have oversight responsibilities. As the Members know, at the j beginning of this Congress the majority caucus adopted a resolution

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to broaden the oversight function of Congress for just the reason the gentleman has stated.

Mr. RoussELOT. I am not suggesting that we should stop the congressional oversight process. I think that is terribly important. But related to that oversight process, we ought to make sure that agencies do not engage in rulemaking that goes either beyond the legislative intent or maybe has not been properly thought out. Four hundred thirty-five ^Members of this body hear from their constituents very regularly on this problem of arbitrary rulemaking. They also hear from those affected by legislation we pass. So is the gentleman really agreeing with me that there is no great harm in this amendment ?

Mr. Murphy of New York. I would say the harm is this: This Congress has worked 2 years, the previous Congress 2 years, and the Congress before that 2 years, to try to bring out a Toxic Substances Control Act to protect the health and the environment of Americans. We can see that we can be vetoed after we have worked these 6 years because of amendments such as this. I think to obviate that possibility we have written the regulatory rules so that the Environmental Protection Administrator can bring forth proper rules. Accordingly I would ask that the committee defeat the amendment.

The Chairman. The question is on the amendments offered by the gentleman from Louisiana (Mr. Moore).

The question was taken ; and on a division (demanded by Mr. Moore) there were - ayes 19, noes 41.

Mr. Moore. Mr. Chairman. I demand a recorded vote.

A recorded vote was ordered.

The vote was taken by electronic device, and there were - ayes 210, noes 157, not voting 64, as follows :

[Roll No. 643]

AYES- 210

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Andrews, N. Dak.

Archer

Armstrong

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Bafalis

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Clausen, Don H.

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Collins, Tex.

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Daniel, R. W.

Daniels, N.J.

Davis

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Dickinson

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Downey, N.Y.

Downing. Va.

Duncan, Tenn.

Edgar

Emery

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Erlenborn

Evans, Ind.

Findley

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Ford. Mich.

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Byron

Duncan Or[<]fr

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Oarney

Early

Ashley

Carter

Eckhardt

Bedell

Clay

Edwards, Ala.

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Collins, 111.

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Bingham

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Evans, Colo.

Boland

Cornell

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Fascell

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Delaney

Fenwick

Brodhead

Dellums

Fisher

Brooks

Dent

Flood

Broyhill

Derwinski

Florio

Burlison, Mo.

Diggs

Foley

Burton, John

Dingell

Ford, Tenn.

Burton, Phillip

Drinan

Forsythe

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Fraser

Giaimo

Gibbons

Gonzalez

Gude

Harrington

Harris

Hawkins

Hayes, Ind.

Heckler, Mass.

Helstoski

Hicks

Holtzman

Horton

Howard

Jordan

Kastenmeier

Koch

Leggett

Long, Md.

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McCloskey

McCollister

McCormack

McDade

McFall

McHugh

McKay

Madden

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Meyner

Mezvinsky

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Miller, Calif.

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Anderson, Calif.

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Badillo

Baldus

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Brown, Calif.

Brown, Mich.

Burke, Calif.

Chappell

Chisholm

Conlan

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Gorman

de la Garza

Derrick

du Pont

Esch

Mitchell, Md.

Moakley

Morgan

Mosher

Murphy, 111.

Murphy, N.Y.

Murtha

Myers, Pa.

Nix

Xolau

Nowak

Oberstar

Obey

O'Neill

Ottinger

Patten, N.J.

Patterson, Calif.

Pattison, N.Y.

Pepper

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Preyer

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NOT VOTING- (

Eshleman

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Hubert

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Smith, Nebr.

Solarz

Snellman

Staggers

Stanton, J. William

Stanton, James Y.

Stark

Steiger, Wis.
Stokes

Studds

Taylor, N.C.

Thompson

Thone

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Vander Veen

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Whalen

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Wilson, Bob

Wilson, Tex.

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Yates

Yatron

Moss

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Peyser

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Santini

Sisk

Steel man

Steiger, Ariz.

Sullivan

Symington

Van Deerlin

Waxman

Wilson, C. H.

Young, Alaska

Young, Ga.

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Mr. Hefner changed his vote from "no" to "aye."

So the amendments were agreed to.

The result of the vote was announced as above recorded.

AMENDMENT OFFERED BY MR. MAGUIRE

Mr. Maguire. Mr. Chairman, I offer an amendment.

The Clerk read as follows :

Amendment offered by Mr. Maguire: Page 208, insert after line 19 the following :

STATE PROGRAMS

Sec. 28. (a) For the purpose of complementing (but not reducing) the authority of, or actions taken by, the Administrator under this Act, the Administrator may make grants to States for the establishment and operation of programs to prevent or eliminate unreasonable risks within the States to health or the environment which are associated with a chemical substance or mixture and with respect to which the Administrator is unable to take action under this Act for their prevention or elimination. The amount of a grant under this subsection shall be determined by the Administrator, except that no grant for any State program may exceed 75 per centum of the establishment and operation costs (as determined by the Administrator) of such program during the period for which the grant is made.

(b) (1) No grant may be made under subsection (a) unless an application therefor is submitted to and approved by the Administrator. Such application shall be submitted in such form and manner as the Administrator may require and shall -

(A) set forth the need of the applicant for a grant under subsection (a),

(B) identify the agency or agencies of the State which shall establish or operate, or both, the program for which the application is submitted,

(C) describe the actions proposed to be taken under such program,

(D) contain or be supported by assurances satisfactory to the Administrator that such program shall, to the extent feasible, be integrated with other programs of the applicant for environmental and public health protection,

(E) provide for the making of such reports and evaluations as the Administrator may require, and

(F) contain such other information as the Administrator may prescribe.

(2) The Administrator may approve an application submitted in accordance

with paragraph (1) only if the applicant has established to the satisfaction of the Administrator a priority need, as determined under rules of the Administrator, for the grant for which the application has been submitted. Such rules shall take into consideration the seriousness of the health effects in a State which are associated with chemical substances or mixtures, including cancer, birth defects, and gene mutations, the extent of the exposure in a State of human beings and the environment to chemical substances and mixtures, and the extent to which chemical substances and mixtures are manufactured, processed, used, and disposed of in a State.

(c) Not later than six months after the end of each of the fiscal years 1979, 1980, and 1981, the Administrator shall submit to the Congress a report respect-

ing the programs assisted by grants under subsection (a) in the preceding fiscal year and the extent to which the Administrator has disseminated information respecting such programs.

(d) For the purpose of making grants under subsection (a) there are authorized [^] appropriated \$1,000,000 for the fiscal year ending September 30, 1978, [^] \$1,000,000 for the fiscal year ending September 30, 1979, and \$1,000,000 for the fiscal year ending September 30, 1980. Sums appropriated under this subsection shall remain available until expended.

Page 208, line 23, strike out "section 27" [^] and insert in lieu thereof "sections 27 and 28 .

Redesignate the succeeding sections accordingly.

Page 103, insert in the table of contents after the item relating to section 27 the following new item.

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Sec. 28. State pro-ams.

Redesignate the succeeding items in the table of contents accordingly.

Mr. Maguire. Mr. Chairman, I support this landmark legislation and rise to offer an amendment which would provide financial assistance to selected State to complement and augment the EPA efforts authorized under this bill.

My amendment will give the Administrator of EPA the authority to make grants to selected States, with severe problems related to toxic chemicals, like New Jersey, to cover up to 75 percent of the costs of establishing and operating programs to prevent or eliminate unreasonable risks in the States to health or the environment associated with chemical substances or mixtures. The grant money is earmarked for use in ways which will complement the activities already underway or being planned by EPA for the implementation of this Act and for activities which the Administrator is unable to undertake, because of inadequate resources or other higher priorities. It is not intended to, and will not replace, EPA's authority to require reporting, testing, or any other of the authorities given in this act.

We have before us a formidable challenge - to take stock of the chemical substances and mixtures now present in the environment

and to undertake, in an equitable manner, the task of determining which substances may pose an unreasonable risk. It is a job so great that the Federal Government cannot be expected to handle it alone. The leadership in this effort properly belongs with the Federal Government but the States too will play an important role in the process.

Under this amendment assistance for programs, in selected States most heavily impacted by chemical pollution problems, will support further innovation and expansion on the existing body of knowledge in this field. The implications are significant for the chemical industry and the Nation. Teamwork of State and Federal Governments in tackling the problem of chemical pollution should ultimately prove more efficient for meeting the purposes of this act and could help to minimize the burden on industry in submitting information and data which will be required of them by this act.

This amendment gives the Administrator the authority to establish rules for evaluating applications for grant assistance. These rules shall take into consideration three basic criteria for determining priority need; first, the seriousness of health effects associated with chemical substances and mixtures including cancer, birth defects and gene mutations; second, the extent of exposure of human beings and the environment in a State to chemical substances and mixtures; and third, the extent to which chemical substances and mixtures are manufactured, processed, used and disposed of within a State. By these criteria we can be assured that a State receiving this assistance has an immediate need and that their experience in developing management procedures and multimedia monitoring and monitoring procedures will bolster EPA's efforts in building a nationwide approach for assessing the impact of chemical pollution on the public health and the environment.

Concern has been expressed that this provision might represent a "foot in the door" whereby the Environmental Protection Agency might take advantage of the grant program to pass some of its testing.

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monitoring, and enforcement responsibilities on to State agencies. This amendment has been carefully drafted to explicitly eliminate

such a possibility.

I have discussed my amendment with the floor manager Chairman Murphy, and with the majority and minority sponsors and I understand that it is acceptable to them. I would like to add that a similar amendment, sponsored by Senators Williams and Case was accepted in the Senate version of the toxic substances bill.

My colleagues from New Jersey (Mr. Florio and Mr. Rinaldo) join me in urging that this amendment be unanimously adopted.

Mr. Murray of New York. . . . I want to compliment my colleague, the gentleman from New Jersey, on a well-thought-out amendment. It does perfect the bill. Some States do have a concentration of chemical industry within the confines of those States. This amendment would permit grants to be given to those States to protect themselves. I think the amendment supplements the legislation, and I will agree to the amendment.

Mr. Maguire. I thank the gentleman.

Mr. Broyhill. . . . I understand this is only a 3-year program as envisioned in the bill ?

Mr. Maguire. That is correct. The amendment is for 3 years.

Mr. Broyhill. For 3 years ?

Mr. Maguire. For 3 years ; that is correct.

Mr. Broyhill. There are only 3 years of authorization; it is not an unlimited authorization ?

Mr. Maguire. The gentleman is correct.

The question is on the amendment offered by the gentleman from New Jersey (Mr. Maguire) . The amendment was agreed to.

AMENDMENTS OFFERED BY MRS. FENWICK

Mrs. Fenwick. Mr. Chairman, I offer amendments. The Clerk read as follows :

Amendments offered by Mrs. Fenwick : Page 205, line 10. [Sec. 26(b)], after "(b) Fees. - and insert "(1)".

Page 205, line 14. after "\$2..500" insert "or, in the case of a small business

concern, any fee in excess of \$100.00".

Page 205, after line 19, insert the following :

(2) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the persons which qualify as small business concerns for purposes of this subsection.

Mrs. Fen WICK. Mr. Chairman, I ask unanimous consent that these amendments be considered en bloc.

The Chairman. Is there objection to the request of the gentlewoman from New Jersey ?

There was no objection.

Mrs. Fenwick. Sir. Chairman, I will not take the time of the House. These are small, simple amendments merely to make it possible for small businesses for which the \$2,500 fee is a very grave difficulty. They are applied to persons required to submit data under sections 4 and 5 on request of the Administrator, and the \$2,500 fee maximum is impossible particularly if there is more than one substance to be tested.

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Mr. McCOLLISTER. ... I commend the gentlewoman on her amendments and support them.

Mrs. Fenwick. I thank the gentleman.

Mr. Murphy of New York. . . . The gentlewoman states the case previously debated on protection for small business. It was inherent in the committee's intent in this legislation. We thank her for clarifying these amendments, and we will be happy to accept them.

Mrs. Fenwick. I thank the gentleman.

Mr. Xox. I commend the gentlewoman for her amendments, and urge their adoption.

Chairman. I rise in support of the amendments. The \$2,500 filing fee would work a severe hardship on small business enterprises who manufacture chemicals.

Many small manufacturers thrive on limited-volume specialty products. These chemicals are often produced in quantities as small as 2,000 pounds per year. This compares with the thousands of tons which some of the large manufacturers produce.

In addition, small companies often manufacture hundreds of these limited-volume chemicals. One Midwest company, for example, handles 1,000 different chemicals. Others produce an average of 200 or 300 chemical products. To impose repeated filing fees on these companies is destructive, unfair and unnecessary.

Proponents of the bill proudly point to its endorsement by 186 manufacturers who produce 90 percent of our chemicals. This amendment is designed to protect the 11,000 small businesses who produce the other 10 percent. Du Pont with \$.5 billion in yearly sales or Union Carbide with \$3.5 can afford a \$2,500 filing fee. But a small manufacturer with a few million dollars in sales will not long survive a series of hefty filing fees.

Mr. Chairman, I believe these amendments are worthy of support and I strongly urge my colleagues to adopt them.

Mrs. Fawcett. I thank the gentleman also for his endorsement and encouragement.

Mr. Maguire. I commend the gentlewoman on her amendments. My colleague, the gentlewoman from New Jersey, has improved the bill in this respect, and I hope the amendments will be accepted.

Mrs. Fenwick. I thank my colleague for his comments.

The Clerk: The question is on the amendments offered by the gentlewoman from New Jersey (Mrs. Fenwick).

The amendments were agreed to.

AMENDMENT OFFERED BY MR. HECHLER OF WEST VIRGINIA

Mr. Hechler of West Virginia. Mr. Chairman, I offer an amendment.

The Clerk read as follows :

Amendment offered by Mr. Hechler of West Virginia : On page 208, between lines 19 and 20, insert the following new section:

"Sunshine in Government

Sec. 28. [Sec. 29, as passed] (a) Each officer or employee of the Administrator and the Secretary of Health, Education and Welfare who -

"(1) performs any function or duty under this Act; and

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"(2) has any known financial interest (A) in any person subject to this Act, or (B) in any person who applies for or receives any grant, contract, or other form of financial assistance pursuant to this Act ;
"shall beginning on -February 1, 1977, annually file with the Administrator or the Secretary of Health, Education and Welfare, as appropriate, a written statement concerning all such interests held by such officer or employee during the preceding calendar year. Such statement shall be available to the public.

"(b) The Administrator and said Secretary shall -

"(1) act within ninety days after the date of enactment of this Act -

"(A) to define the term 'known financial interest' for purposes of subsection (a) of this section; and

"(B) to establish the methods by which the requirement to file written statements specified in subsection (a) of this section will be monitored and enforced, including appropriate provisions for the filing by such officers and employees of such statements and the review by the Administrator and said Secretary of such statements ; and

"(2) report to the Congress on June 1 of each calendar year with respect to such disclosures and the actions taken in regard thereto during the preceding calendar year.

"(c) lii the rules prescribed in subsection (b) of this section, the Administrator and said Secretary may identify specific positions within the appropriate agency which are of a nonregulatory or nonpolicymaking nature and provide that officers or employees occupying such positions shall be exempt from the requirements of this section.

"(d) Any officer or employee who is subject to, and knowingly violates, this section or any regulation issued thereunder, shall be fined not more than \$2,500 or imprisoned not more than one year, or both."

Renumbered the succeeding sections.

Mr. Hecitler of West Virginia. Mr. Chairman, I have a "Sunshine in (Tovernnient'' amendment to H.R. 14032, as reported, at the desk wliich is printed in the August 9, 1976 Record at page H8564. The amendment adds a new section 28 and renumbers the present section

28 and succeeding sections.

Mr. Chairman, the purpose of this amendment is to bring more sunshine into Government. It is the same provision which the Congress adopted last December for the Federal Energy Administration and some of the employees of the Interior Department administering Public Law 94-163 - the Energy Policy and Conservation Act. On May 20, 1976, the House adopted this provision for ERDA employees in H.R. 13350, which authorized appropriations for fiscal year 1977 for P]RI)A. Earlier this year, the House added it to H.R. 8560 for employees of Interior administering the Outer Continental Shelf leasing program and to H.R. 9560 for EPA employees administering the water pollution program. The House also added it to H.R. 1377, the public lands bill, for employees of Interior and to H.R. 13555, the mine health and safety bill, for Interior, HEW, and Labor employees. It was also added to H.R. 88401, the nuclear assurance bill, for ERDA employees. In addition, it is included in H.R. 12112, as reported by three committees, including the Interstate and Foreign Commerce Committee, for ERDA employees and in H.R. 14496 for EPA employees.

My amendment requires officers and employees of the agencies who perform any function under the Toxic Substances Act to file annually statements of any known financial interest in the persons subject to this bill or who receive financial assistance under the bill. Such statements would be available to the public and would have to be reviewed by EPA. Positions within EPA that are of a nonregulatory or nonpolicy-

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making nature could be exempted from this requirement by the Administrator,

The amendment does not prevent any employee from having such interests. It merely requires that they disclose such interests. It does not apply to consultants.

Currently, EPA and other Federal agencies require their employees who are at the GS-13 level or above and in a decisionmaking position to file financial interest statements which are not available to the public. This requirement is not based on any statutory provision but on a 1965 Executive Order No. 11222 and Civil Service Commission regulations. But the Executive order and regulations do not have any teeth. ;My amendment does.

Moreover, in a series of reports on the effectiveness of the financial disclosure system for agency employees, the GAO has found "deficiencies" in the system at Interior and several agencies, including in the collection and timely review of such statements, and the resolution of problems associated with the statements. In a March 3, 1975, report, the GAO said:

Many USGS employees have financial interests which appear to conflict with their Government duties. Many of these holdings violate the Organic Act of 1879. We believe that the ownership of these conflicting interests is due to deficiencies in the Department's financial disclosure system and that they will have to be corrected to prevent the situation that now exists from continuing.

To improve the effectiveness of the USGS financial disclosure system, we recommend that the Secretary of the Interior :

Review, and take remedial action on, the financial interests of USGS officials which raise conflict of interest possibilities or violate the Organic Act.

Prepare, keep current, and issue to USGS personnel specific guidelines, including a list of prohibited securities, concerning financial interests which may violate the Organic Act.

Require the Bureau Counselor to strictly adhere to the restrictions imposed on USGS employees by the Organic Act.

Insure that adequately trained and experienced personnel, who are knowledgeable of employees' duties and potential conflicts of interest, are appointed to counsel employees and review financial disclosure statements.

Insure that officials responsible for reviewing financial disclosure statements are given specific guidelines and reference manuals to enable them to adequately evaluate the statements.

Require reviewing officers to sign and date the financial disclosure statements to indicate they have reviewed them and determined that the financial interests do not violate the Organic Act or raise conflict of interest possibilities.

Require the USGS Counselor to report the results of the annual financial disclosure review to the Department and to note any financial interests questioned and any remedial action taken.

Establish procedures for periodically reviewing financial disclosure statements to insure that Bureau Counselors adequately enforce conflict of interest regulations.

In a later report of December 1975, the GAO said that Interior was

taking steps to improve the situation but the GAO said there were 1.435 additional employees who should file statements, of which 1.100 were below the GS-13 level.

The GAO made similar findings in eight other studies since late 1974.

My amendment makes it clear that the Administrator of EPA must periodically look at the positions to determine who should file and not base his decision on the grade level of the employee. It also mandates annual filing by the affected employee and review by the agency and

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provides criminal penalties for knowing violation. Adequate provision is made for the Administrator to define what a "known financial interest" is. Indeed, as example of such a definition, Interior published proposed regulations defining this term on March 22, 1976, for the purposes of Public Law 94-163. That definition, which is not yet finalized, of course, is as follows :

Any pecuniary interest of which an officer or employee is cognizant or of which he can reasonably be expected to have knowledge. This includes pecuniary interest in any person engaged in the business of exploring, developing, producing, refining, transporting by pipeline or distributing (other than at the retail level) coal, natural gas, or petroleum products, or in property from which coal, natural gas, or crude oil is commercially produced. This further includes the right to occupy or use the aforesaid business or property, or to take any benefits therefrom based upon a lease or rental agreement, or upon any formal or informal contract with a person who has such an interest where the business arrangement from which the benefit is derived or expected to be derived has been entered into between the parties or their agents. With respect to officers or employees who are beneficiaries of "blind trusts," the disclosure is required only of interests that are initially committed to the blind trust, not of interests thereafter acquired of which the employee or officer has no actual knowledge.

Finally, the regulations would be expected to make it clear that public disclosure of financial statements shall be only for lawful purposes. A violation of this requirement is subject to criminal prosecution.

I urge adoption of my amendment.

Mr. Murphy of New York. Mr. Chairman, I think this is a worthy

and constructive amendment. It would certainly prevent conflicts of interest or even allegations of conflicts of interest. The committee would be happy to accept the amendment.

The Chairman. The question is on the amendment offered by the gentleman from West Virginia (Mr. Hechler).

The amendment was agreed to.

Mr. Dr:VTXE. Mr. Chairman. I rise in opposition to pending legislation. I would like to have the Members read and to pay attention to the minority views which appear on page 139 of the report. I will not enlarge on them due to the lateness of the hour.

Also I would like to point out that the administration opposes this legislation as it is now being considered. It objects to the requirements for the premarket notification on all new chemical substances, the reporting requirements on substances prior to manufacture, and the bill's unnecessarily broad definition for requiring testing of chemical substances.

I might add further that the adoption of the Moore amendment a few moments ago, which I voted for, makes the bill, in my opinion, even more objectionable to the administration and I cannot predict what the final outcome might be.

Mr, RousSELOT. Mr. Chairman, I rise in vigorous opposition to the legislation H.E. 140e32, Toxic Substances Control Act. In my estimation, this bill is nothing more than one more attempt to legislate Utopia by an unrealistic and a reckless Congress. The worthy intention of the legislation is good - to protect the health and welfare of the Nation's citizens. But when one considers that this goal is already being accomplished by at least 27 different laws now on the books, that the proposed new law could potentially run about 10,000 small companies out of business, and that the bill may be unconstitutional.

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one questions whether or not H.K. 14032 is really necessary. I think it is not.

There are at least three reasons why this bill should be soundly defeated. First, the bill has serious constitutional problems. Provisions of this legislation - section 11 - provides for unconstitutional search

or entry without a warrant. A person can be subjected to fine and imprisonment without trial by jury – section 16. This is a clear violation of the seventh amendment. Section 6 provides that the EPA Administrator may prohibit the manufacture of new chemicals by rulemaking procedures without due process, a violation of the 14th amendment. On constitutional grounds alone, then, this bill should be rejected.

Second, this bill would result in endless delay and would overload regulatory agencies. Similar regulations covering the safety and effectiveness of drugs currently are in effect in the Federal Drug Administration and have served to greatly burden the development and marketing of new drugs and medicines. With passage of this bill, the same type of testing could be required of all new chemicals. The EPA alone could be forced by environmental groups to process at least 300 and possibly over 1,000 new chemicals every year.

Third, it has been estimated that enactment of H.R. 14032 could force as many as 10,000 small chemical manufacturers out of business. It has pointed out today that the Toxic Substances Control Act is being supported by the chemical industry. While the Manufacturing Chemists Association, representing 186 of the largest chemical companies in the country, has come out in favor of this bill, the other 10,000 smaller companies involved in the chemical business, cannot possibly comply. The costs associated with compliance with many of the restrictive testing measures – testing costs per product have been estimated at between \$50,000 and \$800,000 – would simply force them out of business.

I For these reasons, Mr. Chairman. I urge my colleagues to vote down this unnecessary, costly, and unconstitutional piece of legislation.

AMENDMENT OFFERED BY MR. MURPHY OF NEW YORK

Mr. Murphy of New York. Mr. Chairman, I offer an amendment.
The Clerk read as follows:

Amendment offered by Mr. Murphy of New York : Page 208, in line 23 [Sec. 28; , Sec. 30 as passed], strike out "\$11,100,000" and insert in lieu thereof "\$12,625,000" ; in line 24 strike out "\$10,100,000" and insert in lieu thereof "\$16,200,000" ; and in line 25, strike out "\$11,100,000" and insert in lieu thereof "\$17,850,000".

Mr. Murphy of New York. Mr. Chairman, my amendment increases the authorization levels contained in the legislation. The amendment would increase the authorizations for the 1978 fiscal year from \$11.1 million to \$12,625,000. It would increase the 1979 authorization from \$10 million to \$16.2 million, and it would increase the 1980 authorization from \$11.1 million to \$17.35 million.

The authorizations presently in the bill were based upon estimates

- made when it was assumed the bill would become effective during the 1975 fiscal year. Time delays and the budget deadlines have resulted in the effective date for the legislation being moved back to October 1977. As a result, anticipated inflation and increased costs of operation

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make it necessary to increase the levels of authorizations of appropriations for the first 3 years of operation under the bill.

The increased authorizations have been cleared by the Office of Management and Budget. The ranking minority members of our committee support the increase.

There should be absolutely no inflationary impact upon the economy as a result of this minor increase.

The need for the increased authorization is clearly demonstrated if one compares the authorization levels contained in this bill with the sums appropriated for administering other, similar programs. For example, the Congress has appropriated \$39 million for administration of the Federal Insecticide, Fungicide, Rodenticide Act. Over \$147 million have been appropriated for carrying out the Clean Air Act, and \$422 million for operation of the Water Pollution Control Act. As you can see, the sums authorized here are far below those for any of these other similar programs. Even with the increased level of authorization, we will be authorizing the bare minimum necessary for effective implementation of this highly important legislation. I urge my colleagues to support the amendment.

The Chairmax. The question is on the amendment offered by the gentleman from New York (Mr. Murphy).

The amendment was agreed to.

AMENDMENT OFFERED BY MR. MURPHY OF NEW YORK

Mr. Murphy of Xew York. Mr. Chairman, I offer an amendment.
The Clerk read as follows :

Amendment offered by Mr. Mukphy of Xew York: Page 169 [Sec. 10], insert "DEVELOPMENT," after "research," in line 14.

Viiiie 1(C)1). insert "development." after "research*" in lines 19 and 22.
Page 170, insert after line 26 tlie following :

(c) Screeixg Techniques. – The Administrator shall coordinate with the Assistant Secretary for Health research undertaken by the Administrator and directed toward the development of rapid, reliable, and economical screening techniques for carcinogenic, mutagenic, teratogenic, and ecological effects of chemical substances and mixtures.

(d) Monitoring.– The Administrator shall establish and be responsible for research aimed at the development, in cooperation with local. State, and Federal agencies, of monitoring techniques and instruments which may be used in the detection of toxic chemical substances and mixtures and which are reliable, economical, and capable of being implemented under a wide variety of conditions.

(e) Basic Research. – The Administrator shall establish research programs to develop the fundamental scientific basis of the screening and monitoring techniques described in subsections (c) and (d). the bounds of their reliability of such techniques, and the opportunities for their improvement.

(f) Manpower Training. – The Administrator shall establish and promote programs and workshops to train or facilitate the training of Federal laboratory and technical personnel in existing or newly developed screening and monitoring techniques.

(g) Exchange of Research and Development Results. – The Administrator shall, in consultation with the Secretary of Health, Education, and Welfare and other heads of appropriate agencies, establish and coordinate a system for exchange among Federal. State, and local authorities of research and development results respecting toxic chemical substances and mixtures, including a system to facilitate and promote the development of standard data format and analysis and consistent testing procedures.

I'age 20S [Sec. 28], insert after "other than section 27" in line 23 the following:
•'and sub.sections (a) and (c) through (g) of section 10."

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Mr. Murphy of Xew York. Mr. Chairman, this amendment is an amendment that would have been offered by the gentleman from California (Mr. Browx), who is the chairman of the Subcommittee on Environment and the Atmosphere of the Committee on Science and Technologj\

Mr. Chairman, this amendment provides additional guidance to the Administrator regarding research and development work conducted under the bill. It directs the Administrator to develop improved monitoring techniques and instruments for the detection of toxic chemical substances and mixtures. It also directs the Administrator to establish and promote programs to train Federal laboratory and technical personnel in existing or newly developed chemical screening and monitoring techniques. Because the authorization levels in this bill are extremely low, the moneys to carry on this expanded research and training program will come from authorization of appropriations provided in the legislation originating in the Committee on Service and Technology.

Mr. Chairman, this amendment provides constructive guidance and direction to the Environmental Protection Administration in carrying out research and related programs respecting toxic chemicals.

The subcommittee, chaired by the gentleman from California (Mr. Brown), has invested considerable time and effort in reviewing current EPA research and development activities. This amendment would help overcome some of the shortcomings which exist in the present programs, and it should improve the research activities conducted under the auspices of the toxic substances legislation.

Mr. Chairman, I would urge acceptance of the amendment.

Mr. McCOLLISTER. Mr. Chairman, we have no objection to the amendment.

Mr. Hfxhler of West Virginia. Mr. Chairman, as a member of the Committee on Science and Technology. I strongly support this amendment.

The Chairman. The question is on the amendment offered by the gentleman from New York (Mr. Murphy).
The amendment was agreed to.

Mr. Butler. Mr. Chairman, my purpose in arising is to inquire of the gentleman from Nebraska (Mr. McCollister) if the gentleman can explain the effect of the preemption provision [Sec. 18] on the ability of a State to meet local problems of great magnitude; as for example the Kepone problem, which is not a toxic substance, but one which illustrates a local problem that might arise. Will a State be foreclosed by this legislation from taking effective legislation on their own?

Mr. McCollister. Mr. Chairman, the State law is preempted only

when the EPA has issued a rule under section 4, section 5 or section 6.

If the EPA has not acted, the States are free to act. If the EPA has acted, then the States must apply for an exemption from the preemption.

Before the State can put a different requirement into effect, it has to ask for an exemption from the preemption.

This provision was designed to discourage differing State requirements which would put an undue burden on those companies that do business in a number of States.

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Mr. Butler. Mr. Chairman. I thank the gentleman. I judge that in the absence of action by the EPA under section 4, 5, or 6. that the States are free to take whatever action they deem appropriate under the circumstances.

Mr. Broyhill. Mr. Chairman, there is nothing in this act that affects the right of States to act in their authority over disposal of hazardous properties or hazardous chemicals, for that matter.

Mr. Butler. Mr. Chairman, I recognize that and I appreciate the gentleman's contribution.

The Chairman. If there are no further amendments, the question is on the committee amendment in the nature of a substitute, as amended.

The committee amendment in the nature of a substitute, as amended, was agreed to.

The Chairman, under the rule, the Committee rises.

Accordingly the Committee rises; and the Speaker having resumed the chair, Mr. Mann, Chairman of the Committee of the Whole House on the State of the Union, reported that that Committee having had under consideration the bill (H.R. 14082) to regulate commerce and protect health and the environment by requiring testing and necessary restrictions on certain chemical substances and mixtures, and for other purposes, pursuant to House Resolution 1458. he reported the bill back to the House with an amendment adopted by the Committee of the

Whole.

The Speaker. Under the rule, the previous question is ordered.

Is a separate vote demanded on any amendment to the committee amendment in the nature of a substitute adopted by the Committee of the Whole? If not, the question is on the amendment.

The amendment was agreed to.

The Speaker. The question is on the engrossment and third reading of the bill.

The bill was ordered to be engrossed and read a third time, and was read the third time.

MOTION TO RECOMMIT OFFERED BY MR. COLLINS OF TEXAS

Mr. Collins of Texas. Mr. Speaker, I offer a motion to recommit.

The Speaker. Is the gentleman opposed to the bill?

Mr. Collins of Texas. I am, Mr. Speaker.

The Speaker. The Clerk will report the motion to recommit.

The Clerk read as follows:

Mr. Collins of Texas moves to recommit the bill H.R. 14032 to the Committee on Interstate and Foreign Commerce.

The Speaker. Without objection, the previous question is ordered on the motion to recommit.
There was no objection.

The Speaker. The question is on the motion to recommit.

The motion to recommit was rejected.

The Speaker. The question is on the passage of the bill.

The question was taken; and the Speaker announced that the ayes appeared to have it.

Mr. Collins of Texas. Mr. Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that a quorum is not present.

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The Speaker. Evidently a quorum is not present.
The Serfreant at Arms will notify absent Members.
The vot^ was taken by electronic device, and there were - yeas 319,
nays 45, not voting- 67, as follows :

[Roll No. 644]

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Collins, Tex.

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Steiger, Wis.

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Taylor, N.C.

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Weaver

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Wilson, Bob

Wilson, C. H.

Wilson, Tex.

Winn

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Wolff

Wright

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Yates

Yatron

Young, Fla.

Young, Tex,

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de la Garza

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Young, Alaska

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So the bill was passed.

The result of the vote was announced as above i-ecorded.
A motion to reconsider was laid on the table.

: \rOTIOX OFFERED BY INFR. STAGGERS

Mr. Staggers. Mr. Speaker, pursuant to the provisions of House Resolution 1458. I move that Connnittee on Interstate and Foreio^n Commerce be dischartred from the further consideration of the Senate bill (S. 8140) to regulate commerce and protect human health and the environment by requirin^r testing- and necessary use restrictions on certain chemical substances, and for other purposes.

The Clerk read the title of the Senate bill.

The Speaker pro tempore. The question is on the motion offered by the frentleman from "West Viro^inia (Mr. Sta^r^iei's) .
The motion was agreed to.

MOTTOX offered BY ^klR. STAGGERS

Mr. Staggers. Mr. Speaker, I offer a motion.
The Clerk read as follows :

Mr. Staggers moves to strike out all after the enacting clause of the Senate bill S. 3149 and to insert in lieu thereof the provisions of H.R. 14032, as passed, as follows :

SHORT TITLE

Section 1. This Act may be cited as the "Toxic Substances Control Act".

TABLE OF contexts

Sec. 1. Short title.

Sec. 2. Findings, policy, and intent.

Sec. .S. Definitions.

Sec. 4. Testinjr of chemical substances and mixtures.

Sec. o. Manufacturinjr and))rocessing notices.

Sec. G. Regulation of hazardous chemical substances and mixtures.

Sec. 7. Imminent hazards.

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Sec. 8. Reporting and retention of information.

Sec. 9. Relationship to other Federal laws.

Sec. 10. Research, collection, dissemination, and utilization of data.

Sec. 11. Inspections.

Sec. 12. Exports.

Sec. 13. Entry into customs territory of the United States.

Sec. 14. Disclosure of data.

Sec. 15. Prohibited acts.

Sec. 16. Penalties.

Sec. 17. Specific enforcement and seizure.

Sec. 18. Preemption.

Sec. 19. Judicial review.

Sec. 20. Citizens' civil actions.

Sec. 21. Citizens' petitions.

Sec. 22. National defense waiver.

Sec. 23. Employee protection.

Sec. 24. Employment effects.

Sec. 2.1. Studies.

Sec. 26. Administration of Act.

Sec. 27. Development and evaluation of test methods.

Sec. 28. State programs.

Sec. 29. Sunshine in government.

Sec. 30. Authorization for appropriations.

Sec. 31. Annual report.

Sec. 32. Rule review.

Sec. 33. Effective date.

FINDINGS, POLICY, AND INTENT

Sec. 2. (a) Findings. – The Congress finds that –

(1) humans and the environment are being exposed to a large number of chemical substances and mixtures each year ;

(2) among the many chemical substances and mixtures constantly being developed and produced are some whose manufacture, processing, distribution in commerce, use, or disposal may cause or significantly contribute to an unreasonable risk to health or the environment ; and

(3) the effective regulation of interstate commerce in such chemical substances and mixtures also necessitates the regulation of intrastate commerce in such chemical substances and mixtures.

(b) Policy. – It is the policy of the United States that –

(1) hazardous and potentially hazardous chemical substances and mixtures should be adequately tested with respect to their effect on health and the environment and that such testing should be the responsibility of those who manufacture and those who process such chemical substances and mixtures ;

(2) adequate authority should exist to regulate chemical substances and mixtures which cause or significantly contribute to an unreasonable risk to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and

(3) authority over chemical substances and mixtures should be exercised in such a manner as not unduly to impede, or to create unnecessary economic barriers to, technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not cause or significantly contribute to an unreasonable risk to health or the environment.

(c) Intent of Congress. – It is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Ad-

ministrator shall consider the environmental, economic, and social impact of any action the Administrator proposes to take under this Act.

definitions

Sec. 3. As used in this Act :

(1) The term "Administrator" means the Administrator of the Environmental Protection Agency.

(2) (A) Except as provided in subparagraph (B), the term "chemical substance" means -

(i) any organic or inorganic substance of a particular molecular identity including a combination of such substances occurring (I) in whole or in part as a result of a chemical reaction, or (II) in nature, or

(ii) any element or imcombined radical.

(B) Such term does not include -

(i) any mixture.

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(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide,

(iii) tobacco or any tobacco product,

(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act),

(v) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code), and

(vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

The term "food" as used in clause (vi) of this subparagraph includes poultry and poultry products (as defined in sections 4(e) and 4(f) of the Poultry Products Inspection Act), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act).

(3) The term "commerce" means trade, traffic, or transportation (A) between a place in a State and any place outside of such State, or (B) which affects trade, traffic, or transportation described in clause (A).

(4) The term "distribute in commerce" or "distribution in commerce" when used to describe an action taken with respect to a chemical substance or mixture or article containing a substance or mixture means to sell, or the sale of, the substance, mixture, or article in commerce ; to introduce or deliver for introduction into commerce, or the introducing or delivery for introduction into commerce of, the substance, mixture, or article ; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.

(5) The term "environment" includes water, air, and land and the inter-relationship which exist among and between water, air, and land and all living things.

(6) The term "health and safety study" means any study of any effect of a chemical substance or mixture on health or the environment, including epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act.

(7) The term "manufacture" means to import, produce, or manufacture.

(8) The term "mixture" means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include a combination which occurs, in whole or in part, as a result of a chemical reaction if each of the chemical substances comprising the combination is not a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.

(9) The term "new chemical substance" means any chemical substance not included in the chemical substance list compiled and published under section 8(b).

(10) The term "process" means the preparation of a chemical substance or mixture for distribution in commerce -

(A) in the same form or physical state, or in a different form or physical state from that, in which it was received by the person making such prep-

aration, or

(B) as part of an article containing the chemical substance or mixture.

(11) The term "processor" means any person who processes a chemical substance or mixture.

(12) The term "standards for the development of test data" means a prescription of -

(A) the-

(i) health and environmental effects, and

(ii) information relating to toxicity, persistence, and other characteristics which affect health and the environment,

for which test data for a chemical substance or mixture are to be developed any any analysis that is to be performed on such data, and

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(B) to the extent necessary to assure that such data are reliable and adequate, the manner in which such data are to be developed, the specification of any test protocol or methodology to be employed in the development of such data, and such other requirements as are necessary to provide such assurance.

(13) The term "State" means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, or the Trust Territory of the Pacific Islands.

(14) The term "United States", when used in the geographic sense, means all the States.

TESTING OF CHEMICAL SUBSTANCES AND MIXTURES

Sec 4. (a) Testing Requirements. - If the Administrator finds that -

(1) (A) (i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture or any combination of ,such actions may cause or significantly contribute to an unreasonable risk to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal or combination of such actions on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data ; or

(B) (i) a chemical substance or mixture is or will be produced in substantial quantities, and it enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to such substance or mixture.

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or any combination of such actions on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data ; and

(2) in the case of a mixture, the effects which the mixture's manufacture distribution in commerce, processing, use, or disposal or any combination of such actions may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture ;

the Administrator shall by rule require that testing be conducted on such substance or mixture to develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or any combination of such actions does or does not cause or significantly contribute to an unreasonable risk to health or the environment.

(b)(1) Testing Requirement Rule. - A rule under subsection (a) requiring the testing of a chemical substance or mixture shall include -

(A) identification of the substance or mixture for which testing is required.

(B) standards for the development of test data for such substance or mixture, and

(C) a specification of the period (which period may not be unreasonable) within which the persons required to conduct the testing shall submit to the Administrator data developed in accordance with the standards referred to in subparagraph (B).

In determining the standards and period to be included, pursuant to subparagraphs (B) and (C). in a rule under subsection (a), the costs of the various test protocols and methodologies which may be required under the rule and the reasonably foreseeable availability of facilities and personnel for performing testing under the rule. Such a rule may require the submission of preliminary data during the period prescribed under subparagraph (C).

(2) (A) The health and environmental effects for which standards for the development of test data may be prescribed include carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may cause or significantly contribute to an unreasonable risk to health or the environment, and the characteristics of chemical substances and

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mixtures for which such standards may be prescribed include persistence, acute toxicity, subacute toxicity, chronic toxicity, and any other characteristic which may cause or significantly contribute to such a risk. The methodologies that may be prescribed in such standards include epidemiology, serial, or hierarchical tests : in vitro tests : and whole animal tests. Before prescribing epidemiology tests in such standards, the Administrator shall consult with the Director of the National Institute for Occupational Safety and Health.

(B) From time to time, but not less than once each twelve months, the Administrator shall review the adequacy of the standards for development of data prescribed in rules under subsection (a) and shall, if necessary, institute proceedings to make appropriate revisions of such standards.

(3) (A) A rule under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph (B) to conduct tests and submit data on such substance or mixture, except that the Administrator may permit two or more of such persons to designate one such person or a qualified third party to conduct such tests and submit such data on behalf of the persons making the designation.

(B) The following persons shall be required to conduct tests and submit data on a chemical substance or mixture subject to a rule under subsection (a) :

(i) Each person who manufactures or intends to manufacture such substance or mixture if the Administrator makes a finding described in subsection (a) (1) (A) (ii) or (a) (1) (B) (ii) with respect to the manufacture of such substance or mixture.

(ii) Each person who processes or intends to process such substance or mix-

ture if the Administrator makes a finding described in subsection (a) (1) (A) (ii) or (a) (1) (B) (ii) with respect to the processing of such substance or mixture.

(iii) Each person who manufactures or processes or intends to manufacture or process such substance or mixture for distribution in commerce if with respect to the distribution in commerce of such substance or mixture the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a) (1) (B) (ii).

(iv) Each person who manufactures or processes or intends to manufacture or process such substance or mixture if with respect to the disposal of such substance or mixture the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a) (1) (B) (ii).

(v) Each person who manufactures or processes or intends to manufacture or process such chemical substance or mixture for a use with respect to which the Administrator makes a finding described in subsection (a) (1) (A) (ii) or (a) (1) (B) (ii).

(4) A rule under subsection (a) requiring the testing of a chemical substance or mixture shall expire at the end of the reimbursement period (as defined in subsection (c)(3)(B)) applicable to test data for such substance or mixture, unless the Administrator repeals the rule before such date.

(5) Rules issued under subsection (a) (and any amendment thereto or repeal thereof) shall be promulgated pursuant to section 553 of title 5, United States Code, except that in promulgating, amending, or repealing any such rule (A) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments. In addition to an opportunity to make written submissions: and (B) a transcript shall be made of any oral presentation. The Administrator may not promulgate a rule under subsection (a) respecting a substance or mixture unless the Administrator makes and publishes with the rule the findings described in paragraph (1) (A) or (1)(B) of such subsection and, in the case of a rule respecting a mixture, the finding described in paragraph (2) of such subsection.

(c) Exemption. - (1) Any person required by a rule under subsection (a) to conduct tests and submit data on a chemical substance or mixture may apply to the Administrator (in such form and manner as the Administrator shall prescribe) for an exemption from such requirement.

(2) If, upon receipt of an application under paragraph (1), the Administrator determines that -

(A) the chemical substance or mixture (including any contaminant present in such substance or mixture) with respect to which such application was

submitted is equivalent to a chemical substance or mixture for which data has been submitted to the Administrator in accordance with a rule under subsection (a) or for which data is being developed pursuant to such a rule, and

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(B) submission of data by the applicant on such substance or mixture would be duplicative of data which has been submitted to the Administrator in accordance with such rule or which is being developed pursuant to such rule,

the Administrator shall exempt, in accordance with paragraph (3) or (4), the applicant from conducting tests and submitting data on such substance or mixture.

(3) (A) If the exemption of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the existence of previously submitted test data and if such exemption is granted during the reimbursement period for such test data (as prescribed by subparagraph (B)), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator) -

(i) to the person who previously submitted such test data, for a portion of the costs incurred by such person in complying with the requirement to submit such data, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the

persons to be reimbursed. An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) For purposes of subparagraph (A), the reimbursement period for any test data for a chemical substance or mixture is a period -

(i) beginning on the date such data was submitted in accordance with a rule promulgated under subsection (a), and

(ii) ending -

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later.

(4) (A) If the exemption of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the fact that test data is being developed by one or more persons pursuant to a rule promulgated under subsection (a), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules by the Administrator) -

(i) to each such person who is developing such test data, for a portion of the costs incurred by each such person in complying with such rules, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to the costs of complying with such rule, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall consider the factors described in the second sentence of paragraph (3) (A). An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) If an exemption is granted on the basis of the fact that one or more persons are developing test data pursuant to a rule promulgated under subsection (a) and if after such exemption is granted the Administrator determines that no such person has complied with such rule, the Administrator shall (i) after providing written notice to the person who holds such exemption and an opportunity for a hearing, by order terminate such exemption, and (ii) notify

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in writing such person of the requirements of the rule with respect to which such exemption was granted. «iilu

fd) Notice— Upon the receipt of any test data pursuant to a rule under subsection (a), the Administrator shall, subject to section 14, promptly publish

shall (1) Identify the chemical substance or mixture for which data have been received; (2) list the uses or intended uses of such substance or mixture and the information required by the applicable standards for the development of test data; and (3) describe the nature of the test data developed. Except as otherwise provided in section 14. such data shall be made available by the Administrator for examination by any person.

(e) Priority List.— (1) (A) There is established a committee to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of a rule under subsection (a). In making such a recommendation with respect to any chemical substance or mixture, the committee shall consider all relevant factors, including —

(i) the quantities in which the substance or mixture is or will be manufactured.

(ii) the quantities in which the substance or mixture enters the environment.

(iii) the number of persons who will be exposed to the substance or mixture in their places of employment and the duration of such exposure.

(iv) the extent of human exposure to the substance or mixture.

(v) the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to cause or significantly contribute to an unreasonable risk to health or the environment.

(vi) the existence of data concerning the effects of the substance or mixture on health or the environment.

(vii) the extent to which testing of the substance or mixture may result in the development of data upon which the effects of the substance or mixture on health or the environment can reasonably be determined or predicted, and

(viii) the reasonably foreseeable availability of facilities and personnel for performing testing on the substance or mixture.

The recommendations of the committee shall be in the form of a list of chemical substances and mixtures which shall be listed, either by individual substance or mixture or by groups of substances or mixtures, in the order in which the committee determines the Administrator should take action under subsection (a) with respect to the substances and mixtures.

(B) Not later than twelve months after the effective date of this Act, the committee shall transmit to the Administrator the list required by subparagraph (A) together with the reasons for the committee's inclusion of each chemical substance or mixture on the lists. At least every six months after the transmission to the Administrator of the list pursuant to the preceding sentence, the committee shall make such revisions in the list as it determines to be necessary and shall transmit them to the Administrator together with the committee's reasons for the revisions. The Administrator shall make available to the public the list transmitted by the committee, any revision by the committee in such list (including the date on which such revision was transmitted to the Administrator), and the reasons of the committee for inclusion of a chemical substance or mixture on the list and for any revision in the list. The Administrator shall provide reasonable opportunity to any interested person to file with the Administrator written comments on the committee's list or any revision of the committee of such list and shall make such comments available to the public.

(C) The Administrator may promulgate a rule under subsection (a) with respect to a chemical substance or mixture which is not contained on a list published under this subsection.

(2) (A) The committee established by paragraph (1) (A) shall consist of eight members as follows :

(i) One member (or designee of the member) appointed from the Environmental Protection Agency by the Administrator.

(ii) One member (or designee of the member) appointed by the Secretary of Labor from officers of the Department of Labor engaged in the Secretary's activities under the Occupational Safety and Health Act of 1970.

(iii) One member (or designee of the member) appointed from the Council on Environmental Quality by the Chairman of the Council.

(iv) One member (or designee of the member) appointed from the National Institute for Occupational Safety and Health by the Director of the Institute,

(v) One member (or the designee of the member) appointed from the National Institute of Environmental Health Sciences by the Director of the Institute.

(vi) One member (or designee of the member) appointed from the National Cancer Institute by the Director of the Institute.

(vii) One member (or designee of the member) appointed from the National Science Foundation by the Director of the Foundation.

(viii) One member (or designee of the member) appointed from the Department of Commerce by the Secretary of Commerce. A member may designate an individual to serve on the member's behalf only with the approval of the applicable appointing authority and only if the individual is from the entity from which the member was appointed. A vacancy in the committee shall be filled in the same manner in which the original appointment was made.

(B) (i) The term of office of a member of the committee is four years, except that of the members first appointed, four members shall have initial terms of two years. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of such term. If any member of the committee leaves the office or entity from which the member was appointed, such member may not continue as a member of the committee, and, for purposes of the preceding sentence, the member's position shall be considered as being vacant. A member may serve after the expiration of the member's term of office until a successor has taken office.

(ii) Initial appointments to the committee shall be made not later than the sixtieth day after the effective date of this Act. Not later than the ninetieth day after such date the members of the committee shall hold a meeting for the selection of a chairman from among their number and to determine, by lot, the four members who shall have initial terms of two years.

(C) The Administrator shall provide the committee such administrative support services as may be necessary for the committee to carry out its function under this subsection.

MANUFACTURING AND PROCESSING NOTICES

Sec. f). (a) Notification for Manufacture of New Chemical Substances. - On and after the date on which the Administrator first publishes under section

S(b) a list of chemical substances manufactured or processed in the United States, no person may manufacture a new chemical substance unless (except as provided in subsection (i) (relating to exemptions)) such person -

(1) has, at least ninety days before such manufacture, submitted to the Administrator, in accordance with subsection (f) (relating to notice content), a notice of such person's intention to manufacture such substance, and

(2) has complied with any applicable requirement of subsection (d) (relating to submission of test data).

(b) Notification for the Manufacture or Processing of a Chemical Substance for a Significant New Use. - (1) No person may manufacture or process a chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use of such substance unless (except as provided in subsection (i)) such person -

(A) has, at least ninety days before such manufacture or processing, submitted to the Administrator, in accordance with subsection (f), a notice of such person's intention to manufacture or process such substance for such use, and

(B) has complied with any applicable requirement of subsection (d).

(2) A determination by the Administrator that a new use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) or subsection (c)(1)(B) shall be made by a rule promulgated after a consideration of all relevant factors, including -

(A) the projected volume of manufacturing and processing of such substance for such use.

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(B) the extent to which such use changes the type or form of exposure of humans or the environment to such substance, and

(C) the extent to which such use increases the magnitude and duration of exposure of humans or the environment to such substance.

The last sentence of section 19(c) (1) shall not apply to judicial review of any rule promulgated under this paragraph.

(c) Notification for the Manufacture or Processing of Listed Chemical

Substances. - (1) (A) No person may manufacture a chemical substance -

(i) which is listed under paragraph (2) , and

(ii) which was a new chemical substance at the time of publication of the earliest proposed rule under paragraph (2) listing such substance,

unless (except as provided in subsection (i)) such person has, at least ninety days before such manufacture, submitted to the Administrator, in accordance with subsection (f), a notice of such person's intention to manufacture such substance and has complied with the requirement of subsection (d).

(B) No person may manufacture or process a chemical substance, listed under paragraph (2). for a use which the Administrator has determined, in accordance with subsection (b) (2), is a significant new use of such substance unless (except as provided in subsection (i)) such person -

(i) has, at least ninety days before such manufacture or processing, submitted to the Administrator, in accordance with subsection (f), a notice of such person's intention to manufacture or process such substance for such use, and

(ii) has complied with the requirement of subsection (d).

(2)(A)(i) Within twelve months after the effective date of this Act, the Administrator shall, by rule, compile, and from time to time thereafter revise, a list of chemical substances the manufacture, processing, distribution in commerce, use, or disposal of which, or any combination of such actions reflecting which, the Administrator finds causes or significantly contributes to or may cause or significantly contribute to an unreasonable risk to health or the environment.

(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such actions causes or significantly contributes to or may cause or significantly contribute to an unreasonable risk to health or the environment, the Administrator shall consider all relevant factors, including -

(I) the effects of the chemical substance on health and the magnitude of human exposure to it ; and

(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to it.

(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, in accordance with subsection (b) (2), would constitute a significant new use of such substance. The last sentence of section 19(c)(1)

shall not apply to judicial review of any provision of a rule under subparagraph (A) which provision is prescribed pursuant to this subparagraph.

(C) Any rule under subparagraph (A), and any amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of title 5, United States Code, except that (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, and (ii) a transcript shall be kept of any oral presentation. The Administrator may not promulgate under subparagraph (A) a rule listing a chemical substance unless the Administrator makes and publishes with the rule the finding described in such subparagraph.

(d) Requirement Respecting Submission of Test Data. - (1) (A) If -

(i) a person is required by subsection (a), (b), or (c) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and

(ii) such person is required to submit test data for such substance pursuant to a rule promulgated under section 4 before the submission of such notice or such person has been granted an exemption under section 4(c) from the requirement of such rule.

such person may not, before the expiration of the period prescribed by subparagraph (B), manufacture such substance if the person is subject to subsection

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(a) or (c) (1)(A) or manufacture of process such substance for a significant new use if the person is subject to subsection (b) or (c) (1) (B) .

(B) The period referred to in subparagraph (A) is -

(i) in the case of a person required to submit test data pursuant to a rule promulgated under section 4(a) a period of ninety days which begins on the date on which such person submits to the Administrator such data in accordance with such rule, and

(ii) in the case of a person who under section 4(c) is exempt from a requirement to submit test data pursuant to a rule promulgated under section 4(a), a period of ninety days which begins on the date of the submission in accordance with such rule of the test data the submission or the development of which was the basis for the exemption.

(2) (A) If-

(i) a person is required by subsection (c) to submit a notice to the Administrator before, beginning the manufacture or processing of a chemical substance, and

(ii) (I) a rule promulgated under section 4 before the submission of such notice requiring the submission of test data for such substance does not require such person to submit such data, or

(II) the Administrator has not promulgated such a rule for such substance before the submission of such notice, such person may not, before the expiration of the ninety-day period which begins on the date such person submits to the Administrator data prescribed by subparagraph (B), manufacture such substance if such person is subject to subsection (c) (1) (A) or manufacture or process such substance for a significant new use if such person is subject to subsection (c) (1) (B) .

(B) Data submitted pursuant to subparagraph (A) shall be data which the person submitting the data believes show that -

(i) in the case of a substance for which notice is required under subsection (c) (1) (A), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such actions would not cause or significantly contribute to an unreasonable risk to health or the environment, or

(ii) in the case of a chemical substance for which notice is required under subsection (c)(1)(B). the intended significant new use of the chemical substance would not cause or significantly contribute to an unreasonable risk to health or the environment.

(3) Data submitted under paragraph (1) or (2) shall be made available, subject to section 14. for examination by interested persons.

(e) Extension of Notice Period. - The Administrator may for good cause extend for one additional period of not to exceed ninety days the period, prescribed by subsection (a), (b), (c), or (d), before which the manufacturing or processing of a chemical substance subject to such subsection may begin. Subject to section 14. such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

(f) Content of Notice; Publication in the Federal Register. - (1) The notice required by subsections (a), (b), and (c) respecting a chemical substance shall include -

(A) the name of the chemical substance ;

(B) the chemical identity and molecular structure of the substance, insofar as such are reasonably ascertainable ;

(C) the proposed categories of use of such substance, insofar as such are reasonably ascertainable ;

(D) a reasonable estimate of the amount of the substance to be manufactured or processed and, insofar as reasonably ascertainable, a reasonable estimate of the amount of the substance to be manufactured or processed for each proposed category of use of the substance ;

(E) a description of the byproducts, if any, resulting from the manufacture, processing, use, or disposal of the substance, insofar as such are reasonably ascertainable ; and

(F) any test data in the possession or control of the person giving such notice which are related to the effect on the health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the substance or any article containing such substance.

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Such a notice shall be made available, subject to section 14, for examination by interested persons,

(2) Subject to section 14, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a), (b), or (c) or data under subsection (d) the Administrator shall publish in the Federal Register a notice which—

(A) identifies the chemical substance for which notice or data has been received ;

(B) lists the uses or intended uses of such substance ; and

(C) in the case of the receipt of data under subsection (d), describes the nature of the tests performed on such substance and any data which was developed pursuant to subsection (d) or a rule under section 4.

Notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

(g) Regulation Pending Development of Information. - (1) (A) The district courts of the United States shall, upon application of the Administrator made through attorneys of the Environmental Protection Agency, have jurisdiction to enjoin in accordance with subparagraph (B) the manufacture, processing, or distribution in commerce of a chemical substance subject to a notification requirement of subsection (a), (b), or (c) if the court finds that -

(i) information available to the Administrator is insufficient to permit a reasoned evaluation of the effects on health or the environment of the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance or any combination of such actions, and

(ii) in the absence of such information, the manufacture, processing, distribution in commerce, use, or disposal of such substance or any combination of such actions may cause or significantly contribute to an unreasonable risk to health or the environment.

(B) An injunction issued under subparagraph (A) with respect to a chemical substance subject to a notification requirement under subsection (b) or (c) (1) (B) respecting a significant new use of such substance shall apply only to the manufacture, processing, or distribution in commerce, as the case may be, of the substance for such use.

(C) An injunction issued under subparagraph (A) with respect to a chemical substance shall expire -

(i) upon the expiration of the five-day period beginning on the day after the issuance of the injunction, if the Administrator does not within such period publish the notice required by paragraph (2), or

(ii) if the Administrator publishes such notice within such period, upon the completion or termination of the processing begun by publication of such notice.

(2) (A) Within five days after the issuance of an injunction under paragraph (1) with respect to a chemical substance, the Administrator shall publish, in accordance with section 553(b) of title 5, United States Code, a general notice of proposed rulemaking to begin proceedings for the promulgation of a rule to apply to such substance one or more of the requirements described in section 6(a) as is necessary to adequately protect against the risk to health or the environment found by the court under paragraph (1) (A) (ii). ¹ i. - « „ ci ^

(B) Upon publication of such a notice the Administrator shall, as expeditious as possible, provide reasonable opportunity for a hearing (in accordance with paragraphs (2) and (3) of section 6(c)) on such proposed rule, and either adopt such rule (as proposed or with modifications) or by ¹ f. P ^ ^ V ^ t h o r n ^ P T f Federal Register terminate the proceeding for the promulgation of the rule if such a hearing is requested, the Administrator shall ¹ ^ ^ ^ ^ f J ^ ^ \ ^ ^ ' ^ ^ ^ ^ ^ ^ ^ ^ ^ ^

in fifteen days from the date such request is made unless each person making the request agree upon a later date the hearing is concluded the Administrator shall, within thirty days of the conclusion of the hearing, either adopt such rule as proposed or modifications) or terminate the proceeding (as prescribed in the preceding sentence).

. 3. If a rule promulgated under paragraph (2) has been the subject of a petition the Administrator to initiate a proceeding to amend or repeal such rule. Within thirty days of the receipt of such a petition, the Administrator shall either grant or deny the petition. If the Administrator fails to grant or deny the petition, the Administrator shall promptly initiate a proceeding for the amend-

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ment or repeal, as the case may be, of such rule. Such a proceeding shall be conducted in accordance with paragraphs (2) and (3) section 6(c).

(h) Petition for Standards for the Development of Test Data. – A person intending to manufacture or process a chemical substance for which notice is required under subsection (a), (b), or (c) and who is not required under a rule under section 4 to conduct tests and submit data on such substance may petition the Administrator to prescribe standards for the development of test data for such substance. The Administrator shall either grant or deny any such petition within sixty days of its receipt. If the petition is granted, the Administrator shall prescribe such standards for such substance within seventy-five days of the date the petition is granted. If the petition is denied, the Administrator shall publish in the Federal Register the reasons for such denial.

(i) Exemption. – (1) The Administrator may, upon application (made in such form and manner as the Administrator may prescribe) exempt any person from the requirement of subsection (a), (b), (c), or (d) or of any combination of such subsections to enable such person to manufacture or process a chemical substance for test marketing purposes –

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use and disposal of such substance for such purposes would not cause or significantly contribute to any unreasonable risk to health or the environment, and

(B) under such restrictions as the Administrator considers appropriate. Within forty-five days of the receipt of an application under this paragraph

the Administrator shall either approve or deny such application.

(2) (A) The Administrator may upon application (made in such form and manner as the Administrator may prescribe) exempt any person from the requirement of subsection (d)(2) to submit data for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that -

(i) the chemical substance (including any contaminant present in such substance) with respect to which such application was submitted is equivalent to a chemical substance for which data has been submitted to the Administrator in accordance with subsection (d) (2), and

(ii) submission of data by the applicant on such substance would be duplicative of data which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from submitting such data on such substance. No exemption granted under this subparagraph with respect to the submission of data for a chemical substance may take effect before the beginning of the reimbursement period applicable to such data.

(B) If the Administrator, under subparagraph (A), exempts any person from submitting under subsection (d)(2) data for a chemical substance because of the existence of previously submitted data and if such exemption is granted during the reimbursement period for such data, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator) -

(i) to the person who previously submitted the data on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (d) (2) to submit such data,

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute. . . . ^ 4.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement, in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph shall be considered final agency action, for purposes of

■ (C) For purposes of this paragraph, the reimbursement period for any previously submitted data for a chemical substance is a period—

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(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such data to the Administrator, and

(ii) ending —

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later.

(3) The requirements of subsections (a), (b), (c), and (d) do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for —

(A) scientific experimentation or analysis or

(B) chemical research or analysis on such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer or processor has reason to believe may be associated with such chemical substance.

(4) (A) The requirements of subsections (a) and (c) (1) (A) do not apply with respect to the manufacturing or processing of any chemical substance which is the same as a listed chemical substance.

(B) For purposes of subparagraph (A), a chemical substance shall not be considered as different from a listed chemical substance solely because —

(i) the proportion of the inert chemical substances which are present in the listed chemical substance is different from the proportion of such substances present in the chemical substance being compared to the listed chemi-

cal substance ; or

(ii) an inert listed chemical substance has been added to or deleted from the chemical substance being compared.

(C) For purposes of this paragraph -

(i) the term "inert chemical substance" means a chemical substance which when combined with other chemical substances to produce another chemical substance does not react chemically with such other chemical substances : and

(ii) the term "listed chemical substance" means a chemical substance included in the list compiled and published under section 8(b).

(5) The Administrator may, upon application, by rule exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that such chemical substance will not cause or significantly contribute to an unreasonable risk to health or the environment. A rule under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with paragraphs (2) and (8) of section 6(c). ^ „ , „

(j) Definition.- For purposes of this section, the terms "manufacturer and "process" mean to manufacture or to process for commercial purposes.

REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND MIXTURES

Sec. 6. (a) Scope of Regulation.- If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture or any combination of such actions causes or significantly contributes to or will cause or significantly contribute to an unreasonable risk to health or the environment, the Administrator shall by rule apply to such substance or mixture one or more of the following requirements as is necessary to adequately protect against such

' (DA requirement prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture or limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

(2) \ requirement -

)a) prohibitinir the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or ^n) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or

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(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use or disposal or with respect to both. The form and content of such warnings and instructions shall be prescribed by the Administrator.

(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture.

(5) (A) A requirement regulating the manner or method of disposal of such substance or mixture or article containing such substance or mixture by its manufacturer or processor or any other person who uses it for commercial purposes.

(B) A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of or in effect for a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such requirement.

(G) If the rule imposes on a chemical substance or mixture a requirement described in paragraph (1) or (2), a requirement directing the manufacturer, processor, or distributor in commerce of such substance or mixture or article containing such substance or mixture or directing any combination of such persons (A) to give notice of such risk to processors or distributors in commerce of such substance, mixture, or article, or to both, and to the extent reasonably ascertainable to any other person in possession of or exposed to such substance, mixture, or article; (B) to give public notice of such risk; or (C) to give both such notices. A requirement imposed under this subsection shall be the least burdensome requirement necessary to adequately protect against the risk with respect to which the requirement was imposed and may be limited in application to specified geographic areas.

(b) PROTECTION Against Adulteration or Contamination of Substances
Mixture. – If the Administrator has good cause to believe that a particular manufacturer or processor is manufacturing or processing a chemical substance

or mixture in a manner which unintentionally causes the chemical substance or mixture to cause or significantly contribute to or to be likely to cause or significantly contribute to an unreasonable risk to health or the environment -

(1) the Administrator may by order require such manufacturer or processor to submit a description of the relevant quality control procedures followed in the manufacturing or processing of such chemical substance or mixture : and

(2) if the Administrator determines after the issuance of an order described in paragraph (1) -

(A) that such quality control procedures are inadequate to prevent the chemical substance or mixture from causing or significantly contributing to such risk, the Administrator may order the manufacturer or processor to revise such quality control procedures to the extent necessary to remedy such inadequacy ; or

(B) that the use of such quality control procedures has resulted in the distribution in commerce of chemical substances or mixtures which cause or significantly contribute to an unreasonable risk to health or the environment, the Administrator may order the manufacturer or processor to (i) give notice to such risk to processors or distributors in commerce of any such substance or mixture, or to both, and, to the extent reasonably ascertainable, to any other person in possession of or exposed to any such substance, (ii) to give public notice of such risk, and (iii) to provide such replacement or repurchase of any such substance or mixture as is necessary to adequately protect health or the environment.

A determination under subparagraph (A) or (B) of paragraph (2) shall be made on the record after opportunity for hearing in accordance with section 5.54 of title 5, United States Code. The manufacturer or processor subject to a requirement to replace or repurchase a chemical substance or

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mixture may decide whether to replace or repurchase the substance or mixture and shall take either such action in the manner prescribed by the Administrator.

(c) Promulgation of Subsection (a) Rules. - (1) In promulgating any rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider all relevant factors and make findings with respect

to-

(A) the effects of such substance or mixture on health and the magnitude of human exposure to such substance or mixture,

(B) the effects of such substance or mixture on the environment and the magnitude of environmental exposure to such substance or mixture,

(C) the benefits of such substance or mixture for various uses and the availability of other substances or mixtures for such uses, and

(C) the benefits of such substance or mixture for various uses and the availability of other substances or mixtures for such uses, and

(D) the reasonably ascertainable economic consequences of such rule taking into account the impact on small business.

If the Administrator determines that a risk to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not promulgate a rule under subsection (a) to protect against such risk unless the Administrator makes a finding that it is in the public interest to protect against such risk under such rule taking into consideration all aspects of the risk, the authorities under this Act and such other law (or laws) to enforce actions taken under this Act or such law (or laws) to protect against such risk, a comparison of the estimated costs of complying with actions taken under this Act and under such law (or laws), and the relative efficiency of actions under this Act and under such law (or laws). In the judicial review of a rule under subsection (a) the last sentence of section 19(c)(1) shall not apply with respect to the determinations and findings required to be made by this paragraph.

(2) (A) Rules under subsection (a) shall be promulgated pursuant to section 553 of title 5 of the United States Code ; except that in promulgating any such rule (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions: (ii) a transcript shall be kept of any oral presentation; and (iii) during any such oral presentation, the Administrator shall include an opportunity for cross-examination as provided in subparagraph (B). The Administrator may not promulgate a rule under subsection (a) respecting a chemical substance or mixture unless the Administrator makes and publishes with the rule the finding described in such subsection. «

(B) An interested person is entitled, if the Administrator determines that it is necessary to resolve disputed issues of material fact, to conduct or have conducted by the Administrator such cross-examination of persons as the Administrator determines (i) to be appropriate in view of any need for expedition, the nature of the issues involved, and the number of participants and the nature of

their interests, and (ii) to be required for a full and true disclosure with respect to such issues.

(C) (i) If the Administrator determines that a group of persons, each of whom would but for this subparagraph be entitled to conduct (or have conducted) cross-examination, has the same or similar interests in a proceeding, the Administrator may (I) conduct cross-examination on behalf of such group, or (II) require such group to designate a single representative of such interests for purposes of conducting cross-examination in such proceeding and such representative shall, except as provided in clause (ii), conduct such cross-examination. If such group cannot arrange upon a single representative for such purposes, the Administrator may limit the representation of such interests for such purposes.

(ii) When any person who is a member of a group with respect to which the Administrator has made a determination under clause (i) is unable to agree upon group representation with the other members of the group, then such person shall not be denied under the authority of such clause the opportunity to conduct (or have conducted) cross-examination as to issues affecting the person's particular interests if (I) the person satisfies the Administrator that the person has made a reasonable and good faith effort to reach agreement upon group representation with the other members of the group and (II) the Ad-

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ministrator determines that there are substantial and relevant issues which are not adequately presented by the group representative.

(D) The Administrator may issue procedural rules for the conduct of any oral presentation (including cross-examination) under this paragraph and may impose such reasonable time limits on each person's oral presentations authorized by this paragraph as may be appropriate in view of any need for expedition, the nature of the issues involved, and the number of participants and the nature of their interests.

(E) In the judicial review of a rule under subsection (a) the last sentence of section 19(c) (1) shall not apply to any determination of the Administrator under this paragraph.

(3) (A) The Administrator may, pursuant to rules prescribed by it, provide compensation for reasonable attorneys' fees, expert witness fees, and other costs of participating in a rulemaking proceeding for the promulgation of a rule under subsection (a) to any person who represents an interest which will substantially contribute to a fair determination of the issues to be resolved in the proceeding taking into account the number and complexity of such issues and whether rep-

resentation of such interest will contribute to widespread public participation in the proceeding and representation of a fair balance of interests for the resolution of such issues if -

(i) the economic interest of such person is small in comparison to the costs of effective participation in the proceeding by such person, or

(ii) such person demonstrates to the satisfaction of the Administrator that such person does not have sufficient resources adequately to participate in the proceeding in the absence of compensation under this subparagraph.

In determining whether compensation should be provided to a person under this subparagraph and the amount of such compensation, the Administrator shall take into account the financial burden which will be incurred by such person in participating in the rulemaking proceeding.

(B) The aggregate amount of compensation paid under this paragraph in any fiscal year to all persons who, in rulemaking proceedings in which they receive compensation, are persons who either -

(i) would be regulated by the proposed rule, or

(ii) represent persons who would be so regulated, may not exceed 25 per centum of the aggregate amount paid as compensation under this paragraph to all persons in such fiscal year.

(4) Paragraphs (1), (2), and (3) of this subsection apply to the promulgation of a rule repealing, or making a substantive amendment to, a rule promulgated under subsection (a).

(d) Effective Date. - (1) The Administrator shall specify in any rule under subsection (a) the date on which it shall take effect, which date shall be as soon as feasible.

(2) (A) The Administrator may declare a proposed rule under subsection (a) to be effective upon its publication in the Federal Register and until the effective date of final action taken, in accordance with subparagraph (B), respecting such rule if -

(i) the Administrator determines that -

(I) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities is likely to result in an unreasonable risk of serious or widespread harm to health or the environment before such effective date ; and

(II) making such proposed rule so effective is necessary to protect

the public interest ; and

(ii) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under clause (i)(I), a court has in an action under section 7 granted relief with respect to such risk associated with such substance or mixture.

(B) If the Administrator makes a proposed rule effective upon its publication in the Federal Register, the Administrator shall, as expeditiously as possible, give interested persons prompt notice of such action, provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c), for a hearing on such rule, and either affirm such rule (as proposed or with modifications) or revoke it; and if such a hearing is requested, the Administrator shall commence the hearing within five days from the date such request is made unless the

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Administrator and the person making the request agree upon a later date for the hearing to begin, and after the hearing is concluded the Administrator shall, within ten days of the conclusion of the hearing, either affirm such rule (as proposed or with modifications) or revoke it.

(e) Poly chlorinated Biphenyls. – (1) within 6 months after the effective date of this Act the Administrator shall initiate proceedings for the promulgation of rules to –

(A) prescribe methods for the disposal of polychlorinated biphenyls, and

(B) require polychlorinated biphenyls to be marked with clear and adequate warnings and instructions with respect to their processing, distribution in commerce, use, or disposal or with respect to any combination of such activities.

Requirements prescribed by rules under this paragraph shall be consistent with the requirements prescribed by or under paragraphs (2) and (3).

(2) (A) Except as provided under subparagraph (B), effective one year after the effective date of this Act no person may manufacture, process, or distribute in commerce any polychlorinated biphenyl for any use other than a use in a totally enclosed manner.

(B) The Administrator may by rule authorize the manufacture, processing, or distribution in commerce (or any combination of such activities) of any poly-

chlorinated biphenyl for any use other than a use in a totally enclosed manner if the Administrator finds that such manufacture, processing, or distribution in commerce (or combination of such activities) will not cause or significantly contribute to an unreasonable risk to health or the environment.

(C) for the purposes of this paragraph, the term "totally enclosed manner" means any manner which will ensure that any leakage of a polychlorinated biphenyl from its enclosure will be insignificant as determined by the Administrator by rule.

(3) (A) Except as provided in subparagraphs (B) and (C), effective two years after the effective date of this Act no person may manufacture any polychlorinated biphenyl, and effective two and one-half years after such effective date no person may process or distribute in commerce any polychlorinated biphenyl.

(B) Any interested person may petition the Administrator for an exemption from the requirements of subparagraph (A) for a particular use of a polychlorinated biphenyl, and the Administrator may grant by rule such an exemption the Administrator determines that -

(i) the exemption is necessary for the protection of the health or environment, and

(ii) good faith efforts have been made to develop a chemical substance which may be substituted for such polychlorinated biphenyl in such use and which does not cause or significantly contribute to an unreasonable risk to health or the environment.

An exemption granted under this subparagraph shall be subject to such terms and conditions as the Administrator may prescribe and shall be in effect for such period (but not more than one year from the date it is granted) as the Administrator may prescribe.

(C) Subparagraph (A) shall not apply to the distribution in commerce of any article containing any polychlorinated biphenyl if such article was manufactured before two and one-half years after the effective date of this Act.

(4) Any rule under paragraph (1), (2)(B), or (3) (B) shall be promulgated in accordance with paragraphs (2) and (3) of subsection (c).

IMMINENT HAZARDS

Sec. 7. (a) Actions Authorized and Required. - (1) The Administrator may file an action in a district court of the United States -

(A) for seizure of an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture,

(B) for relief (as authorized by subsection (b)) against any person who manufactures, processes, or distributes in commerce an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture, or

(C) for both such seizure and relief.

An action may be filed under this paragraph notwithstanding the existence of a rule under section 4, 5, or 6, and notwithstanding the pendency of any administrative or judicial proceeding under any provision of this Act.

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(2) If the Administrator has not made a rule under section 6(a) immediately effective (as authorized by subsection 6(d) (2) (A) (i)) with respect to an imminently hazardous chemical substance or mixture, the Administrator shall file in a district court of the United States with respect to such substance or mixture or article containing such substance or mixture an action described in subparagraphs (A), (B), or (C) or paragraph (1).

(b) Jurisdiction of Court. – (1) The district court of the United States in which an action under subsection (a) is brought shall have jurisdiction to grant such temporary or permanent relief as may be necessary to protect health or the environment from the unreasonable risk associated with the chemical substance, mixture, or article involved in such action.

(2) In the case of an action under subsection (a) brought against a person who manufactures, processes, or distributes in commerce a chemical substance or mixture or an article containing a chemical substance or mixture, the relief authorized by paragraph (1) may include the issuance of a mandatory order requiring (A) in the case of purchasers of such substance, mixture, or article known to the de[^]endant, notification to such purchasers of the risk associated with it ; (B) public notice of such risk; (C) recall; (D) the replacement or repurchase of such substance, mixture, or article; or (E) any combination of the actions described in the preceding clauses.

(3) In the case of an action under subsection (a) against a chemical substance, mixture, or article, such substance, mixture, or article may be proceeded against by process of libel for its seizure and condemnation. Proceedings in such an action shall conform as nearly as possible to proceedings in rem in admiralty.

(c) Venue and Consolidation. – (1) (A) An action under subsection (a) against a i[^]erson who manufactures, processes, or distributes a chemical substance or mixture or an article containing a chemical substance or mixture may

be brought in the United States District Court for the District of Columbia or for any judicial district in which any of the defendants is found, resides, or transacts business ; and" process in such an action may be served on a defendant in any other district in which such defendant resides or may be found. An action under subsection (a) against a chemical substance, mixture, or article may be brought in any United States district court within the jurisdiction of which the substance, mixture, or article is found.

(B) In determining the judicial district in which an action may be brought under subsection (a) in instances in which such action may be brought in more than one judicial district, the Administrator shall take into account the convenience of the parties.

(C) Subpenas requiring attendance of witnesses in an action brought under subsection (a) may run into any judicial district.

(2) Whenever proceedings under subsection (a) involving identical chemical substances, mixtures, or articles are pending in courts in two or more judicial districts, they shall be consolidated for trial by order of any such court upon application reasonably made by any party in interest, upon notice to all parties in interest.

(d) Action Under Section 6. - ^Where appropriate, concurrently with the filing of an action under subsection (a) or as soon thereafter as may be practicable, the Administrator shall initiate a proceeding for the promulgation of a rule under section 6(a).

(e) Representation. - Notwithstanding any other provision of law, in any action under subsection (a), the Administrator may direct attorneys of the Environmental Protection Agency to appear and represent the Administrator in such an action.

(f) Definition. - ^^For purposes of subsection (a), the term "imminently hazardous chemical substance or mixture" means a chemical substance or mixture which causes or significantly contributes to an imminent and unreasonable risk of serious or widespread harm to health or the environment. Such a risk to health or the environment shall be considered imminent if it is shown that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture or any combination of such actions is likely to result in such harm to health or the environment before a final rule under section 6 can protect against such risk.

REPORTING AND RETENTION OF INFORMATION

Sec. 8. (a) Reports. - (1) The Administrator shall promulgate rules under which -

(A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B) (ii)) shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require, and

(B) each person (other than a small manufacturer or processor) who administrator by rule) solely for scientific-experimentation or analysis or

(i) a mixture, or

(ii) a chemical substance in small quantities (as defined by the Administrator by rule) solely for scientific-experimentation or analysis or for chemical research or analysis on such substance or another substance, including such research or analysis for the development of a product.

shall maintain records and submit to the Administrator reports but only to the extent the Administrator determines the maintenance of records or submission of reports, or both, if necessary for the effective enforcement of this Act.

The Administrator may not require in a rule promulgated under this paragraph the maintenance of records or the submission of reports with respect to changes in the proportions of the components of a mixture unless the Administrator finds that the maintenance of such records or the submission of such reports, or both, is necessary for the effective enforcement of this Act. For purposes of the compilation of the list of chemical substances required under subsection (b), the Administrator shall promulgate rules pursuant to this subsection not later than one hundred and eighty days after the effective date of this Act.

(2) The Administrator may require under paragraph (1) reporting with respect to the following :

(A) The common or trade name, the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required, insofar as known to the person making the report or insofar as reasonably ascertainable.

(B) The categories or proposed categories of use of each such substance or mixture, insofar as known to the person making the report or insofar as reasonably ascertainable.

(C) Reasonable estimates of the amount of each substance and mixture to be manufactured or processed and, insofar as known to the person making the report or insofar as reasonably ascertainable, a reasonable estimate of the amount of each such substance and mixture to be manufactured or processed for each of its categories or proposed categories of use.

(D) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture, insofar as known to the person making the report or insofar as reasonably ascertainable.

(E) All existing data concerning the adverse environmental and health effects of such substance or mixture, insofar as known to the person making the report.

(F) Estimates of the number of persons who will be exposed to such substance or mixture in their places of employment and the duration of such exposure, insofar as known to the person making the report.

To the extent feasible the Administration shall not require under paragraph (1) unnecessary or duplicate reporting.

(3) (A)(i) The Administrator may by rule require a small manufacturer or processor of a chemical substance to submit to the Administrator such information respecting the chemical substance as the Administrator may require for publication of the first list of chemical substances required by subsection (b).

(ii) The Administrator may by rule require a small manufacturer or processor of a chemical substance or mixture -

(I) subject to a rule proposed or promulgated under section 4, 5(c). 5(g), or. 6. or

(II) with respect to which relief has been granted pursuant to a civil action brought under section 7, to maintain such records on such substance, or mixture, and to submit to the Administrator such reports on

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such substance or mixture, as the Administrator may reasonably require. A rule under this clause requiring reporting may require reporting with respect to the matters referred to in paragraph (2).

(B) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining

the manufacturers and processors which qualify as small manufacturers and processors for purposes of this paragraph and paragraph (1).

(b) Inventory. – (1) The Administrator shall compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States. Such list shall at least include each chemical substance which any person reports, under section 5 or subsection (a) of this section, is manufactured or processed in the United States or was manufactured or processed in the United States within three years before the effective date of the rules promulgated pursuant to the last sentence of subsection (a) (1). In the case of a chemical substance for which a notice is submitted in accordance with section 5, such chemical substance shall be included in such list as of the earliest date (as determined by the Administrator) on which such substance was manufactured or processed in the United States. The Administrator shall first publish such a list not later than one year after the effective date of this Act. The Administrator shall not include in such list any chemical substance which is manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for scientific experimentation or analysis or for chemical research or analysis on such substance or another substance, including such research or analysis for the development of a product.

(2) To the extent consistent with the purposes of this Act, the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.

(c) Records. – Any person who manufactures, processes, or distributes in commerce or proposes to manufacture, process, or distribute in commerce any chemical substance or mixture shall, as required by the Administrator by rule, maintain records of adverse reactions to health or the environment alleged to have been caused by the substance or mixture. In such a rule the Administrator may require that –

(1) records of adverse reactions to the health of employees be retained for a period of not more than fifty years from the date such reactions were first reported to or known by the person maintaining such records, and

(2) any other record be retained for a period of not more than five years from the date the information contained in the record was first reported to or known by the person maintaining the record.

Records required to be maintained under this subsection may include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce by individuals or governmental agencies. Upon request of an officer or employee duly designated by the Administrator, each person who is required to maintain records under this subsection shall permit the inspection of such records and shall submit copies of such records.

(d) Health and Safety Studies. – The Administrator shall promulgate rules under which the Administrator may require any person who manufactures, processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce any chemical substance or mixture (or with respect to paragraph (2), any person who has possession of a study) to submit to the Administrator –

(1) lists of health and safety studies conducted or initiated by or for such person at any time or known to such person ; and

(2) copies of any such studies appearing on a list submitted pursuant to paragraph (1) or (2), or otherwise known by such person.

(e) Notice to Administrator of Unreasonable Risks. – Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture causes or significantly contributes to a substantial risk to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

(f) Definitions. – For purposes of this section, the terms "manufacture" and "process" mean manufacture or process for commercial purposes.

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RELATIONSHIP TO OTHER FEDERAL LAWS

Sec. 9(a) Laws Not Administered by the Administrator. – (1) If the Administrator has reason to believe that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture or any combination of such actions causes or significantly contributes to or is likely to cause or significantly contribute to an unreasonable risk to health or the environment and determines that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so causes or contributes to such risk. Such report shall also request such agency –

(A) (i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and

(ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk causes or significantly contributes to such risk : and

(B) to report such determination and order to the Administrator.

Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be published in the Federal Register. The agency receiving a request under such a report shall make the requested determination, issue the requested order, and make the requested report within such time as the Administrator specifies in the request, but such time specified may not be less than ninety days from the date the request was made. The report of an agency in response to a request of the Administrator shall be accompanied by a detailed statement of the findings and conclusions of the agency respecting the order and determination requested to be made and shall be published in the Federal Register.

(2) If the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which such report was made either -

(A) issues an order declaring that the activity or combination of activities specified in the description of the risk described in the report does not cause or significantly contribute to the risk described in the report, or

(B) initiates, within ninety days of the publication in the Federal Register of the report of the agency under paragraph (1) in response to the Administrator's report, action under the law (or laws) administered by such agency to protect against such risk,

the Administrator may not take any action under section 6 or 7 with respect to such risk.

(3) If the Administrator has initiated action under section 6 or 7 with respect to a risk associated with a chemical substance or mixture which was the subject of a report made to an agency under paragraph (1), such agency shall before taking action under the law (or laws) administered by it to protect against such risk consult with the Administrator for the purpose of avoiding duplication of Federal action against such risk.

(b) Laws Administered by the Administrator. - The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such

authorities to protect against such risk unless the Administrator determines that it is in the public interest to protect against such risk by actions taken under this Act. This sub.section shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

(c) AccrPATiONAL Safety and Health. - In exercising any authority under this Act. the Administrator shall not. for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970. be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

(d) Coordination.- In administering this Act, the Administrator shall consult and coordii^ate with the Secretary of Health. Education, and Welfare and

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the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes. The Administrator shall report annually to the Congress on actions taken to coordinate with such other Federal departments, agencies, or instrumentalities, and on actions taken to coordinate the authority under this Act with the authority granted under other Acts referred to in subsection (b).

RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA

Sec. 10. (a) Authority. - The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare and with other heads of appropriate departments and agencies, conduct such research, development, and monitoring as is necessary to carry out the purposes of this Act. The Administrator may enter iiito contracts and may make grants for such re-search, d-^velopment, and monit< ring. C 'iitrMcts m -y be entered into under this sul^seeUon withoi t regard to sections 3048 and 3709 of the Revised Statutes (81 T'.S.C. 529, 41 U.S.C. T)) .

(b) Data Systems. - (1) The Administrator shall establish, administer, and be responsible for the continuing activities of an interagency committee which will design, establish, and coordinate an efficient and effective system, within

the Environmental Protection Agency, for the collection, dissemination to other Federal departments and agencies, and use of data submitted to the Administrator under this Act.

(2) (A) The Administrator shall, in consultation with the Secretary of Health, Education, and Welfare and other heads of appropriate departments and agencies design, establish, and coordinate an efficient and effective system for the retrieval of toxicological and other scientific data which could be useful to the Administrator in carrying out the purposes of this Act. Systematized retrieval shall be developed for use by all Federal and other departments and agencies with responsibilities in the area of regulation or study of chemical substances and mixtures and their effect on health or the environment.

(B) The Administrator, in consultation with the Secretary of Health, Education, and Welfare, is authorized to make grants and enter into contracts for the development of a data retrieval system described in subparagraph (A). Contracts may be entered into under this subparagraph without regard to sections 3645 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5).

(c) Screening Techniques. – The Administrator shall coordinate with the Assistant Secretary for Health research undertaken by the Administrator and directed toward the development of rapid, reliable, and economical screening techniques for carcinogenic, mutagenic, teratogenic, and ecological effects of chemical substances and mixtures.

(d) Monitoring. – The Administrator shall establish and be responsible for research aimed at the development, in cooperation with local, State, and Federal agencies, of monitoring techniques and instruments which may be used in the detection of toxic chemical substances and mixtures and which are reliable, economical, and capable of being implemented under a wide variety of conditions.

(e) Basic Research. – The Administrator shall establish research programs to develop the fundamental scientific basis of the screening and monitoring techniques described in subsections (c) and (d), the bounds of their reliability of such techniques, and the opportunities for their improvement.

(f) Manpower Training. – The Administrator shall establish and promote programs and workshops to train or facilitate the training of Federal laboratory and technical personnel in existing or newly developed screening and monitoring techniques.

(g) Exchange of Research and Development Results. – The Administrator shall, in consultation with the Secretary of Health, Education, and Welfare and other heads of appropriate agencies, establish and coordinate a system for exchange among Federal, State, and local authorities of research and development results respecting toxic chemical substances and mixtures, including a system to facilitate and promote the development of standard data format and

analysis and consistent testing procedures.

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IXSPEXTIONS

Sec. 11. (a) Is General. – For purposes of enforcement of this Act the Administrator, or any representative of the Administrator, duly designated by the Administrator, may inspect any establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce and any conveyance being used to transport chemical substances or mixtures in connection with distribution in commerce. Such an inspection may only be made upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge of the premises or conveyance to be inspected. A separate notice shall be given for each such inspection but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness and shall be conducted at reasonable times, within reasonable limits, and in a reasonable manner.

(b) Scope. – (1) Except as provided in paragraph (2), an inspection under subsection (a) shall extend to all things within the premises or conveyance inspected (including records, files, papers, processes, controls, and facilities) bearing on whether the requirements of this Act applicable to the chemical substances or mixtures within such premises or conveyance have been complied with.

(2) No inspection under subsection (a) shall extend to –

(A) financial data.

(B) sales data other than shipment data.

(C) pricing data,

(D) personnel data, or

(E) research data (other than research data required by this Act), unless the nature and extent of such data are described with reasonable specificity in the written notice required by subsection (a) for such inspection.

EXPORTS

Sec. 12. (a) General. - (1) Except as provided in paragraph (2) and subsection (b), this Act (other than section 8) shall not apply to any chemical substance, mixture, or an article containing a chemical substance or mixture if-

(A) it can be shown that such substance, mixture, or article is being manufactured, processed, sold, or held for sale, for export from the United States, unless such substance, mixture, or article was, in fact manufactured, processed, or distributed in commerce, for use in the United States, and

(B) such substance, mixture, or article when distributed in commerce, or any container, bears a stamp or label stating that such substance, mixture, or article is intended for export.

(2) Paragraph (1) shall not apply to any chemical substance, mixture, or article if the Administrator finds that the substance, mixture, or article will cause or significantly contribute to an unreasonable risk to health within the United States or to the environment of the United States. The Administrator may require, under section 4. testing of a chemical substance or mixture exempted from this Act by paragraph (1) to determine whether or not such substance or mixture causes or significantly contributes to an unreasonable risk to health within the United States or to the environment of the United States,

(b) Notice. - (1) If any person exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under section 4 or 5(d), such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of the availability of the data submitted to the Administrator under such section for such substance or mixture.

(2) If any person exports or intends to export to a foreign country a chemical substance or mixture for which a rule has been proposed or promulgated under section 5 or 6, or with respect to which an action is pending, or relief has been granted under section 7. such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of such rule, action, or relief.

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ENTRY INTO CUSTOMS TERRITORY OF THE UNITED STATES

Sec. 13 (a) In General. - (1)The Secretary of the Treasury shall refuse entry into the customs territory of the United States (as defined in general headnote 2 to the Tariff Schedules of the United States) of any chemical sub-

stance, mixture, or article containing a chemical substance or mixture offered for entry if -

(A) it fails to comply with any rule in effect under this Act, or
 { B) it is offered for entry in violation of section .j. a rule or order under section 5 or 6, or an order issued in an action brought under section 5 or 7.

(2) If a chemical substance, mixture, or article is refused entry under paragraph (1), the Secretary of the Treasury shall notify the consignee of such entry refusal, shall not release it to the consignee, and shall cause its disposal or storage (under such rules as the Secretary of the Treasury may prescribe) if it has not been exported by the consignee within ninety days from the date of receipt of notice of such refusal, except that the Secretary of the Treasury may, pending a review by the Administrator of the entry refusal, release to the consignee such substance, mixture, or article on execution of bond for the amount of the full invoice of such substance, mixture, or article (as such value is set forth in the customs entry), together with the duty thereon. On failure to return such substance, mixture, or article for any cause to the custody of the Secretary of the Treasury when demanded, such consignee shall be liable to the United States for liquidated damages equal to the full amount of such bond. All charges for storage, cartage, and labor on substances, mixtures, or articles which are refused entry or release under this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future entry made by such owner or consignee.

(b) Rules. - The Secretary of the Treasury, after consultation with the Administrator, shall issue rules for the enforcement of subsection (a) of this section.

disclosure ok DATA

Sec. 14. (a) In General. - Except as provided by subsection (b), any information reported to, or otherwise obtained by, the Administrator (or any representative of the Administrator) under this Act, which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b) (4) of such section, shall not be disclosed by the Administrator or by any officer or employee of the United States, except that such information may be disclosed -

(1) to officers and employees of the United States -

(A) in connection with their official duties under laws for the protection of health or the environment, or

(R) for specific law enforcement purposes ;

(2) to contractors with the United States and employees of such contractors if in the opinion of the Administrator such disclosure is necessary

for the satisfactory performance by the contractor of a contract with the United States entered into on or after the effective date of this Act for the performance of work in connection with this Act : or

(3) when relevant in any proceeding under this Act. except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding.

(b) Data From Health and Safety Studies. - (1) Subsection (a) does not prohibit the disclosure of -

(A) any health and safety study submitted under this Act with respect to-

ll) any chemical substance or mixture which on the date the study is to be disclosed has been offered for commercial di.<tribution. or

(ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5, and

(R) any data reported to, or otherwise obtained by the Administrator from a health and safety study which relates to a chemical .substance or mixture described in clause (i) or (ii) of subparagraph (A).

This paragraph does not authorize the release of data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

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(2) If a request is made to the Administrator under subsection (a) of section 552 of title 5, United States Code, for information which is described in the first sentence of paragraph (1) and which is not information described in the second sentence of such paragraph, the Administrator may not deny such request on the basis of subsection (b) (3) or (b) (4) of such section.

(c) Designation of Confidential Data; Disputes. - (1) In submitting under this Act, a person may (A) designate the data which the person believes is entitled to confidential treatment under subsection (a), and (B) submit such designated data separately from other data submitted under this Act.

(2) If the Administrator proposes to release for inspection data which has been designated under paragraph (1)(A). the Administrator shall notify, in writing and by certified mail, the person who submitted such data of the intent

to release such data. If the release of such data is to be made pursuant to a request made under section 5.12(a) of title 5, United States Code, such notice shall be given immediately upon approval of such request by the Administrator. The Administrator may not release such data until the expiration of thirty days after the person submitting such data has received the notice required by this paragraph.

(d) Criminal Penalty for Wrongful Disclosure. - (1) Any officer or employee of the United States or former officer or employee of the United States, who by virtue of such employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a), and who knowing that disclosure of such material is prohibited by such subsection, willfully discloses the material in any manner to any person not entitled to receive it. shall be guilty of a misdemeanor and fined not more than \$5,000 or imprisoned for not more than one year, or both. Section 1005 of title 18, United States Code, does not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported or otherwise obtained under this Act.

(2) For the purposes of paragraph (1), any contractor with the United States who is furnished information as authorized by subsection (a) (2), and any employee of any such contractor, shall be considered to be an employee of the United States.

(e) Access by Congress. - Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this Act shall be made available, upon written request of any duly authorized committee of the Congress, to such committee.

prohibited acts

Sec. 15. It shall be unlawful for any person to -

(1) fail or refuse to comply with (A) any rule or order promulgated or issued under section 4. (B) any requirement prescribed by section 5, or (C) any rule or order promulgated under section 5 or 6 :

"(2) use for commercial purposes a chemical substance or mixture which such person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5. a rule or order under section 5 or 6. or an order issued in an action brought under section 5 or 7 :

(3) fail or refuse to (A) establish or maintain records. (B) submit reports, notices, or other information, or (C) permit access to or copying of records, as required by this Act or a rule thereunder: or

(4) fail or refuse to permit entry or inspection as required by section 11.

penalties

Sec 16 (a) Civil – (1) Any person who violates a provision of section 15 of this Act shall be liable to the United States for a civil penalty in an amount not to exceed \$10,000 for each such violation. Each day such a violation continues shall for purposes of this subsection constitute a separate violation of section 15

(2) (A) A civil penalty for a violation of section 15 shall be assessed by the Administrator by an order made on the record after

accordance with this subparagraph) for a hearing in accordance with the provisions of title 5 United States Code. Before issuing such an order, the Administrator shall give written notice to the person to be assessed a civil penalty under such

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order of the Administrator's proposal to issue such order and provide such person an opportunity to request, within fifteen days of the date the notice is received by such person, such a hearing on the order.

(B) In determining; the amount of a civil penalty, the Administrator shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Administrator may, in the Administrator's discretion, compromise, modify, or remit, with or without conditions, any civil penalty which may be imposed under this subsection. The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(3) Any person who requested in accordance with paragraph (2) (A) a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the thirty-day period beginning on the date the order making such assessment was issued.

(4) If any person fails to pay an assessment of a civil penalty after it has

become a final order and does not file a petition for judicial review of the order in accordance with paragraph (3) or after a court in an action brought under paragraph (3) has entered final judgment in favor of the Administrator, the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from such date) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(b) Criminal. - Any person who knowingly or willfully violates any provision of section 15 shall, in addition to or in lieu of a civil penalty which may be imposed under subsection (a) of this section for such violation, be subject, upon conviction, to a fine of not more than \$25,000 for each day of violation, or to imprisonment for not more than one year, or both.

(c) Notice, Repurchase, or Replacement. - If in a proceeding for the issuance of an order under paragraph (1) to assess a civil penalty against a person the Administrator determines that such person manufactured, processed, or distributed in commerce a chemical substance or mixture in violation of a requirement applicable to such substance or mixture under paragraph (1) or (2) of section 6(a) or otherwise determines by order made on the record after opportunity for agency hearing that a person has so violated such a requirement, the Administrator may, in such order, require such person (1) to give notice of the risk associated with the chemical substance or mixture subject to such requirement to processors or distributors in commerce of such substance or mixture, or to both, and, to the extent reasonably ascertainable, to any other person in possession of or exposed to such substance or mixture ; (2) to give public notice of such risk ; (3) to either replace or repurchase such substance or mixture, as determined by the person (or persons) to whom the requirement is directed, in the manner prescribed by the Administrator: or (4) to take any combination of the actions described in the preceding clauses.

/ SPECIFIC enforcement AND SEIZURE

Sec. 17. (a) Specific Enforcement. - (1) The district courts of the United States shall have jurisdiction over civil actions to -

(A) restrain any violation of section 15,

(B) restrain any person from manufacturing or processing a chemical substance before the expiration of the period before which such manufacturing or processing is prohibited under section 5,

(C) restrain any person from taking any action prohibited by section 5 or by any rule or order under section 5 or 6, or

(D) compel the taking of any action required by or under this Act.

<2) A civil action described in paragraph (1) may be brought -

(A) in the case of a civil action described in sub)aragraph (A) of such paragraph, in the United States district court for the judicial district wherein any act, omission, or transaction constituting a violation of section 15 occurred or wherein the defendant is found or transacts business, or

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(B) in the case of any other civil action described in such paragraph, in the United States district court for the judicial district wherein the defendant is found or transacts business.

In any such civil action process may be served on a defendant in any judicial district in which a defendant resides or may be found. Subpenas requiring attendance of witnesses in any such action may run into any judicial district.

(b) Seizure. – Any chemical substance or mixture which was manufactured, processed, or distributed in commerce in violation of this Act or any rule or order promulgated under this Act or any article containing such a substance or mixture shall be liable to be proceeded against, by process, of libel for the seizure and condemnation of such substance, mixture, or article, in any district court of the United States within the jurisdiction of which such substance, mixture, or article is found. Such proceedings shall conform as nearly as possible to proceedings in rem in admiralty.

PREEMPTIOX

Sec. 18. (a) Effect ox State Law. – (1) Except as provided in paragraph (2), nothing in this Act shall affect the authority of any State or political subdivision of a State to establish or continue in effect regulation of any chemical substance, mixture, or article containing a chemical or mixture.

(2) Except as provided in subsection (b) –

(A) if the Administrator requires by a rule promulgated under section 4 the testing of a chemical substance or mixture, no State or political subdivision may, after the effective date of such rule, establish or continue in effect a requirement for the testing of such substance or mixture for purposes similar to those for which testing is required under such rule; and

(B) if the Administrator prescri^les a rule or order under section 5 or 6 of this Act (other than a rule imposing a requirement described in subsection (a) (5 of section 6) which is applicable to a chemical substance or mixture, and which is designed to protect against a risk to health or the environment associated with such substance or mixture, no State or political

subdivision of a State may, after the effective date of such requirement, establish or continue in effect a requirement applicable to such substance or mixture, or an article containing such substance or mixture, and designed to protect against such risk unless such requirement is identical to the requirement prescribed by the Administrator or unless such requirement is adopted under the authority of the Clean Air Act or any other Federal law.

(b) ExE^rPTioN. – Upon application of a State or political subdivision of a State the Administrator may by rule exempt from subsection (a)(2), under such conditions as may be prescribed in such rule, a requirement of such State or political subdivision designed to protect against a risk to health or the environment associated with a chemical substance, mixture, or article containing a chemical substance or mixture if –

(1) compliance with the requirement would not cause the manufacturing, processing, distribution in commerce, or use of the substance, mixture, or article to be in violation of the applicable requirement under this Act described in subsection (a) (2), and

(2) the State or political subdivision requirement (A) provides a significantly higher degree of protection from such risk than the requirement under "this Act described in subsection (a) (2) and (B) does not, through difficulties in marketing, distribution, or other factors, unduly burden interstate commerce.

JUDICIAL REVIEW

Sec. 19. (a) In General.– Not later than sixty days following the promulgation of a rule under section 4, 5. or 0(a) of this Act. any person may file a petition for judicial review of such rule with the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which such person resides or in which such person's principal place of business is located. Copies of the petition shall be forthwith transmitted by the clerk of such court to the Administrator and to the Attorney General. The Administrator shall transmit to the Attorney General, who shall" file in the court, the record of the proceedings on which the Administrator leased such rule as provided in section 2112 of title 28, United

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states Code. For purposes of this section, the term "record" means such rule ; any transcript required of any oral presentation ; any written submission of interested parties; and any other information which the Administrator considers to be relevant to such rule and with respect to which the Administrator, on or before the Administrator, the court may rule, published a notice in the Federal Register

identifying such information.

(b) Additional Data. – If the petitioner applies to the court for leave to adduce additional data, views, or arguments, and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there are reasonable grounds for the petitioner's failure to adduce such data, views, or arguments in the proceeding before the Administrative, the court may order the Administrator to provide additional opportunity for oral presentation of data, views, or arguments and for written submissions. The Administrator may modify findings or determinations upon which the rule subject to review by such court was based, or make new findings or determinations by reason of the additional data, views or arguments so taken and shall file such modified or new findings or determinations, and the Administrator's recommendation, if any, for the modification or setting aside of such rule, with the return of such additional data, views, or arguments.

(c) Authority and Review Standard. – (1) Upon the filing of a petition under subsection (a), the court shall have jurisdiction (A) to review the rule involved in accordance with chapter 7 of title 5, United States Code, and (B) to grant appropriate relief, including interim relief, as provided in such chapter. Any rule promulgated by the Administrator under section 4, 5, or 6 of this Act and reviewed under this section shall be affirmed, unless the determination or findings required to be made by the Administrator under the applicable section are not supported by substantial evidence on the record taken as a whole.

(2) The judgment of the court affirming or setting aside, in whole or in part, any rule reviewed in accordance with this section shall be final to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

(3) The judgment of the court in an action brought pursuant to subsection (a) may include an award of costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. The Supreme Court of the United States in its decision on a review of a judgment in such an action may provide for the award of costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(d) Other Remedies. – The remedies provided in this section shall be in addition to and not in lieu of any other remedies provided by law.

citizen's civil actions

Sec. 20. (a) In General. – Except as provided in subsection (b), any person may commence a civil action –

(1) against any person (including (A) the United States, and (B) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution) who is alleged to be in violation

of this Act or any rule prescribed under section 4, 5, or 6(a) to restrain such violation, or

(2) against the Administrator to compel the Administrator to perform any act or duty under this Act which is not discretionary.

Any civil action under paragraph (1) shall be brought in the United States district court for the district in which the alleged violation occurred or in which the defendant resides or in which the defendant's principal place of business is located. Any action brought under paragraph (2) shall be brought in the United States District Court for the District of Columbia, or the United States district court for the judicial district in which the plaintiff is domiciled. The district courts shall have jurisdiction over suits brought under this section, without regard to the amount in controversy or the citizenship of the parties. In any civil action under this subsection process may be served on a defendant in any judicial district in which the defendant resides or may be found and subpoenas for witnesses may run into any judicial district.

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(b) Limitation. - No civil action may be commenced -

(1) under subsection (a)(1) to restrain a violation of this Act or rule under this Act -

(A) before the expiration of sixty days after the plaintiff has given notice of such violation (i) to the Administrator, and (ii) to the person who is alleged to have committed such violation, or

(B) if the Administrator (or the Attorney General on behalf of the Administrator) has commenced and is diligently prosecuting a civil action in a court of the United States to require compliance with this Act or such rule, but if such action is commenced after the giving of notice, any person giving such notice may intervene as a matter of right in such action ; or

(2) under subsection (a) (2) before the expiration of sixty days after the plaintiff has given notice to the Administrator of the alleged failure of the Administrator to perform an act or duty which is the basis for such action or, in the case of an action under such subsection for the failure of the Administrator to file an action under section 7, before the expiration of ten days after such notification.

Notice under this subsection shall be given in such manner as the Administrator

shall prescribe by rule.

(c) General. – (1) In any action under this section, the Administrator, if not a party, may intervene as a matter of right.

(2) The court, in issuing any final order in any action brought pursuant to subsection (a), may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(3) Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of this Act or any rule under this Act or to seek any other relief.

(d) Consolidation. – When two or more civil actions brought under subsection (a) involving the same defendant and the same issues or violations are pending in two or more judicial districts, such pending actions, upon application of such defendants to such actions which is made to a court in which any such action is brought, may, if such court in its discretion so decides, be consolidated for trial by order (issued after giving all parties reasonable notice and opportunity to be heard) of such court and tried in –

(1) any district which is selected by such defendant and in which one of such actions is pending,

(2) a district which is agreed upon by stipulation between all the parties to such actions and in which one of such actions is pending, or

(3) a district which is selected by the court and in which one of such actions is pending.

The court issuing such an order shall give prompt notification of the order to the other courts in which the civil actions consolidated under the order are pending.

citizen's petitions

Sec. 21. (a) In General. – Any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 4, 5(c), or 6(a).

(b) Procedures.– (1) Such petition shall be filed in the principal office of the Administrator and shall set forth the facts which it is claimed established that it is necessary to issue, amend, or repeal a rule under section 4, 5(c), or 6(a).

(2) The Administrator may hold a public hearing or may conduct such investi-

gation or proceeding as the Administrator deems appropriate in order to determine whether or not such petition should be granted.

(3) Within ninety days after filing of a petition described in paragraph (1), the Administrator shall either grant or deny the petition. If the Administrator grants such petition, the Administrator shall promptly commence an appropriate proceeding in accordance with section 4, 5(c), or 6(a). If the Administrator denies such petition, the Administrator shall publish in the Federal Register the Administrator's reasons for such denial.

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(4) (A) If the Administrator denies a petition filed under this section (or if the Administrator fails to grant or deny such petition within the ninety-day period) the petitioner may commence a civil action in a United States district court to compel the Administrator to initiate a rulemaking proceeding to take the action requested. Any such action shall be filed within sixty days after the Administrator's denial of the petition or if the Administrator fails to grant or deny the petition within ninety days after filing the petition, within sixty days after the expiration of the ninety-day period.

(B) If in an action under subparagraph (A) respecting a petition to initiate a proceeding to issue a rule under section 4, 5(c) or 6(a) the petitioner demonstrates to the satisfaction of the court, by a preponderance of the evidence in a de novo proceeding before the court, that -

(i) in the case of a petition to initiate a proceeding for the issuance of a rule under section 4, shall the manufacture, distribution in commerce, processing, use, or disposal of the chemical substance or mixture to be subject to such rule may cause or significantly contribute to an unreasonable risk to health or the environment,

(ii) in the case of a petition to initiate a proceeding for the issuance of a rule under section 5(c), that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance petitioned to be included in a list compiled under such rule causes or significantly contributes to an unreasonable risk to health or the environment, or

(iii) in the case of a petition for the issuance of a rule under section 6 (a), that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture to be subject to such rule causes or significantly contributes to or will cause or significantly contribute to an unreasonable risk to health or the environment,

the court shall order the Administrator to initiate the action requested by the petitioner unless the court finds, after considering the extent of the risk to health or the environment alleged by the petitioner in relation to the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act. the resources available to the Administrator to take action requested by the petitioner, and other relevant factors, the failure of the Administrator to initiate such action was not unreasonable.

(C) The court in issuing any final order in any action brought pursuant to subparagraph (A) may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(5) The remedies under this section shall be in addition to, and not in lieu of other remedies provided by law.

NATIONAL DEFENSE WAIVER

Sec 22. The Administrator shall waive compliance with any provision of this Act upon a request and determination by the President that the requested waiver is necessary in the interest of national defense. The Administrator shall maintain a written record of the basis upon which such waiver was granted and make such record available for in camera examination when relevant in a judicial proceeding under this Act. Upon the issuance of such a waiver, the Administrator shall publish in the Federal Register a notice that the waiver was granted for national defense purposes, unless, upon the request of the President, the Administrator determines to omit such publication because the publication itself would be contrary to the interests of national defense, in which event the Administrator shall submit notice thereof to the Armed Services Committees of the Senate and the House of Representatives.

EMPLOYEE protection

Sec. 23. (a) In General. - No employer may discharge any employee or otherwise discriminate against any employee with respect to the employee's compensation, terms, conditions, or privileges of employment because the employee (or any person acting pursuant to a request of the employee) has -

(1) commenced, cause to be commenced, or is about to commence or cause to be commenced a proceeding under this Act ;

(2) testified or is about to testify in any such proceeding: or

(3) assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes of this Act.

(b) Remedy. - (1) Any employee who believes that the employee has been discharged or otherwise discriminated against by any person in violation of subsection (a) of this section may, within thirty days after such alleged violation occurs, file (or have any person file on the employee's behalf) a complaint with the Secretary of Labor (hereinafter in this section referred to as the "Secretary") alleging such discharge or discrimination. Upon receipt of such a complaint, the Secretary shall notify the person named in the complaint of the filing of the complaint.

(2) (A) Upon receipt of a complaint filed under paragraph (1), the Secretary shall conduct an investigation of the violation alleged in the complaint. "Within thirty days of the receipt of such complaint, the Secretary shall complete such investigation and shall notify in writing the complainant (and any person acting on behalf of the complainant) and the person alleged to have committed such violation of the results of the investigation conducted pursuant to this paragraph. Within ninety days of the receipt of such complaint the Secretary shall, unless the proceeding on the complaint is terminated by the Secretary on the basis of a settlement entered into by the Secretary and the person alleged to have committed such violation, issue an order either providing the relief prescribed by subparagraph (B) or denying the complaint. An order of the Secretary shall be made on the record after notice and opportunity for agency hearing. The Secretary may not enter into a settlement terminating a proceeding on a complaint without the participation and consent of the complainant.

(B) If in response to a complaint filed under paragraph (1) the Secretary determines that a violation of subsection (a) of this section has occurred, the Secretary shall order (i) the person who committed such violation to take affirmative action to abate the violation, (ii) such person to reinstate the complainant to the complainant's former position together with the compensation (including back pay), terms, conditions, and privileges of the complainant's employment, (iii) compensatory damages, and (iv) where appropriate, exemplary damages. If such an order is issued, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorney's fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

(c) Review. - (1) Any person adversely affected or aggrieved by an order issued under subsection (b) may obtain review of the order in the United States

Court of Appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred. The petition for review must be filed within sixty days from the issuance of the Secretary's order. Review shall conform to chapter 7 of title 5 of the United States Code.

(2) An order of the Secretary, with respect to which review could have been obtained under paragraph (1), shall not be subject to judicial review in any criminal or other civil proceeding.

(d) Enforcement. – (1) Whenever a person has failed to comply with an order issued under subsection (b)(2), the Secretary shall file a civil action in the United States district court for the district in which the violation was found to occur to enforce such order. In actions brought under this subsection, the district courts shall have jurisdiction to grant all appropriate relief, including injunctive relief and compensatory and exemplary damages. Civil actions brought under this subsection shall be heard and decided expeditiously.

(2) Any nondiscretionary duty imposed by this section is enforceable in mandamus proceeding brought under section 1361 of title 28. United States Code.

(e) Exclusion. – Subsection (a) of this section shall not apply with respect to any employee who, acting without direction from the employee's employer (or any agent of the employer), deliberately causes a violation of any requirement of this Act.

EMPLOYMENT EFFECTS

Sec. 24. (a) In General. – The Administrator shall evaluate on a continuing basis the potential effects on employment (including reductions in employment or loss of employment from threatened plant closures of –

(1) the issuance of a rule or order under section 4, 5, or 6, or

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(2) a requirement of section 5.

{b}(1) Investigations. – Any employee (or any representative of an employee) may request the Administrator to make an investigation of –

(A) a discharge or layoff or threatened discharge or layoff of the employee, or

(B) adverse or threatened adverse effects on the employee's employment, allegedly resulting from a rule or order under section 4, 5, or 6 or a requirement

of section 5. Any such request shall be made in writing, shall set forth with reasonable particularity the grounds for the request, and shall be signed by the employee, or representative of such employee, making the request.

(2) (A) Upon receipt of a request made in accordance with paragraph (1) the Administrator shall (i) conduct the investigation requested, and (ii) if requested by any interested person, hold public hearings on any matter involved in the investigation unless the Administrator determines that there are no reasonable grounds for holding such hearings. If the Administrator makes such a determination respecting a request for a hearing, the Administrator shall notify in writing the person requesting the hearing of the determination and the reasons therefor.

(B) If public hearings are to be held on any matter involved in an investigation conducted under this subsection -

(i) at least five days' notice shall be provided the person making the request for the investigation and any person identified in such request,

(ii) a transcript shall be made of the hearings, and

(iii) each employee who made or for whom was made a request for such hearings and the employer of such employee shall be required to present information respecting the applicable matter referred to in paragraph (1)

(A) or (1) (B) together with the basis for such information.

(3) Upon completion of an investigation under paragraph (2), the Administrator shall make findings of fact, shall make such recommendations as the Administrator deems appropriate, and shall make available to the public such findings and recommendations.

(4) In connection with any investigation or public hearing conducted under this subsection, the Administrator may issue subpoenas for the attendance and testimony of witnesses and the production of relevant papers, books, and documents, and the Administrator may administer oaths. Witnesses summoned shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. In case of contumacy or refusal to obey a subpoena served upon any person under this paragraph, the United States district court for any district in which such person is found or resides or transacts business, upon application by the United States and after notice to such person, shall have jurisdiction to issue an order requiring such person to appear and give testimony before the Administrator to appear and produce papers, books, and documents before the Administrator, or both, and any failure to obey such order of the court may be punished by such court as a contempt thereof.

STUDIES

Sec. 25. (a) Indemnification Study. - The Administrator shall conduct a

study of all Federal laws administered by the Administrator for the purpose of determining whether and under what conditions, if any, indemnification should be accorded an individual person as a result of any action taken by the Administrator under any such law. The study shall -

(1) include an estimate of the probable cost of any indemnification programs which may be recommended :

(2) include an examination of all viable means of financing the cost of any recommended indemnification : and

(3) be completed and submitted to Congress not less than two years from the effective date of this Act.

The General Accounting Office shall review the adequacy of the study submitted to Congress pursuant to paragraph (3) and shall report the results of its review to the Congress within six months of the date such study is submitted to Congress.

(b) Classification, Storage, and Retrieval Study. - The Council on Environmental Quality, in consultation with the Administrator, the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate Federal departments or agencies, shall coordinate a study of

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the feasibility of establishing (1) a standard classification system for chemical substances and related substances, and (2) a standard means for storing; and obtaining rapid access to information respecting such substances. A report on such study shall be completed and submitted to Congress not later than eighteen months after the effective date of this Act.

ADMINISTRATION OF ACT

Sec. 26. (a) Cooperation of Federal Agencies. - Upon request by the Administrator, each Federal department and agency is authorized -

(1) to make its services, personnel, and facilities available (with or without reimbursement) to the Administrator to assist the Administrator in the administration of this Act ; and

(2) to furnish to the Administrator such information, data, estimates, and statistics, and to allow the Administrator access to all information in its possession as the Administrator may reasonably determine to be necessary

for the administration of this Act.

(b) Fees. – (1) The Administrator may, by rule, require the payment of a reasonable fee in any case in which any person required to submit data under section 4 or 5 of this Act to defray the cost of administering this Act. Such rules shall not provide for any fee in excess of \$2,500 or in the case of a small business concern, any fee in excess of \$100. In setting such a fee, the Administrator shall take into account the ability to pay of the person required to submit such data and the cost to the Administrator of reviewing such data. Such rules may provide for sharing such a fee in any case in which the expenses of testing are shared under section 4 or 5 of this Act.

(2) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the persons which qualify as small business concerns for purposes of this subsection.

(c) Action "With Respect to Categories. – (1) Any action authorized or required to be taken by the Administrator under any provision of this Act with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the Administrator takes action under a provision of this Act with respect to a category of chemical substances or mixtures, any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category.

(2) For purposes of paragraph (1) :

(A) The term "category of chemical substances" means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

(R) The term "category of mixtures" means a group of mixtures the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some way suitable for classification as such for purposes of this Act.

(d) Assistance Office.– The Administrator shall establish in the Environmental Protection Agency an identifiable office to provide technical and other non-financial assistance to manufacturers and processors of chemical substances and mixtures respecting the requirements of this Act applicable to such manufacturers and processors, the policy of the Agency respecting the application of such

requirements to such manufacturers and processors, and the means and methods by which such manufacturers and processors may comply with such requirements.

development and evaluation of test methods

Sec 27. (a) The Secretary of Health, Education, and Welfare, in consultation with the Administrator and acting through the Assistant Secretary for Health, may conduct, and make grants to public and nonprofit private entities and enter

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into contracts with public and private entities for, projects for the development and evaluation of inexpensive and efficient methods (1) for determining and evaluating the health and environmental effects of chemical substances and mixtures, and their toxicity, persistence, and other characteristics which affect health and the environment, and (2) which may be used for the development of test data to meet the requirements of rules promulgated under section 4. The Administrator shall consider such methods in prescribing under section 4 standards for the development of test data.

(b) No grant may be made or contract entered into under subsection (a) unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be submitted in such form and manner and contain such information as the Secretary may require. The Secretary may apply such conditions to grants and contracts under subsection (a) as the Secretary determines are necessary to carry out the purposes of such subsection. Contracts may be entered into under such subsection without regard to sections 3048 and 3709 of the Revised Statutes (31 U.S.C. 529 ; 41 U.S.C. 5).

(c) (1) The Secretary shall prepare and submit to the President and the Congress on or before January 1 of each year a report of the number of grants made and contracts entered into under this section and the results of such grants and contracts.

(2) The Secretary shall periodically publish in the Federal Register reports describing the progress and results of any contract entered into or grant made under this section.

STATE PROGRAMS

Sec. 28. (a) For the purpose of complementing (but not reducing) the authority of, or actions taken by, the Administrator under this Act, the Administrator may make grants to States for the establishment and operation of programs to

prevent or eliminate unreasonable risks within the States to health or the environment which are associated with a chemical substance or mixture and with respect to which the Administrator is unable to take action under this Act for their prevention or elimination. The amount of a grant under this subsection shall be determined by the Administrator, except that no grant for any State program may exceed 7.5 percentum of the establishment and operation costs (as determined by the Administrator) of such program during the period for which the grant is made.

(b) (1) No grant may be made under subsection (a) unless an application therefor is submitted to and approved by the Administrator. Such an application shall be submitted in such form and manner as the Administrator may require and shall -

(A) set forth the need of the applicant for a grant under subsection (a),

(B) identify the agency or agencies of the State which shall establish or operate, or both, the program for which the application is submitted,

(C) describe the actions proposed to be taken under such program,

(D) contain or be supported by assurances satisfactory to the Administrator that such program shall, to the extent feasible, be integrated with other programs of the applicant for environmental and public health protection,

(E) provide for the making of such reports and evaluations as the Administrator may require, and

(F) contain such other information as the Administrator may prescribe.

(2) The Administrator may approve an application submitted in accordance

with paragraph (1) only if the applicant has established to the satisfaction of the Administrator a priority need, as determined under rules of the Administrator, for the grant for which the application has been submitted. Such rules shall take into consideration the seriousness of the health effects in a State which are associated with chemical substances or mixtures, including cancer, birth defects, and gene mutations, the extent of the exposure in a State of human beings and the environment to chemical substances and mixtures, and the extent to which chemical substances and mixtures are manufactured, processed, used, and disposed of in a State.

(c) Not later than six months after the end of each of the fiscal years 1979, 1980, and 1981, the Administrator shall submit to the Congress a report respecting the programs assisted by grants under subsection (a) in the preceding fiscal year and the extent to which the Administrator has disseminated information respecting such programs.

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(d) For the purpose of inakiiij; j^runt under subsection (u) there are au-
 tiorized to be appropriated .1;1,(K>0,0C)0 for the liscal year ending? September 30
 1978, .l;i,(C)00.00C) for the liscal year ending' Septeml)er 30, 107J) and SI 000 (k)(>
 for the liscal year ending' September 30, 11)80. Sums appropriated under this
 subsection shall remain avaihible until expended.

SUNSHINE IN (iOV-EKN.MENT

Si;c. (a) Each officer or employee of the Admini.s^rator and the Secretary
 of Health, Education and Welfare who -

(1) performs any function or duty under this Act ; and

(2) has any known linancial interest (A) in any person subject to this
 Act, or (B) III any person who applies for or receives any grant, contract,
 or other form of linancial assistance pursuant to this Act ;

shall, beginninj; on February 1, 1κ)77, annually file with the Administrator or
 the Secretary of Health, Education and Welfare, as appropriate, a written
 statement concerninj;- all such interests held by such officer or employee during?
 the precedin;;- calendar year. Such statement shall be available to the public,
 (bj 'J'he Administrator and said Secretary shall -

(1) act within ninety days after the date of enactment of this Act-

(A) to detine the term "known financial interest" for purposes of

subsection (a) of this section ; and

(H> to establish the methods by which the recuiirement to file written
 statements specified in subsection (a) of this section will be monitored
 and enforced, includin;; approu-iate provisions for the filinjf by such
 officers and employees of such statements and the review by the Admin-
 istrator and said Secretary of such statements ; and

(2) report to the Congress on June 1 of each calendar year with respect
 to such disclosures and the actions taken in regard thereto during the
 preceding calendar year.

(c) In the rules prescribed in subsection (b) of this section, the Administrator and said Secretary may identify specific positions within the appropriate agency which are of a nonregulatory or nonpolicymaking nature and provide that officers or employees occupying such positions shall be exempt from the requirements of this section.

(d) Any officer or employee who is subject to, and knowingly violates, this section or any regulation issued thereunder, shall be fined not more than \$2,500 or imprisoned not more than one year, or both.

AUTHORIZATION FOR ALLOCATIONS

Sec. 30. There are authorized to be appropriated to the Administrator for purposes of carrying out this Act (other than sections 27 and 28 and subsections (a) and (c) through (g) of section 10 thereof) \$10,200,000 for the fiscal year ending September 30, 1978, \$17,300,000 for the fiscal year ending September 30, 1979, and \$17,300,000 for the fiscal year ending September 30, 1980. No part of the funds appropriated under this section may be used to construct any research laboratories.

ANNUAL REPORT

Sec. 31. The Administrator shall prepare and submit to the President and the Congress on or before January 1, 1979, and on or before January 1 of each succeeding year a comprehensive report on the administration of this Act during the preceding fiscal year. Such report shall include -

(1) a list of the testing required under section 4 during the year for which the report is made and an estimate of the costs incurred during such year by the persons required to perform such tests :

(2) the number of notices received during such year under section 4, the number of such notices received during such year under such section for chemical substances subject to a section 4 rule, and a summary of any action taken during such year under section 5(g) :

(3) a list of rules issued during such year under section 5 :

(4) a list, with a brief statement of the issues, of completed or pending judicial actions under this Act during such year ; , . . .

(5) a summary of major problems encountered in the administration of

and such recommendations for additional legislation as the Administrator deems necessary to carry out the purposes of this Act.

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RULE KEVIKW

Sec. 32. (a) Any rule prescribed pursuant to this Act by the Administrator may by resolution of either House of Congress be disapproved, in whole or in part, if such resolution of disapproval is adopted not later than the end of the first period of (90 calendar days when Congress is in session (whether or not continuous) which period begins on the date such rule is finally adopted by the Administrator, Secretary of the Treasury, or Secretary of Health, Education, and Welfare, as the case may be. The authority which prescribes a rule pursuant to this Act shall transmit such rule to each House of Congress immediately upon its final adoption. Upon adoption of such a resolution of disapproval by either House of Congress within such (90-day period, such rule, or part thereof, as the case may be, shall cease to be in effect.

(b) Congressional inaction on or rejection of a resolution of disapproval of a rule promulgated under this Act shall not be deemed an expression of approval of such rule.

EFFECTIVE DATE

Sec. 38. This Act shall take effect October 1, 1977.
The motion was {i<>:mMl to.

The Senate bill was ordered to be read a third time, was read the third time, and passed, and a motion to reconsider was laid on the table.

A similar House bill (H.R. 14012) was laid on the table.

CHAPTER IV

CONFERENCE REPORT AND DEBATES

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79-313 - 77 - 43

94th Congress) HOUSE OF REPRESENTATIVES (Report
2d Session) (No. 94-1679

TOXIC SUBSTANCES CONTROL ACT

September 23, 1976. - Ordered to be printed

Mr. Staggers, from the committee of conference,
submitted the following

CONFERENCE REPORT

[To accompany S. 3149]

The committee of conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 3149) to regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows :

That the Senate recede from its disagreement to the amendment of the House and agree to the same with an amendment as follows :

In lieu of the matter proposed to be inserted by the House amendment insert the following :

(667)

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JOINT EXPLANATORY STATEMENT OF THE COMMITTEE OF CONFERENCE

The managers on the part of the House and the Senate at the conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S, 3149) to regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes, submit the following joint statement to the House and the Senate in explanation of the effect of the action agreed upon by the managers and recommended in the accompanying conference report:

The House amendment struck out all of the Senate bill after the enacting clause and inserted a substitute text.

The Senate recedes from its disagreement to the amendment of the House with an amendment which is a substitute for the Senate bill and the House amendment. The differences between the Senate bill, the House amendment, and the substitute agreed to in conference are noted below, except for clerical corrections, conforming changes made necessary by agreements reached by the conferees, and minor drafting and clarifying changes.

FINDINGS, POLICY, AND INTENT

Senate bill {section 2)

Section 2(a) outlines Congressional policy underlying the Toxic Substances Control Act. Congress finds that : human beings and the environment are exposed to numerous chemical substances and mixtures ; some of these may cause or contribute to an unreasonable risk of injury to health or the environment; and the effective regulation of such substances and mixtures in interstate commerce necessitates regulation of intrastate commerce as well.

Subsection (b) sets forth that it is the policy of the United States that adequate data on the health and environmental effects of such chemical substances and mixtures should be developed. Such data development should be the responsibility of those who manufacture and process such chemical substances and mixtures. Adequate authority should exist to regulate chemical substances and mixtures, but the exercise of such authority should not unduly impede technological innovation.

Subsection (c) contains a declaration of Congressional intent as to how the Administrator shall fulfill the responsibilities under this Act. The Administrator shall carry out this Act in a reasonable and pru-

dent manner and consider the environmental, economic, and social impact of any action taken or proposed under this Act.

Home amendment {section 2)

The House amendment is nearly identical to the Senate bill. However, the House amendment confines its data development man-

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date to hazardous or potentially hazardous substances and mixtures, in contrast to the broader mandate contained in the Senate bill.

Conference substitute {section 2)

The conference substitute follows the Senate provision. Adequate data should be developed concerning the health and environmental effects of chemical substances and mixtures. Such data development should be the responsibility of those who manufacture or process such substances and mixtures. Adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment and to take action with respect to chemical substances and mixtures which are imminent hazards.

DEFINITIONS

Senate bill {sections)

The Senate bill includes definitions for the Act, the principal ones of which are as follows :

1. Chemical substance is defined as (i) any organic or inorganic substance of a particular molecular identity including a combination of such substances occurring as a result of a chemical reaction, or (ii) any element or uncombined radical. The term specifically excludes any mixture ; any pesticide ; tobacco and tobacco products ; special nuclear materials or by-product materials as defined in the Atomic Energy Act of 1954; articles which if sold would be subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (i.e., pistols, firearms, revolvers, shells and cartridges) ; any substance found in or on any food, drug, cosmetic or device and any substance produced for research and development purposes intended only for use in or

on any food, drug cosmetic or device.

2. The term "environment" includes human beings and their environment, water, atmosphere, and land and the interrelationships which exist among and between these.

3. "Manufacture" means to import, produce, or manufacture for commercial purposes.

4. The term "mixture" means any combination of two or more chemical substances if such substances do not react chemically with each other and if the combination is not a result of the chemical reaction. Mixture also includes combinations of substances which occur in nature.

The Senate bill authorizes the Administrator to exclude from coverage of the Act any chemical substance or mixture if the Administrator determines, by rule, that the substance or mixture does not present an unreasonable risk of injury to health or the environment. However, the exclusion shall not apply to section 7 or section 8(e) of the Senate bill.

House amendment (section 3)

1. The House definition of "chemical substance" is similar to that of the Senate bill, except that the term includes organic or inorganic substances or combinations of such substances occurring in nature. The exclusions from the definition of chemical substances are similar to the Senate bill, although the House amendment specifically excludes food additives along with foods, drugs, cosmetics, and devices.

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2. The House amendment defines "environment" to include water, air and land, and the interrelationships which exist among and between water, air and land, and all living things.

3. The House amendment, like the Senate bill, defines manufacture to mean import, produce, or manufacture, but the definition is not limited to such activities done for commercial purposes.

4. The term "mixture" is defined to mean any combination of two or

more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction. However, certain reaction-produced combinations are included in the term "mixture" in order to prevent disparate treatment of identical combinations simply because of the number of steps used in the manufacture of the combination. If each of the chemical substances comprising the combination is not a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction occurring at the time the substances comprising the combination were combined, then the combination is included within the term "mixture".

The House bill does not contain general authority for the Administrator to exclude any chemical substance or mixture from the provisions of the bill. However, section 5(i) (5) of the House amendment authorizes the Administrator to exclude any chemical substance from the notification requirements of section 5 if the Administrator determines, by rule, that the substance will not cause or significantly contribute to an unreasonable risk to health or the environment.

Conference substitute {section 3)

The conference substitute adopts the definitions contained in the House amendment.

The conferees recognize that virtually no chemical substance exists in a completely pure state and intend that any reference to a chemical substance includes all impurities and concomitant products, including incidental reaction products, contaminants, co-products, and trace materials. Thus the definition of term "chemical substance" shall be applied to chemical substances as actually produced and marketed. For example, when the Administrator promulgates a rule under section 6(a) to regulate a particular substance, such rule will apply to the identified substance, including all the impurities and other concomitant products, without explicitly identifying such impurities and concomitant products within the rule.

It is expected that the Administrator will develop guidelines for the purpose of clarifying the extent to which impurities and concomitant products will be included within a reference to "chemical substance" as it relates to the various provisions of the Act. "^^Tiile impurities and concomitant products are included within references to a "chemical substance" under the Act, the Administrator is obviously authorized to move against them separately under the applicable provisions of the Act.

The term "health and safety study" is important as it describes information to which various provisions of the Act are applicable. For

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example, section 8(d) requires manufacturers, processors, and distributors in commerce to list such studies with the Administrator. Moreover, section 14(b) contains provisions concerning the availability of health and safety studies to the public.

The conference substitute defines health and safety study to mean any study of any effect of a chemical substance or mixture on health or the environment, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, chemical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act.

It is intended that the term be interpreted broadly. Not only is information which arises as a result of a formal, disciplined study included but other information relating to the effects of a chemical substance or mixture on health and the environment is also included. Any data which bears on the effects of a chemical substance on health or the environment would be included.

TESTING OF CHEMICAL SUBSTANCES AND MIXTURES

Senate bill {section 4)

Section 4 authorizes the Administrator to require testing of chemical substances and mixture^s to ascertain potential effects on human health and the environment. Under subsection (a), the Administrator must, by rule, require the testing of a chemical substance or mixture if the Administrator finds (1) that the chemical substance or mixture may present an unreasonable risk of injury to health or the environment, or that there may be significant human or environmental exposure because substantial quantities will be produced and such substance or mixture may perhaps present an adverse effect on health or the environment ; (2) there are insufficient data or experience to reasonably determine or predict its health and environmental effects; and (By testing is necessary to develop such data. If no reliable data is available to the Administrator, the finding that such substance or mixture may perhaps present an adverse effect on health or the environ-

ment shall be presumed. In the case of a mixture, the bill requires an

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additional finding that testing the chemical substances which comprise the mixture is not a more efficient and reasonable method to determine effects on health and the environment. When requiring tests under subsection (a), the Administrator shall consider reasonably ascertainable costs and other burdens associated with conducting tests and publish such considerations in the Federal Register.

Subsection (b) sets forth the required contents of the testing rule and provides an illustrative list of health and environmental effects for which test standards may be required. This subsection also describes some of the methodologies which the testing rule may prescribe. In addition, it describes which manufacturers and processors will be required to conduct the testing.

The Administrator shall review and, if appropriate, revise the standards for development of data at least once per year. Testing rules shall be issued in accordance with the rulemaking procedures of section 553, of title 5, United States Code, except that the Administrator shall allow interested persons the opportunity to make oral presentations of data, views, or arguments in addition to written submissions. A transcript of such oral presentations is required.

Subsection (c) provides a procedure whereby persons may apply to the Administrator for an exemption from a testing requirement rule in order to avoid submission of duplicative data. If an exemption is granted, a cost-sharing procedure is provided. A person providing reimbursement may have access to test data, subject to the confidentiality provisions of section 14.

Subsection (d) requires the Administrator to publish a notice of receipt of test data in the Federal Register and to make the data available to the public within 15 days of receipt.

Subsection (e) establishes an interagency advisory committee comprised of qualified and appropriate Federal officials to make recommendations to the Administrator regarding testing priorities.

The committee shall submit a list of chemical substances and mix-

tures in the order in which the committee determines the Administrator should promulgate testing rules under subsection (a). Within 12 months after the inclusion of a chemical on such list, the Administrator shall either initiate a rulemaking proceeding under subsection (a) or publish reasons for not initiating a proceeding in the Federal Register. Subsection (e) also contains specific conflict of interest provisions applicable to members of the interagency advisory committee.

Subsection (f) specifies required actions by the Administrator in response to test data or other information which indicate that a substance or mixture has a potential to induce cancer, gene mutations, or birth defects at levels for which human exposure exists or may exist with appropriate safety margins. The Administrator shall either take appropriate action under section 5 (e) , 6 (a) , or 7 within 180 days after the date of receipt of such data or information or publish in the Federal Register a finding that no unreasonable risk of injury is presented and reasons for making such a finding. Such requirement shall not take effect until two years after enactment.

House amendment {section 4.)

Like the Senate bill, the House amendment requires that the Administrator find that there are insufficient data and experience upon which

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to determine or predict the effects of the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture. It also requires a finding that testing of the substance or mixture is necessary to develop such data. However, the House bill differs from the Senate bill in that it requires a finding that a chemical substance or mixture may "cause or significantly contribute" to an unreasonable risk, whereas the Senate bill requires a finding that the substance or mixture may "present" an unreasonable risk.

Section 4(a) (1) (B) of the House amendment sets forth a second set of conditions under which the Administrator shall require testing. If the Administrator finds (1) (A) that a chemical substance or mixture is or will be produced in substantial quantities; and (B) (i) either that it enters or may reasonably be anticipated to enter the environment in substantial quantities or (ii) there is or may be significant or substantial human exposure to the substance or mixture,

(2) there is an insufficiency of data, and (3) testing is necessary to develop the data, the Administrator shall, by rule, require testing.

The House amendment requires the Administrator to consult with the Director of the National Institute for Occupational Safety and Health before prescribing epidemiologic studies under the testing requirement rule. The House bill requires the Administrator to make and publish findings under subsection (a)(1)(A) or (a)(1)(B) before the issuance of a rule ordering persons to conduct tests. The House amendment also provides for the expiration of a testing requirement rule at the end of the reimbursement period.

The House amendment provides for exceptions from the testing rule in order to avoid submission of duplicative data. If an exemption is granted, reimbursement requirements similar to those in the Senate bill apply, except that the reimbursement period may last as long as five years, instead of the two-year period in the Senate bill. In promulgating rules to use in determining fair and equitable reimbursement, the House amendment does not require the Administrator to consult with the Attorney General and the Federal Trade Commission.

With respect to the interagency committee's priority list submitted to the Administrator, the House amendment does not require the Administrator either to initiate a rulemaking proceeding or to publish in the Federal Register the Administrator's reasons for not initiating such a proceeding. The House amendment does not include the conflict of interest provisions found in the Senate bill relating to members of the interagency advisory committee.

Conference substitute {section i)

The conference substitute is similar to the House amendment with respect to the findings which the Administrator must make in order to require a manufacturer or processor to test a chemical substance or mixture, except that the term "presents" is used in lieu of "cause or significantly contribute to". The conference substitute includes this term throughout the bill when speaking of a risk.

In using the term, the conferees intend that the Administrator be able to address substances and mixtures which indirectly present unreasonable risks, as well as those which directly present such risks. Further, the conferees do not intend that a substance or mixture must be the single factor which results in the presentation of the risk.

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Oftentimes an unreasonable risk will be presented because of the interrelationships or cumulative impact of a number of different substances or mixtures. The conferees intend that the Administrator have authority to protect health and the environment in such situations.

In following the House language, the conference substitute requires testing not only (1) in situations in which a substance or mixture may present an unreasonable risk, but also (2) in situations in which there may be substantial environmental or significant or substantial human exposure to a substance or mixture about which there is inadequate information to predict effects on health or the environment.

In the first situation, the conferees intend to focus the Administrator's attention on those chemical substances and mixtures about which there is a basis for concern, but about which there is inadequate information to reasonably predict or determine their effects on health or the environment. The Administrator need not show that the substance or mixture does or will present a risk.

The second situation reflects the conferees' recognition that there are certain situations in which testing should be conducted even though there is an absence of information indicating that the substance or mixture per se may be hazardous.

The conference substitute follows the House amendment with respect to the contents of the testing rule. The Senate provision concerning which manufacturers and processors are required to conduct the testing and submit test data is included. Like both the Senate bill and the House amendment, the conference substitute permits the Administrator to grant exemptions from a testing rule. To grant an exemption, the Administrator must determine whether the chemical substance or mixture is equivalent to a chemical substance or mixture for which test data is already being developed. In making this determination the conferees expect the Administrator to look at any contaminants in the chemical substance or mixture for which an exemption is being sought and ascertain whether any contaminants present might cause differences in test data which would be significant and which would, therefore, cause the Administrator to determine that the chemical substances or mixtures in that instance were not equivalent. It also follows the House amendment concerning reimbursement, except that the Administrator must consult with the Attorney General and the Federal Trade Commission in issuing rules which establish the general criteria for determining reimbursement.

The conference substitute retains a modified version of the Senate

provision on the interagency committee which is established to make recommendations concerning testing priorities to the Administrator.

The Administrator shall provide administrative services to support such activities. These services shall encompass such things as clerical staff assistance and supplies. The conferees recognize the importance of the interagency committee recommendations and expect the interagency committee to deliberate with care; therefore, the conferees intend that members of the interagency committee shall be given adequate support services by EPA. They also shall be relieved of responsibilities within the entity they represent to the extent necessary to carry out their duties to the committee. Each entity represented shall provide its member with professional and research services. Here,

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as in all places in the bill where specific officers of the Federal Government are referred to by title, the conferees intend that such references be construed to mean successors to such offices as affected by any reorganization plan or the like.

The interagency committee may designate a maximum of 50 substances or mixtures with respect to which the Administrator should initiate a testing rulemaking proceeding within a year. No more than 50 substances or mixtures may be so designated at any one time. If the Administrator does not take such action within a year, the Administrator must publish in the Federal Register an explanation as to why such action has not been taken.

The conferees have given discretion to the interagency committee as to how many substances or mixtures should be designated. Although the committee may designate up to 50 substances or mixtures at any one time, the conferees wish to stress that the committee need not designate the maximum number. While it is intended that the recommendations of the interagency committee be given great weight by the Administrator, it should be emphasized that the decision to require testing rests with the Administrator.

The conferees do not intend that, in complying with the requirements of the statute, the Administrator divert from the regulatory activities of the Agency an inordinate amount of resources to justify the failure to require testing.

If the Administrator receives information which indicates to the Administrator that there may be a reasonable basis to conclude that a substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects, the Administrator shall initiate appropriate action under section 5, 6, or 7 to protect against the risk or publish in the Federal Register a finding that the risk is not unreasonable. Such action must be taken within 180 days of the receipt of the data, except that the Administrator may extend that period for an additional 90 days for good cause. This requirement does not take effect until two years after the date of enactment.

The conference substitute adopts a provision contained in the House amendment which enables any person who intends to manufacture or process a chemical substance which is not subject to a rule under section 4(a) to petition the Administrator to prescribe standards for the development of test data for such substance. The Administrator must grant or deny the petition within sixty days. If the petition is granted, the Administrator shall prescribe such standards within seventy-five days of the date on which the petition is granted. Any denial of such a petition must be published in the Federal Register.

MANUFACTURING AND PROCESSING NOTICES

Senate till {section 5)

The Senate bill requires any manufacturer of a new chemical substance to notify the Administrator at least ninety days prior to the commencement of commercial manufacture of the new substance. The notice is to include the common and the trade name of the substance, its chemical identity and molecular structure, categories or proposed cate-

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gories of use, reasonable estimates of the amount to be manufactured or processed, a description of the by-products, estimates of the number of people who will be exposed to the substance in their places of employment, and existing data concerning environmental and health effects of the substance.

In addition, if a testing rule applicable to the substance is in

effect prior to submission of the notice, the manufacturer is required to submit along with the notification, the test data required to be developed by the testing rule.

The ninety day notification period may be extended by the Administrator for an additional ninety days for good cause shown. Notice of such extension must be published in the Federal Register.

Similar notification is required of any person intending to manufacture or process a chemical substance for a distribution in commerce, use, or disposal that has been identified by the Administrator, by rule, as a significant new use, distribution, or disposal. The Administrator is, by rule, to establish criteria defining a significant new distribution in commerce, use, or disposal. In establishing such criteria, the Administrator is to take into account the projected volume of production and category or categories of uses, increases in magnitude and duration of human or environmental exposure, routes of exposure, and the human health and environmental effects.

The Senate bill authorizes the Administrator to issue immediately effective administrative orders during the notification period to halt or limit the manufacture, processing, distribution in commerce, use or disposal of new chemical substances subject to the notification requirements in two situations.

First, the Administrator is required to issue such an order if the Administrator finds that a testing requirement under section 4 (a) should be established or modified. The order is to remain in effect until an expedited rulemaking proceeding under section 4(a) to require testing can be completed, the testing performed and the test data submitted. Second, if the Administrator finds that a new substance presents or is likely to present an unreasonable risk of injury to health or the environment, the Administrator is also required to issue an immediately effective order. If such an order is issued, the Administrator must conduct an expedited rulemaking proceeding in accordance with the provisions of section 6(c) (2) and (3).

If the Administrator does not take action to prohibit or limit the manufacture, processing, distribution in commerce, use or disposal of a new substance during the notification period, the Administrator is required to publish a statement of reasons in the Federal Register for not taking such action. The statement must be published prior to the expiration of the notification period. Manufacture or processing of the new substance may commence following publication of the Administrator's statement. Failure to take action against a substance is an action subject to judicial review.

The Senate bill provides certain exemptions from the requirement

to submit manufacturing and processing notice. The Administrator is authorized to grant such an exemption for test marketing or other specially limited purposes. In addition, the Administrator may exempt chemical substances which are intermediate reaction products

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formed during the manufacture of another chemical substance and to which there is no human or environmental exposure. In addition, the notification provisions of the Senate bill do not apply to any chemical substance manufactured in small quantities solely for scientific experimentation or analysis or for chemical research or analysis, including such research or analysis for the development of a product. However, the Administrator may, by rule, require notification prior to the manufacture or processing of such a substance upon a finding that the substance may cause or contribute to an unreasonable risk of injury to health or the environment. Although the section, by its terms, does not apply to mixtures, the Administrator is authorized to specify any mixture which shall be subject to the provisions of the section.

House amendment {section 6)

Like the Senate bill, the House amendment requires manufacturers of new chemical substance to notify the Administrator ninety days prior to the commencement of commercial manufacture of such new substance. The notice is to include information similar to that required by the Senate bill, including test data required to be developed by any applicable testing rule which has been promulgated under section 4 prior to the submission of the notice.

In addition, the House amendment requires the Administrator to compile and maintain a list of chemical substances which cause or significantly contribute to or may cause or significantly contribute to an unreasonable risk to health or the environment. If a person intends to manufacture a new chemical substance included on this list and if no testing rule applicable to the substance has been issued under section 4, the person must submit to the Administrator information which the person believes indicates that the chemical substance will not cause or significantly contribute to an unreasonable risk. Such information must be submitted along with the notice.

The House amendment also requires manufacturers or processors of an existing chemical substance for a new use which has been designated by the Administrator, by rule, as a significant new use, to provide similar notice ninety days prior to such manufacture or processing. The House amendment does not require notification prior to the manufacture or processing of a chemical substance for a significant new distribution in commerce or disposal.

In instances in which there is inadequate information to evaluate the effects of a new substance or of an existing substance for a significant new use, the Administrator is authorized to seek a court injunction to halt manufacture, processing or distribution in commerce. The Federal district courts are empowered to grant injunctions if the court finds that (1) there is inadequate information to reasonably evaluate the health and environmental effects of the new substance and (2) in the absence of such information, the substance may cause or significantly contribute to an unreasonable risk. If an injunction is granted, the Administrator shall conduct an expedited rulemaking proceeding to determine if a lesser restriction (rather than a total halt of manufacture, processing or distribution) would be adequate to protect health or the environment until adequate test data is developed and evaluated.

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The House amendment does not require the Administrator to publish a statement of reasons for not taking action during the notification period to prohibit or limit the manufacture, processing, distribution, use or disposal of a new substance or of an existing substance manufactured or processed for a significant new use.

The House amendment also provides for exemptions from the notification requirements. The Administrator is authorized to provide an exemption for the manufacture and processing of a substance for test marketing purposes. The House bill specifically exempts from the notification requirements those chemical substances manufactured or processed in small quantities for scientific experimentation or analysis or for chemical research or analysis on such substance or another substance, including research and analysis for the development of a substance or another substance into a commercial product. However, all persons engaged in such experimentation, research or analysis for a manufacturer or processor must be notified of any risk to health which

the manufacturer or processor has reason to believe may be associated with the substance.

The House amendment authorizes the Administrator, by rule, to exempt a manufacturer or processor of any new chemical substance from all or part of the requirements of this section if the Administrator determines that such chemical substance will not cause or significantly contribute to an unreasonable risk to health or the environment. The House amendment also contains an exemption clarifying that a chemical substance which, except for its inert ingredients, is identical to a chemical substance contained on the section 8(b) inventory will not be treated as a new chemical substance.

The House amendment does not authorize the Administrator to specify that a manufacturer of a mixture shall be subject to the notification requirements.

Conference substitute (section 5)

In general. – Section 5 sets out the notification requirements with which manufacturers of new chemical substances and manufacturers and processors of existing substances for significant new uses must comply. The requirements are intended to provide the Administrator with an opportunity to review and evaluate information with respect to the substance to determine if manufacture, processing, distribution in commerce, use or disposal should be limited, delayed or prohibited because data is insufficient to evaluate the health and environmental effects or because the substance or the new use presents or will present an unreasonable risk of injury to health or the environment.

The provisions of the section reflect the conferees recognition that the most desirable time to determine the health and environmental effects of a substance, and to take action to protect against any potential adverse effects, occurs before commercial production begins. Not only is human and environmental harm avoided or alleviated, but the cost of any regulatory action in terms of loss of jobs and capital investment is minimized. For these reasons the conferees have given the Administrator broad authority to act during the notification period.

Any person who intends to manufacture a new chemical substance or manufacture or process a chemical substance for a use which the Administrator, by rule, has determined is a significant new use, must

give the Administrator at least 90 days notice before beginning such manufacture or processing, The 90-day period shall begin upon receipt of the notice by the Administrator or the Administrator's duly designated representative.

The conferees have not included the Senate provision which requires notification of significant new distributions or disposals. However, the conference substitute requires that the Administrator consider the reasonably anticipated manner and method of manufacturing, processing, distribution in commerce and disposal of a substance in determining when a use will be considered a significant new use. Thus, the conferees intend that any potential threats to health or the environment from the manufacture, processing, distribution in commerce, or disposal of a substance associated with a new use be considered by the Administrator when determining the significance of a new use. In addition, the Administrator shall consider the projected volume of manufacturing and processing of the substance for a use, the extent to which a use changes the type or form of exposure of human beings or the environment to a substance, and the extent to which such use increases the magnitude and duration of human or environmental exposure to a substance. Thus, a significant increase in the projected volume of manufacture or processing for a substance, a significant change in the type or form of human or environmental exposure, or a significant increase in the magnitude or duration of human or environmental exposure could be the basis for determining that a use is a significant new use.

Submission of test data. - Subsection (b) describes the instances in which a person subject to a notification requirement with respect to a chemical substance under subsection (a) must submit test data to the Administrator before manufacture of the substance or manufacture or processing of the substance for a significant new use can begin. If a rule under section 4 respecting a substance has been promulgated before submission of the notice required by subsection (a), then a person who is required by the section 4 rule to submit test data for the substance must submit 'such test data at the time the notice is submitted in accordance with subsection (a). This assures that the Administrator will have at least 90 days to evaluate the test data before the manufacture or processing begins. If a person has been granted an exemption from a testing rule under section 4 applicable to a new substance or to a significant new use of an existing substance, such person shall not begin manufacture or processing until 90 days after the date of submission of the test data on which the exemption is based.

It should be noted that if a testing rule under section 4 respecting a substance has not been promulgated prior to the submission of a notice required by section 5, the Administrator may promulgate a testing rule under section 4 for such substance without taking separate action under this section. However, such a rule would not delay the manufacture or processing of the substance.

The conferees adopted a provision from the House bill to insure that information respecting the health and environmental effects of any chemical substance which the Administrator has identified as a suspect chemical substance is submitted at the time of notification. Under

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the conference substitute the Administrator may, by rule, compile a list of chemical substances the manufacture, processing, distribution in commerce, use or disposal of which presents or may present an unreasonable risk of injury to health or environment. If a testing rule under section 4 has not been promulgated with respect to such substance before the submission of the notice, then the person submitting the notice must submit to the Administrator data which the person believes shows the manufacture, processing, distribution in commerce, use and disposal of the substance or any combination of such activities will not present an unreasonable risk to health or the environment.

Extension of notice period. - The Administrator, for good cause, may extend the 90 day notification period for additional periods not to exceed in the aggregate 90 days. Notice of any extension together with the reasons for it shall be published in the Federal Register and shall constitute final agency action subject to judicial review.

The conferees intend that the Administrator have a large degree of flexibility in extending the notification period, so that manufacture or processing may begin as soon as the Administrator has sufficient information to evaluate the substance. For example, if the Administrator expects that sufficient data will be available 30 days after the original notification period will expire, then the conferees expect that the Administrator will settle on an extension period which will reasonably accommodate production of that data and time for administrative consideration. If production of the data is delayed, of course the Administrator may extend the original extension period. However, in no case may the extensions exceed a total of 90 days. Every time that the

notification period is extended, the Administrator must publish notice of the extension in the Federal Register along with reasons therefor.

Content of notice; publications in the Federal Register. – The conference substitute requires the notice required under subsection (a) to include certain information described in section 8(a) (Reporting and Retention of Information) whether or not the Administrator has required its submission under that section ; any test data in the possession or control of the person giving the notice which is related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use or disposal of the substance ; and a description of any other data concerning the health and environmental effects of the substance, insofar as known to the person making the report or insofar as reasonably ascertainable. The notice shall be made available, subject to section 14, for examination by interested persons.

In order that the public receive timely notification of any new chemical substance or any significant new use of an existing chemical substance, the conference substitute includes a provision which requires the Administrator to publish in the Federal Register a notice which identifies the chemical substance, lists the uses or intended uses of the substance, and describes the nature of tests performed on such substance and any data developed pursuant to subsection (b) or a rule under section 4. Such publication must occur within 5 days after the Administrator receives notice from the person who intends to manufacture or process.

The conference substitute also requires the Administrator to publish monthly a list of each chemical substance for which notice has been

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received under subsection (a) and for which the notification period has not expired. The Administrator must also include on the list those substances for which the notification period has expired since the last monthly publication.

Regulation pending development of information. – Subsection (e) sets out the procedures under which the Administrator can halt or limit the manufacture, processing, distribution in commerce, use, or disposal of a new substance or an existing substance for a significant new use when there is insufficient information to evaluate the health and en-

vironmental effects of the substance.

Action to prohibit or limit manufacture, processing, distribution in commerce, use, or disposal is required in instances in which the Administrator determines that :

(1) Information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the substance, and

(2) (a). In the absence of information sufficient to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of the substance may present an unreasonable risk of injury to health or the environment, or

(b) . The substance is or will be produced in substantial quantities, and (i) enters or may reasonably be anticipated to enter the environment in substantial quantities or (ii) there is or may be significant or substantial human exposure to the substance.

If the Administrator makes the above determination at least 45 days before the expiration of the notification period, then the Administrator may issue a proposed order to prohibit or limit the manufacture, processing, distribution in commerce, use or disposal of the substance. A limitation on manufacture or processing could, of course, include a labeling requirement. The proposed order will take effect upon the expiration of the notification period unless the manufacturer or processor subject to the order files objections with the Administrator, specifying with particularity the provision of the order deemed objectionable and stating the grounds for the objection. To prevent the order from becoming effective, the objections must be filed within 30 days after the manufacturer or processor has received in writing from the Administrator a notice of the proposed order. The conferees wish to stress that the Administrator must provide actual notice in writing to the manufacturer or processor who will be subject to the order. Notice is not to be published in the Federal Register, but is, of course, available to the public if it is not prohibited from disclosure under section 14.

This provision thus represents a melding of the Senate bill and the House amendment. In order to insure that timely action may be taken by the Administrator, the conference substitute authorizes the Administrator to issue an administrative order to take effect immediately upon the expiration of the notification period. However, to protect against unilateral action by the administrator without an adequate basis for action, the conference substitute borrows the procedure from section 701 (^) of the Federal Food, Drug, and Cosmetic Act which permits the filing of objections by manufacturers and processors spe-

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cifying with particularity the provisions of the order deemed objectionable and stating the grounds for the objections.

If such objections are filed, then the Administrator is instructed to seek an injunction in a Federal district court to prohibit or limit the manufacture, processing, distribution in commerce, use or disposal of the substance. Of course, if the objections filed with the Administrator indicate to the Administrator that the injunction is not necessary, then the Administrator is not required to seek the injunction.

If the court finds in such injunction action that (1) information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the substance, and (2) (A) in the absence of such information, the manufacture, processing, distribution in commerce, use, or disposal of the substance may present an unreasonable risk of injury to health or the environment or (B) such substance is or will be produced in substantial quantities and it enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance, then the court shall grant an injunction. The conferees intend that this two-part standard totally supplant the traditional elements which a party must ordinarily show before a court will exercise its equitable jurisdiction to grant an injunction. The conferees do not intend that the Administrator be required to make any showing other than that which is required for the court to make the two findings described above. Application of any other standard by the court would frustrate the purposes of this section that suspect chemicals be adequately tested to determine their health and environmental effects before commercial manufacture or processing begins.

The conference substitute authorizes such courts to grant a temporary restraining order or a preliminary injunction to prohibit manufacture, processing or distribution of a new substance or of an existing substance for a significant new use if the court finds that the notification period may expire before the action for an injunction can be completed. The conferees recognize that a manufacturer or

processor, merely by beginning to manufacture, process, or distribute a new chemical or an existing chemical for a significant new use, could defeat the objective of section 5 to totally prevent environmental or human exposure to suspect new chemical substances or significant new uses of existing chemical substances until adequate testing can be performed and the data evaluated. Therefore, the conferees intend that the court freely exercise the authority to grant preliminary relief as is necessary to preserve the status quo in order to insure that the policy of this section can be fulfilled.

After submission of adequate test data to the Administrator and evaluation of such data, the district courts may, upon petition, dissolve the injunction unless the Administrator has initiated a proceeding under section 6(a) with respect to the substance. In such a situation, the injunction shall remain in effect until the effective date of a rule under section 6(a) or until the section 6 proceeding is terminated, whichever occurs first.

Protection against unreasonable risk. – Section 5(f) of the conference substitute requires the Administrator to take immediate action

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to prohibit or limit human or environmental exposure to a new chemical substance or to an existing chemical substance for a significant new use in certain situations. In section 5(f) the conference substitute authorizes the Administrator to issue a proposed rule under section 6(a), but such rule is to be effective upon its publication in the Federal Register. Such action is authorized in instances in which there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the substance presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 6(a) could protect against the risk. The conferees recognize, of course, that there is authority in section 6(d) under which the Administrator may make a proposed section 6(a) rule immediately effective. However, to invoke the section 6(d) authority the Administrator must find an imminent, unreasonable risk of serious or widespread injury. With respect to new chemical substances or substances for significant new uses, immediate action is authorized under section 5(f) when there is an imminent, unreasonable risk of injury, regardless of whether the injury will be serious or widespread.

The section 6(a) rule proposed and made immediately effective pursuant to the authority of this section may (A) limit the amount of a substance which may be manufactured, processed, or distributed in commerce, (B) contain any of the requirements described in paragraph (2), (3), (4), (5), (6), or (7) of subsection 6(a), or (C) contain any combination of the requirements described in clauses (A) and (B). Immediately following the publication in the Federal Register of a section 6(a) rule as authorized by this section, the Administrator must conduct an expedited rulemaking proceeding in accordance with the provisions of section 6(d) (2).

A rule under section 6(a) authorized by this section may not totally prohibit the manufacture, processing, or distribution in commerce of a new substance or an existing substance for a significant new use. In order to totally prohibit the manufacture, processing, or distribution in commerce of a new substance, or of an existing substance for a significant new use, the Administrator must either issue a proposed order which shall be subject to all the procedures applicable to the situation when there is an insufficiency of information, as described above, or obtain a court injunction. If the court finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use or disposal of a new substance or of an existing substance for a significant new use presents or will present an unreasonable risk of injury to health or the environment, the court shall issue an injunction. Again, the conferees intend that the court will not use the normal equity standard to determine if an injunction should be issued. Instead, the standard set out in section 5(f) (3) (B) of the conference substitute is intended to totally replace the normal injunction standard.

The conferees recognize that there will be instances in which there are a limited number of practical uses for a chemical substance and that by issuing an immediately effective proposed rule prohibiting those uses, the Administrator could effectively prohibit manufacture or processing altogether. The conferees view such a prohibition as a

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total prohibition of manufacture or processing and intend that the Administrator comply with the procedures of section 5 (f) (3) in order to obtain a total prohibition on manufacture or processing. The

authority to issue an immediately effective rule to prohibit manufacture or processing for a use should be utilized only when there is more than one practical use of a substance and when the prohibition does not effectively ban all such uses. Likewise, the conferees do not intend that the Administrator utilize the authority to issue an immediately effective proposed rule so severely limiting the amount of a substance which may be manufactured, processed, or distributed in commerce as to effectively prohibit manufacture, processing, or distribution.

Statement of reasons for not taking action. – If, within the notification period, the Administrator has not initiated action under this section or section 6 or 7 to prohibit or limit the manufacture, processing, distribution in commerce, use or disposal of certain new chemical substances or of existing chemical substances for significant new uses, then subsection (g) requires the Administrator to issue a statement of reasons in the Federal Register for not initiating such action. The statement must be published prior to the expiration of the notification period. The chemical substances for which such a statement is required are those for which the Administrator, because of prior administrative action with respect to such chemical substances, has indicated there may be particular cause for concern. Specifically, a statement of reasons for not initiating action is required if a testing rule under section 4 applies to a new substance or an existing substance for a significant new use, or if a substance is listed under section 5(b) (4). In addition, if notification is required because a use constitutes a significant new use and, if no action is initiated during the notification period, the Administrator must issue a statement of reasons for not initiating such action.

Publication of the statement of reasons in accordance with this subsection is not a prerequisite to the manufacture or processing of the substance with respect to which the statement is to be published. Thus, the Administrator, merely by not issuing the statement of reasons, cannot delay the beginning of manufacture or processing of a new substance or a substance for a significant new use. Nonetheless, the Administrator must perform this non-discretionary duty and will subject himself not only to criticism by the Congress for not doing so, but may also subject himself to suit under section 20 of this Act or other provisions of law relating to the required performance of non-discretionary duties.

Exemption.s. – Subsection (h) describes the situations in which a chemical substance may be manufactured or processed without regard to the notice and test data submission requirements of subsections (a) and (b). Paragraph (1) provides the authority for granting an exemption for test marketing purposes. Under paragraph (2) an exemption from the test data submission requirements of subsection (b) may be obtained if submission of data for the substance to be exempted would be duplicative of data already submitted to the

Administrator. Paragraph (3) adopts the language in the House amendment specifically exempts: from the notification requirements those chemical substances manufactured or processed or proposed to be manufactured or processed in small quantities (as defined by the

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Administrator by rule) for scientific experimentation or analysis or for chemical research or analysis, including research and analysis for the development of the substance or another chemical substance into a commercial product. All persons engaged in such experimentation, research, or analysis for a manufacturer or processor must be notified or any risk to health which the manufacturer or processor or Administrator has reason to believe may be associated with the substance.

Under paragraph (4), the Administrator may, upon application and by rule, exempt the manufacturer of a new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use or disposal of the substance will not present an unreasonable risk of injury to health or the environment. A rule granting such an exemption must be promulgated in accordance with paragraphs (2), (3), and (4) of section 6(c).

Paragraph (5) authorizes the Administrator to make the requirements of subsection (a) and (b) inapplicable with respect to the manufacture or processing of a chemical substance which may temporarily exist as a result of a chemical reaction in the manufacture or processing of a mixture or another chemical substance and to which there is not or will not be any human or environmental exposure.

The conference substitute deletes the provision in the House amendment which clarified that a chemical substance is not to be treated as a new chemical substance solely because of the change in proportions of inert ingredients. This provision of the House amendment was deleted because under the definition of "mixture" in section 3 of the conference substitute the same result would occur, as any change in inert ingredients would constitute a new mixture not a new chemical substance. Mixtures are not covered by section 5.

Definition. - The terms "manufacture" and "process" as used in this section mean to manufacture or to process for commercial purposes.

Since the term "manufacture" is defined to include import, persons who intend to import substances for commercial purposes will be treated in the same manner as domestic manufacturers under section 5.

REGULATION OF CHEMICAL SUBSTANCES AND MIXTURES

'Senate bill (section 6)

The Senate bill requires the Administrator to impose restrictions on a chemical substance or mixture if the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal presents or is likely to present an unreasonable risk of injury to health or the environment. The Administrator shall impose one or more of several specified requirements as is necessary to adequately protect against the risk, using the least burdensome of effective controls.

A range of requirements is provided, from complete prohibitions on the manufacturing, processing, or distribution in commerce to labeling requirements. Among these is the authority to regulate the manner of method of use or disposal of such substance or mixture and the authority to require manufacturers or processors to replace or repurchase substances or mixtures found to present unreasonable risks.

The Senate bill also contains the authority to limit the amount of a substance or mixture which may be manufactured, processed, or dis-

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tributed in commerce, or which may be manufactured, processed, or distributed in commerce for a particular use. A procedure for assigning permissible quotas if the applicable parties are unable to agree is provided. Supervision by the Attorney General and the Federal Trade Commission is provided for any voluntary efforts to establish quotas.

The Senate bill authorizes the Administrator to order manufacturers or processors to submit descriptions of relevant quality control procedures if the Administrator has good cause to believe that the manufacture or processing causes the adulteration of a chemical substance or mixture. If the Administrator determines that the quality control procedures of the manufacturer or processor are inadequate, the Administrator may order revisions in the quality control procedures to the extent necessary to remedy the inadequacy.

The Senate bill also requires the Administrator to consider relevant factors in imposing restrictions and to make findings with respect to certain factors.

The Senate bill contains a specific rulemaking procedure for rules imposing restrictions under this section. The procedure is an informal one, similar to the procedures in section 553 of title 5, United States Code, but there are exceptions, including an opportunity for an informal hearing. An opportunity for appropriate cross-examination in the hearing is provided under the supervision of the Administrator. Participants in a rulemaking proceeding may be compensated by the Administrator under specified criteria.

The Administrator may specify the date on which a rule under this section becomes effective, which shall be as soon as administratively feasible.

The Administrator may waive the required notice and comment period in those situations where compliance with the rulemaking provisions would present an unreasonable risk of death, serious or substantial personal injury, or serious or substantial environmental harm.

Finally, the Senate bill provides for the control of polychlorinated biphenyls (PCBs). Effective one year after the date of enactment of the Act, PCBs may not be used in any manner other than a totally enclosed manner, except that the Administrator may, by rule, authorize exceptions if the Administrator finds that no unreasonable risk of injury to health or the environment is presented. Effective two years after the date of enactment, the manufacture of any polychlorinated biphenyl would become unlawful. Effective two and one-half years after such date, the processing or distribution in commerce of PCB's would become unlawful, except that the Administrator may make exceptions if no unreasonable risk of injury to health or the environment is presented. Disposal regulations concerning PCB's shall be promulgated within six months after the date of enactment.

House amendment {section 6)

The standard for taking action against unreasonable risks under this section in the House amendment is slightly different from that contained in the Senate bill. If the Administrator finds that there is a reasonable basis on which to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or any combination of such actions causes or significantly contributes to, or will cause or significantly contribute to, an unrea-

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sonable risk to health or the environment, the Administrator shall impose requirements as necessary to protect against the risk. The requirements generally are similar to the requirements of the Senate bill, with several exceptions. The Administrator may not regulate the manner or method of use. Nor may the Administrator impose replacement or repurchase requirements for substances regulated. Requirements regulating the manner or method of disposal may not require any person to take an action in violation of a State or local law. Also, a person subject to a disposal requirement shall notify the State in which a required disposal may occur of such requirement. The House amendment does not contain authority to impose manufacturing or processing quotas.

The House amendment provides a procedure for protecting against unintentional contamination of a chemical substance due to the manner of manufacturing or processing. Quality control procedures may be required to be submitted. If found inadequate, the Administrator may order such procedures to be changed. In addition, if the quality control procedures have resulted in the distribution in commerce of substances or mixtures which cause or significantly contribute to an unreasonable risk to health or the environment, the Administrator may require manufacturers or processors to give notice and to replace or repurchase any such substance or mixture as is necessary to protect health or the environment.

In promulgating any rule under section 6(a), the Administrator shall consider all relevant factors and make findings with respect to certain factors.

The Administrator shall not promulgate a rule under this section if the risk could be eliminated or reduced to a sufficient extent under another federal law administered by the Administrator unless the Administrator makes a finding that it is in the public interest to do so, taking into consideration a number of enumerated factors.

The rulemaking procedures of the House amendment are generally similar to those contained in the Senate bill.

The Administrator may make a rule immediately effective if an unreasonable risk of serious or widespread liarm to health or the environment will occur prior to the completion of the rulemaking proceedings,

and making the rule so effective is necessary to protect the public interest. If a proposed rule totally prohibits the manufacture, processing or distribution of a chemical substance or mixture, a court must have previously taken action against a substance or mixture in an imminent hazard' proceeding under section 7. An expedited rulemaking procedure is provided for immediately effective rules.

The provision of the House amendment relating to PCBs is similar to the Senate bill with a few exceptions. For example, the prohibitions effective in one year apply only to the manufacture, processing or distribution in commerce for a use other than a use in a totally enclosed manner. In addition, exemptions from the prohibitions relating to the manufacture, processing, and distribution of PCB's may be granted, if the Administrator determines that the exemption is necessary to protect health or the environment, and good faith efforts have been made to develop substitutes.

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Conference substitute {section 6)

The conference substitute requires the Administrator to take action under this section against chemical substances or mixtures for which there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substances or mixtures, or any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment. Requirements shall be imposed to the extent necessary to protect against the risk.

The requirements must be the least burdensome feasible for those subject to the requirement and for society while providing for an adequate margin of protection against the unreasonable risk.

The requirements which may be imposed are similar to those included in both the Senate bill and the House amendment. The Administrator may impose requirements regulating the manner or method of the commercial use of a substance or mixture and also requirements regulating the manner or method of disposal of a substance or mixture or an article containing a substance or mixture by the manufacturer or processor or by any other person who uses or disposes of it for commercial purposes. The provision of the House amendment that

a disposal requirement may not require any person to take action in violation of any State law or political subdivision is included. The conference substitute also includes the Senate provision which authorizes the Administrator to require replacement or repurchase by manufacturers or processors of substances or mixtures with respect to which action has been taken under this section.

The provisions of the House bill relating to quality control are included.

The provisions of the Senate bill which authorize the Administrator to assign manufacturing or processing quotas are not included.

The conferees appreciate that if the Administrator chooses to impose a production limitation on any chemical substance, such limitation, if not carefully drawn, could produce monopoly profits. The conferees believe that the Administrator should consult with the Attorney General and the Federal Trade Commission in order to avoid any anticompetitive consequences.

The conference substitute requires the Administrator to consider certain enumerated factors and to publish a statement in the Federal Register with respect to them at the time of promulgation of a rule under section 6(a). Specifically, the Administrator must consider and publish a statement concerning the effects of the substance or mixture on health and the magnitude of human exposure to such substance or mixture; the effects of the substance or mixture on the environment and the magnitude of environmental exposure to such substance or mixture; the benefits of such substance or mixture for various uses and the availability of substitutes for such uses; and the reasonably ascertainable, economic consequences of the rule, after consideration of the effects on the national economy, small business, innovation, the environment, and the public health. This requirement was contained in both the Senate bill and the House amendment. The purpose in requiring such a statement is to assure that the basis for the Administrator's rule are publicly enumerated. By requiring the statements,

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the conferees intend to emphasize key considerations which must be addressed. The conferees do not intend that the statement be detailed or voluminous. A succinct and precise statement of these key con-

siderations will suffice. Of course, the statements will provide part of the rulemaking record for judicial review of a rule promulgated under section 6(a).

Moreover, if the Administrator determines that a risk may be eliminated or reduced to a sufficient extent by actions taken under another Federal law administered by the Administrator, action may not be taken under this section unless the Administrator finds, in the Administrator's discretion, that it is in the public interest to take action under this Act. By committing such determination to the Administrator's discretion, the conferees intend that such determination not be subject to judicial review.

The House provision relating to compensation for the costs of participating in a rulemaking proceeding and the provisions relating to the effective date of a rule are included. Generally rules are to be effective as soon as procedurally and administratively feasible. However, proposed rules may be declared to be immediately effective by the Administrator in certain instances. The rule may be declared immediately effective if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of a substance or mixture is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before the normal effective date and making the rule immediately effective is necessary to protect the public interest. In the case of a rule to prohibit the manufacture, processing, or the distribution, a court must have granted relief in an imminent hazard action under section 7. An expedited rulemaking procedure is provided if a rule is made immediately effective.

The conference substitute includes procedures contained in both bills for prescribing rules. In general, rules under this section are to be prescribed in accordance with the informal rulemaking procedures of section 553 of title 5, United States Code, except that an opportunity for an oral hearing and for limited cross-examination is provided. The procedures are patterned after those contained in section 18 of the Magnuson-Moss Warranty-Federal Trade Commission Improvements Act.

The Senate bill, unlike the House amendment, specifically authorizes the Administrator to conduct cross-examination on behalf of the participants to the proceeding. Although the conference substitute retains the Senate provision, the conferees expect that in most instances the participants themselves would conduct the cross-examination, subject to the Administrator's time limitations and other rules.

Under the Act states that the transcripts shall be available to the public, the conferees intend that such availability be construed in a reasonable manner. No person may be denied access to such informa-

tion, but at the same time the Administrator shall not be required to assume the burden of copying what may be a formidable amount of material. Therefore, the conferees intend that the Administrator furnish copies of transcripts as long as a supply exists within EPA. However, if the amount of material is vast, or if EPA has run out of copies, then the person may inspect the transcript which shall be available at every regional office of EPA. EPA may photocopy a reasonable num-

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ber of pages, such as 200, but shall in all cases afford any person the opportunity to photocopy as much of the transcript as the person desires. The cost of copying pages beyond a reasonable number shall be borne by the person ; however, the Administrator shall not charge an unreasonable fee per page.

Generally, the provisions of the Senate bill relating to the control of polychlorinated biphenyls are included. The standard that must be satisfied before exemptions from the complete ban on polychlorinated biphenyls are granted contains elements of both the House and Senate provisions. Exemptions may be granted only if the Administrator finds that there is no unreasonable risk to health or the environment, and that good faith efforts have been made to develop a substitute. So that existing PCBs may be reused rather than disposed of, the prohibitions do not apply to distributions in commerce of PCBs sold for purposes other than resale before the effective date of the prohibition on distribution of PCBs.

IMMINENT HAZARDS

Senate bill {section 7)

The Senate bill authorizes the Administrator to initiate a judicial proceeding against an imminently hazardous chemical substance or mixture or against any person who manufactures, processes, distributes in commerce, uses or disposes of such substance or mixture or against both. The court is authorized to grant such temporary or permanent relief as is necessary to protect against the hazard. Such relief may include seizure and condemnation of the imminently hazardous substance or mixture. Further, the court is specifically authorized to require manufacturers, processors, or distributors to provide notice of the hazard to purchasers of the substance or mixture and to the

public, and to recall and replace or repurchase the substance or mixture. Under the Senate bill an imminent hazard is considered to exist when the evidence is sufficient to show that a situation exists in which the continued use of a substance or mixture would be likely to result in unreasonable adverse effects on the environment or an unreasonable hazard to the survival of an endangered species. An unreasonable adverse effect is defined to mean an unreasonable risk to man or the environment taking into account the economic, social, and environmental costs and benefits of the use of the substance or mixture.

House amendment {section 7)

The House amendment differs from the Senate bill in three ways. First, in addition to authorizing action against imminently hazardous substances and mixtures, the House amendment explicitly authorizes actions against articles containing such substances or mixtures. Second, if the Administrator has not acted under section 6(d) of the House amendment which authorizes immediate administrative action against an imminent hazard, the Administrator is required to take action under section 7. Third, the House amendment differs from the Senate bill in its definition of an imminent hazard. Under the House amendment an imminently hazardous chemical substance or mixture is one which causes or significantly contributes to an imminent and unreasonable risk of serious or widespread harm to health or the environment. Such risk shall be considered imminent if it is shown that the

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manufacture, processing, distribution in commerce, use or disposal of a substance or mixture is likely to result in an unreasonable risk of serious or widespread harm to health or the environment before a final rule under section 6 can protect against the risk.

Conference substitute {section 7)

The conference substitute follows the House language with a clarification (contained in the Senate bill) that relief is authorized against persons who use or dispose of an imminently hazardous substance or mixture in addition to persons who manufacture, process, or distribute in commerce such substances or mixtures. If the Administrator has not used the authority provided in section 6(d)(2)(A)(i) to make a section 6(a) rule immediately effective in order to protect against an

imminently hazardous substance or mixture, the Administrator must bring an action under section 7. The conferees have imposed such a nondiscretionary duty upon the Administrator to insure that protection is provided against imminently hazardous substances, mixtures, and articles containing such substances and mixtures.

The conferees wish to note that while the unreasonable risk of injury must be imminent, the physical manifestations of the injury itself need not be. Rather, an imminent hazard may be found at any point in the chain of events which may ultimately result in injury to health or the environment. The observance of actual injury is not essential to establish that an imminent hazard exists. The conferees intend that action under the imminent hazard section be able to occur early enough to prevent the final injury from materializing. In using the term "widespread injury" the conferees do not intend that the imminent hazard authority with respect to widespread harm be limited to instances in which the risk of injury is geographically widespread. Rather an unreasonable risk of harm affecting a substantial number of people, even though it is within a rather limited geographic area, should be deemed adequate to satisfy the requirement of an unreasonable risk of widespread injury to health. Of course if the risk of injury to health or environment is serious, it need not be widespread.

REPORTING AND RETENTION OF INFORMATION

Senate bill (sections)

Section 8 sets forth requirements for reporting and retention of information. Under subsection (a) the Administrator shall issue rules which require each person who manufactures or processes a chemical substance or mixture to maintain records and to make such reports as the Administrator may reasonably require. Such rules shall require manufacturers or processors of chemical substances or mixtures who produce such substances or mixtures in small quantities solely for scientific experimentation or analysis for chemical research or analysis to maintain records and to submit reports only to the extent necessary for the effective enforcement of the Act. This subsection also contains an illustrative list of the kinds of information which the Administrator may require from manufacturers or processors of chemical substances

To determine which substances are new chemical substances for the purpose of the pre-market notification provisions of section 5, sub-

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section (b) requires the Administrator to publish an inventory of existing chemical substances or mixtures which any person report to be commercially manufactured or processed within the United States under subsection (a) or under section 5(a). The Administrator shall publish such list not later than 270 days after the date of enactment.

Subsection (c) requires any person who manufactures, processes, or distributes chemical substances or mixtures to maintain records of adverse reactions to health or the environment alleged to have been caused by any such substance or mixture. These records shall be maintained for 5 years from the date the information was reported to such person, except that reports dealing with adverse reactions of employees shall be retained for 30 years.

Subsection (d) requires the Administrator to promulgate rules with respect to the submission of lists of health and safety studies conducted or initiated by an}- manufacturer, processor, or distributor in commerce of any chemical substance or mixture. The Administrator may require the submission of any study appearing on the list.

Subsection (e) requires manufacturers, processors, or distributors in commerce of a chemical substance or mixture as well as their liability insurers to inform the Administrator when they receive information which supports the conclusion that such substance or mixture causes or contributes to an unreasonable risk of injury to health or the environment. Such persons are relieved of such requirement when they have reason to believe that the Administrator has been adequately informed of the risk.

House amendment {section 8)

Subsection (a) of the House amendment is substantially similar to the Senate bill except that it exempts small manufacturers or processors from the reporting requirements. The Administrator may, by rule, require such persons to maintain records and submit reports on a chemical substance or mixture subject to a rule or a proposed rule under section 4, 5 (c) , 5 (g) , or 6. In addition, if relief has been granted in an imminent hazard proceeding under section 7, the Administrator may, by rule, require a small manufacturer or processor to maintain records and submit reports. After consultation with the Administrator of the Small Business Administration, the Administrator, shall, by rule, prescribe standards for determining which manufacturers and processors will be considered "small" manufacturers and processors.

As a further limitation, section 8(a) (1) (B) specifies that the Ad-

ministrator may not require the maintenance of records or the submission of reports with respect to changes in the proportions of the components of a mixture, unless the Administrator finds that such recordkeeping or reporting is necessary for the effective enforcement of the Act.

With respect to the inventory of existing chemical substances required by subsection (b), the House amendment provides that the inventory shall include at least each chemical substance which any person reports under section 5 or under section 8(a) was commercially manufactured or processed in the United States within 3 years before the effective date of the rules promulgated under section 8(a). The House amendment requires the publication of such inventory within 1 year after the effective date of the Act.

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Subsection (c) differs from the Senate bill in that it allows the Administrator to determine, by rule, the requirements respecting the maintenance of records of adverse reactions to health or the environment alleged to have been caused by a substance or mixture. The Administrator may require that records relating to adverse reactions to employee health be retained for up to 50 years.

Subsection (d) concerning submission of lists of health and safety studies is similar to the Senate bill.

Subsection (e) of the House amendment does not require liability insurers to report to the Administrator information which supports the conclusion that a substance or mixture may cause or significantly contribute to an unreasonable risk of injury. Manufacturers, processors, and distributors must report information relating to a substantial risk to health or the environment unless they have actual knowledge that the Administrator has been adequately informed of such risk.

Subsection (f) of the House amendment provides definitions of "manufacture" and "process" for the purposes of section 8.

Conference substitute {section 8)

The conference substitute follows with some modification the House

amendment of section 8 which outlines the policies and procedures for reporting and retention of information. Subsection (a) identifies which persons must, pursuant to rules promulgated by the Administrator, maintain records and make reports. The conference substitute provides an illustrative list of the kinds of activities for which recordkeeping and reporting may be required. The list includes such information as the identity of the chemical, categories of use, amounts manufactured or processed, by products, existing data, employees exposed, and the manner or method of disposal. The information specified may be required by the Administrator "insofar as known to the person making the report or insofar as reasonably ascertainable". The conferees intend that the "reasonably ascertainable" standard be an objective, rather than a subjective one. Thus, the manufacturer or processor must provide information of which a reasonable person similarly situated might be expected to have knowledge.

The conference substitute retains the exemptions in the House amendment relating to reporting by small businesses. The intent of the conferees is to protect small manufacturers and processors from unreasonably burdensome reporting requirements. However, the conferees do not intend to deny the Administrator access to information which may be necessary either to determine whether a rule or order should be promulgated or to enforce a final rule or order. Therefore, the conferees have specifically authorized the Administrator to obtain reports from small manufacturers and processors of a chemical substance or mixture with respect to which a rule has been proposed or promulgated under section 4, 5(b) (4), or 6, or with respect to which an order or rule is in effect under section 5(e) or 5(f). Thus, once a rule has been proposed, the Administrator may, by rule, issued in accordance with the informal rulemaking procedures of section 55a of title 5, United States Code, require reporting from small manufacturers and processors. Under such procedures, the Administrator will

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be able to obtain timely access to needed information. Similarly, reporting may be obtained from small manufacturers and processors of a substance or mixture with respect to which relief has been granted in a civil action under section 5 or 7.

The conference substitute adopts, with some clarification, the House amendment in subsection (b) which requires the Administrator to

compile, keep current, and publish an inventory of chemical substances and mixtures manufactured or processed in the United States. The conference committee compromised on the date that the Administrator' shall first publish the inventory, which publication shall take place 315 days after the effective date of the Act.

The conference substitute accepts the substance of the Senate bill in subsection (c), which states that records of significant adverse reactions (as defined by the Administrator by rule) shall be retained for five years after such reactions are reported. Under this provision an officer or employee designated by the Administrator may inspect the records maintained on adverse reactions. The conferees intend that persons under contract with the Administrator be considered employees of the Administrator. Such contractors and their employees may have access to records for purposes of this section and throughout the Act. The conferees recognize the special dangers presented to persons who are exposed to substances on a daily basis; therefore, records of adverse occupational effects must be retained for thirty years.

The seriousness, duration, and the frequency of reactions should be taken into account in establishing what constitutes a significant adverse reaction. For example, if an individual reports that a chemical substance causes his or her eyes to become inflamed and to tear, such reaction may be attributed to an isolated allergic reaction. However, if several persons report a similar reaction, then the reaction may indeed be significant. Because the ultimate significance of adverse reactions is difficult to predict, the conferees intend that the requirement to retain records err on the side of safety. Some very serious neurological disorders, for instance, at first present what appear to be trifling symptoms.

The conference substitute includes the Senate version of subsection (d) concerning health and safety studies with slight modifications. As with the provision concerning adverse reactions, the conferees emphasize the importance of gaining information which errs on the side of too much rather than too little. Of course, the Administrator is to avoid imposing unnecessary or overly burdensome reporting requirements. In cases where test results are submitted, supporting data and the sources for such data must be included.

The conference substitute follows the House amendment for subsection (e) which provides that any manufacturer, processor, or distributor of a chemical substance or mixture who obtains information supporting the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall notify the Administrator, unless such person has actual knowledge that the Administrator already possesses the information.

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RELATIONSHIP TO OTHER FEDERAL LAWS

Senate bill {section 9)

Section 9(a) of the Senate bill provides that if the Administrator (A) has reason to believe that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture causes or contributes to, or is likely to cause or contribute to, an unreasonable risk of injury to health or the environment, and (B) determines, in the Administrator's discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by EPA, then the Administrator must request the agency which administers such law to issue an order. Such agency shall consider all data submitted by the Administrator and issue an order declaring whether or not the manufacture, processing, distribution in commerce, use, or disposal of such substance or mixture causes or contributes to or is likely to cause or contribute to such a risk. If such agency makes such determination it shall also determine if such risk may be prevented or reduced to a sufficient extent by action taken under the law (or laws) administered by the agency.

The Administrator may specify the time within which the other agency must issue the order, but such time may not be less than 90 days from the date the request was made. The other agency must issue a report including a detailed statement of its findings and conclusions in response to the Administrator's request.

The Administrator shall not take any action under section 6 or 7 of this Act if such other agency (A) issues an order declaring that there is no unreasonable risk of injury, or (B) initiates action under the law (or laws) administered by such agency within 90 days of publication in the Federal Register of its report in response to the EPA request.

Section 9(a) of the Senate bill also states that nothing in this section shall prevent the Administrator from making any subsequent request or taking subsequent action under the Toxic Substances Control Act with respect to such risks if the requirements of section 9(a) are satisfied.

Section 9(a) of the Senate bill provides that if the Administrator has initiated action under section 6 or 7 of this bill with respect to a risk of injury which is the subject of a request to another agency, such other agency must consult with the Administrator to avoid duplication of Federal action against such risk before taking action under the law or laws it administers.

Section 9(b) of the Senate bill directs the Administrator to coordinate actions taken under this bill with actions taken under other Federal laws administered wholly or partially by the Administrator. The Administrator must use the authorities contained in such other Federal laws to protect against any risk to health or the environment associated with a chemical substance or mixture unless the Administrator, in the Administrator's discretion, determines that such risk might be more appropriately protected against under this Act. Section 9(b) does not relieve the Administrator of any duties or responsibilities imposed by other Federal law. Nor does section 9(b) affect any final action taken under such other Federal law or the extent to which

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human health or the environment is protected under such other law.

Section 9(c) of the Senate bill states that, in exercising any authority under this bill, the Administrator shall not, for purposes of section 4(b) (1) of the Occupational Safety and Health Act of 1970, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

Section 9(d) of the Senate bill requires the Administrator to consult and coordinate with the Secretary of Health, Education, and Welfare and the heads of other appropriate Federal agencies, departments or instrumentalities for the purpose of achieving the maximum enforcement of this legislation while imposing the least burdens of duplicative requirements on those subject to the bill, and for other purposes. The Administrator shall report annually to the Congress on actions taken to so coordinate authority under this bill with the authority granted under other EPA-administered laws and laws administered by other Federal agencies.

Section 9(e) of the Senate bill provides that nothing in section 9

limits any requirement of section 4, 5 (other than section 5(e) (2)), or 8, or rules promulgated thereunder.

House amendment {section 9)

Section 9(a) of the House bill is similar to section 9(a) of the Senate bill; however, there are certain differences. First, the Administrator's determination that an unreasonable risk to health or the environment may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator is not discretionary. Second, if such a determination is made, the Administrator shall submit a report to the agency administering such other law. Such report shall describe such risk and include a specification of the activity or activities which the Administrator has reason to believe caused or contributed to such risk.

Such report shall request such agency to determine whether the risk might be prevented or reduced to a sufficient extent by action taken under such law. Conditioned upon such a determination shall be a request that the agency issue an order declaring whether the activity or activities specified in the Administrator's description caused or significantly contributed to such risk, which determination and order shall be reported to the Administrator.

Like the Senate bill, section 9(b) of the House bill requires the Administrator to coordinate actions taken under this legislation with actions taken under other laws administered in whole or in part by the Administrator; however, the language of the House bill differs regarding the Administrator's authority to regulate a risk to health or the environment associated with a chemical substance or mixture. Unless the Administrator determines that it is in the public interest to protect against such risk by actions taken under this Act, the House amendment requires the Administrator to use the authorities contained in other laws, if such risk could be eliminated or reduced to a sufficient extent.

Sections 9(c) and (d) of the House amendment are identical to the Senate bill. The House amendment contains no provision similar to section 9(e) of the Senate bill.

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Conference substitute {section 9)

The conferees have drawn from both the Senate bill and the House amendment to assure that overlapping or duplicative regulation is avoided while attempting to provide for the greatest possible measure of protection to health and the environment.

Section 9(a) establishes the relationship between the Act and Federal laws not administered by the Administrator. If the Administrator has a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture presents or will present an unreasonable risk of injury and if the Administrator makes a discretionary determination (which is not subject to judicial review) that the risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, then the Administrator must give the other agency an opportunity to act to protect against the risk before the Administrator uses the authorities in section 6 or 7 to protect against the risk.

If the Administrator determines that another Federal law contains authorities adequate to prevent or reduce the suspected risk to a sufficient extent, the Administrator shall submit to the agency which administers the law a report which describes the risk, including a specification of the activity or combination of activities associated with the substance or mixture which the Administrator believes presents the risk. The report must also include a detailed statement of the information on which it is based. The report shall also request the agency to determine if the risk described in the report may be prevented or sufficiently reduced by action taken under its law and, if such determination is affirmative, to issue an order declaring whether or not the activity specified in the report presents an unreasonable risk.

The agency receiving the request from the Administrator must respond to the Administrator within such time as the Administrator specifies. However, the Administrator must give the other agency at least 90 days.

Section 9(a) prohibits the Administrator from acting under section 6 or 7 with respect to the risk about which the Administrator notified the other agency if the other agency takes one of two alternative courses of action. First, if the other agency issues an order declaring that the activity specified in the Administrator's report does not present the unreasonable risk described in the report, then the Administrator may not take action under section 6 or 7 with respect to such risk. Alternatively, if within 90 days of the publication in the Federal Register of the other agency's response, the other agency initiates

action to protect against such risk, then the Administrator is precluded from taking action under section 6 or 7 with respect to such risk. If the other agency does not take one of these actions, then the Administrator is permitted to act under section 6 or 7 to protect against the risk.

The conferees recognize that the other agency may not because of time constraints be able to initiate formal regulatory action to protect against the risk within the specified time period. As long as the other agency has officially initiated an action which will culminate as soon as

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practicable in effective regulatory action to protect against the unreasonable risk and sets forth a general time schedule of steps for such action, the requirement should be deemed satisfied. However, the requirement that the other agency initiate action to protect against the risk is not satisfied by the mere open-ended possibility of action by the other agency.

Subsection (b) establishes the relationship between this Act and other laws administered in whole or in part by the Administrator. Subsection (b) requires the Administrator to coordinate actions taken under this Act with actions taken under other Federal laws administered by the Administrator.

If the Administrator determines that a risk to health or the environment associated with a substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in other Federal laws, then the Administrator shall use such other authorities unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk under this Act. While it is clear that the Administrator's determination that it is in the public interest to use this Act, is a completely discretionary decision not subject to judicial review in any manner, it is expected that the Administrator will review the other authorities and present the results of that review at the same time the Administrator takes action under this Act. While the Administrator's

decision to use this Act, notwithstanding the other authorities, is unreviewable by any court, a reviewing court is expected to require that the Administrator have examined the other authorities and present the results of that examination when making the finding that it is in the public interest to use this Act. Of course, the requirement to examine other EPA laws and to make determinations applies only when the Administrator takes regulatory action to protect against an unreasonable risk under this Act. It does not apply when the Administrator takes action necessary for the administration or enforcement of the Act, such as issuing recordkeeping requirements.

This provision is not to be construed to relieve the Administrator of any requirement imposed by other Federal laws upon the Administrator, and of course nothing in this Act shall affect any final action taken under other Federal laws administered by the Administrator or in any way affect the extent to which health or the environment is to be protected under such other Federal laws.

SECTION" 10. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION AND UTILIZATION OF DATA

Senate hill {section 10}

Section 10 authorizes the Administrator to conduct research and monitoring in cooperation with the Secretary of Health, Education, and Welfare and the heads of other appropriate agencies, as is necessary to carry out the purposes of the Act.

The Administrator shall imdertake and support programs of research and monitoring of polychlorinated biphenyls to develop safe methods of disposal. The Administrator shall also establish, administer, and assume responsibility for the activities of an interagency

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committee to construct within the EPA an efficient system for the collection, dissemination, and use of data submitted to the Administrator under this Act among other Federal agencies. This interagency committee shall also direct its attention to coordinating the regulation of chemical substances among the federal agencies. The Administrator shall design, establish, and coordinate an effective system for the re-

trieval of toxicological and other scientific data which could be useful to the Administrator in carrying out this Act. This section also authorizes the Administrator to make grants and to enter into contracts in order to carry out his responsibilities under this section.

House arweivdrrent {section 10)

The House version of section 10 is substantially similar to the Senate bill. However, the House amendment omits the requirement that the Administrator undertake and support programs of research and monitoring of poly chlorinated biphenyls. The House amendment contains additional specific provisions for various research programs such as the development of rapid, reliable and economical screening and monitoring techniques for carcinogenic, mutagenic, teratogenic, and ecological effects of chemical substances and mixtures.

Conference substitute {section 10)

The conference substitute includes provisions found in both the Senate bill and the House amendment, but generally follows the language from the House version. Subsection (a) requires the Administrator to conduct such research, development, and monitoring as is necessary to carry out the purposes of this Act. In doing so, the Administrator must consult and cooperate with the Secretary of Health, Education, and Welfare and with heads of other appropriate departments and agencies. The Administrator may enter into contracts and make grants for the purpose of research and development in this area.

Subsection (b) authorizes the establishment of an interagency committee whose primary responsibility shall be to design an efficient system within the Environmental Protection Agency for the collection of data (submitted to the Administrator under this Act), the dissemination of such data to other instrumentalities of the Federal Government, and the use of such data.

Subsection (b) specifies that an efficient and effective data retrieval system shall be developed. The conferees emphasize that sufficient data is necessary for successful implementation of this Act, yet they also acknowledge the burden placed on industry by excessive or duplicative reporting. It is essential that toxicological and other relevant scientific data already in the possession of the Federal Government be made available to the Administrator. The efficient exchange of information among Federal agencies and departments will facilitate implementation of this Act, and every effort should be made to achieve this goal and to avoid duplicative requirements in information-gathering.

Subsections (c), (d), (e), (f), and (g) of the conference substitute

adopt provisions from the House amendment which concern research and development in the area of data collection. The conferees do not intend that Such projects should detract from the primary purposes of the Act, but rather that those purposes should be enhanced by

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allowing the development of proper tools. Thus the purpose of these subsections is to provide the means to an end. They should in no case detract from the main purposes of the Act nor from other equally important research conducted by the Administrator, but should contribute to the achievement of those purposes where appropriate. Of course, such research and development should not duplicate any research and development already being conducted by other Federal agencies and departments. Thus, careful coordination and consultation with such departments and agencies is required.

INSPECTIONS AND SUBPOENAS

Senate bill {section 11)

The Senate bill authorizes the Administrator or any duly designated representative to inspect any establishment, facility or other premises in which chemical substances or mixtures are manufactured, processed, stored or held before or after distribution in commerce. Inspections are also authorized of conveyances used to transport chemical substances or mixtures in connection with distribution in commerce. Inspections may extend to all things within the premises or conveyances inspected bearing on whether the requirements of the Act have been complied with.

The Senate bill also authorizes the Administrator to issue subpoenas to require the attendance and testimony of witnesses and the production of reports, papers, documents, and answers to questions or other information necessary for the Administrator carry out his or her duties under the Act.

Home ainendment {section 11)

The House amendment contains a similar provision authorizing inspections for the purpose of enforcement of the Act. However, the House amendment provides that no inspection shall extend to financial

data, sales data other than shipment data, pricing data, personnel data, or research data (other than research data required by the Act) unless the nature and extent of the data are described with reasonable specificity in the written notice presented to the owner, operator or agent in charge of the premises or conveyance to be inspected. The House amendment contained no subpoena authority.

Conference substitute {section 11)

The conference substitute includes the provision from the Senate bill with the addition of the House provision relating to inspections of financial data, sales data other than shipment data, pricing data, personnel data or research data (other than research data required by the Act or pursuant to any rule issued under the Act).

The conferees recognize that the Administrator will have access to much information under section 5 and section 8 of the Act. Therefore, the conferees expect that the Administrator will use the subpoena authority only when information otherwise available through voluntary means or under other provisions of this Act is inadequate to meet the Administrator's needs under this Act.

It should be noted that the conferees intend that representatives of the Administrator authorized to make inspections should have the

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opportunity to record the results of such inspections because such records might be required at some later date ; therefore, it is intended that persons making the inspection shall be allowed, for example, to photocopy records or photograph premises.

EXPORTS

Senate hU1 {section 12)

This section outlines the policy for chemical substances and mixtures manufactured, processed, sold, or held for sale solely for export from the United States. Subsection (a) provides that unless the Administrator finds that such substances or mixtures will cause or contribute to an unreasonable risk to the health of persons within the United States or the environment of the United States, such substances are

exempt from the Act (other than the reporting requirements of section 8) if proper labeling shows that they are intended for export use only.

However, subsection (b) allows the Administrator to require testing under section 4 to see if such substance or mixture may cause or contribute to a risk of health within the United States or to the environment of the United States. Subsection (b) also requires that any person engaged in export activities shall notify the Administrator if such activities involve chemical substances or mixtures for which data is required under section 4 or 5 or for which a rule has been proposed or promulgated under section 5 or 6 or for which action is pending or relief has been granted under section 7. Should any such circumstance arise, the Administrator shall furnish the appropriate foreign government with relevant information pertaining to the chemical substance subject to the limitations of section 14.

Home amendment {section 12)

Except for minor differences in language, the House amendment follows the Senate provision. The House provision also specifically covers articles containing chemical substances.

Conference substitute {section 12)

The conference substitute follows the policy set forth in both the Senate and House provisions to protect the health and environment of persons in the United States and to provide information to foreign governments regarding chemical substances and mixtures, so that such foreign governments can protect their own citizens.

ENTRY INTO CUSTOMS TERRITORY OF THE UNITED STATES

Senate hU1 {section IS)

The Senate bill instructs the Secretary of the Treasury to refuse entry into the United States of any chemical substance or mixture offered for entry if it fails to conform, with any requirement of the Act or any rule in effect under the Act or if it is otherwise prohibited from being distributed in commerce. If a substance or mixture is refused ent[^] the Secretary of the Treasury is required to notify the consignee of'^the entry refusal. If the substance or mixture is not exported within 90 days, the Secretary is to cause the disposal or storage of the substance or mixture.

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House amendment {section 13)

The House amendment contains a similar provision.

Conference substitute {section 13)

The conference substitute adopts the provision found in both the Senate bill and the House amendment relating to entry into the customs territory of the United States. Although the Secretary of the Treasury is authorized to cause the disposal of substances and mixtures which have been refused entry, and are not exported within 90 days, the conferees intend that the Secretary consult with the Administrator before determining the disposal methods for the substance or mixture.

DISCLOSURE OF DATA

Senate bill {section H)

The Senate bill provides generally that all information obtained by the Administrator under this Act shall be subject to the Freedom of Information Act (5 U.S.C. 552). The Freedom of Information Act makes such information available to the public upon request, unless the information requested falls into one of nine exceptions.

The Senate bill also requires the disclosure of data in certain further specified situations. If officers or employees of the United States request information in connection with their official duties under laws protecting human health or the environment or for specific law enforcement purposes, then the Administrator must disclose the information to them.

Likewise, the Administrator must disclose information to the public whenever the Administrator determines it is necessary to protect human health or the environment. If the Administrator determines that disclosure of information is necessary for a contractor or the contractor's employee to perform official duties satisfactorily under contracts for the United States in connection with this Act, then the Administrator must disclose the information. Finally, the Administrator must disclose information to any duly authorized committee of Congress upon written request.

House amendment {section H)

The House amendment contains some similarities to, but also some differences from, the Senate bill. Whereas the Senate bill states that the Freedom of Information Act applies except in certain areas where disclosure is mandatory, the House bill statutorily prohibits the disclosure of information which falls into one of the exemption categories (subsection (b) (4) (5 U.S.C. 552(b) (4))) of the Freedom of Information Act.

Subsection (b) (4) of that Act encompasses matters that are trade secrets and commercial or financial information obtained from a person and privileged or confidential. The Administrator may not disclose information under that classification except to officers or employees of the United States in connection with their duties to protect health or the environment or for specified law enforcement purposes or to contractors with the United States or their employees in connection with this Act. Such information may be disclosed when relevant to a proceeding under this Act, but the disclosure must pre-

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serve confidentiality as much as possible without impairing the proceeding.

Subsection (b)(1) specifically provides that disclosure of any health and safety study for any chemical substance or mixture which is already being distributed or for which testing is required under section 4 or for which notification is required under section 5, is not prohibited. Data in such a study which discloses a manufacturing process or the proportions of a mixture may not be disclosed if such process or proportions would otherwise be entitled to protection from disclosure.

Subsection (c) authorizes any person Avho submits data under the bill to designate information he believes is entitled to confidential treatment under section (a). Designated information may not be released for 30 days after notification of release has been received by the person submitting such data.

Conference substitute {section H)

The conference substitute adopts elements of both the Senate bill and the House amendment. The prohibition against disclosure of in-

formation exempt from mandatory disclosure under section (a) of section 552 of title 5, United States Code, by reason of its falling within the exemption under subsection (b) (4) of such section, is included. Section 14 applies to any release of information obtained under the Act.

Mandatory exceptions from this prohibition are also provided. Disclosure of information described in section 552(b)(4) of title 5 is required in the following situations :

(1) To officers or employees of the United States in connection with their official duties to protect health or the environment, and for specific law enforcement purposes.

(2) To contractors with the United States when the Administrator determines it to be necessary for the satisfactory performance of their duties in connection with this Act and under such conditions as necessary to preserve confidentiality as the Administrator may specify.

(3) If the Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment.

In addition, the Administrator may disclose such information when relevant under a proceeding under this Act, except that disclosure under such proceeding shall be made in such a manner as to preserve confidentiality to the extent practicable without impairing the hearing. It is intended that the Administrator exercise due care to prevent the release of confidential information to competitors of persons submitting data merely because the competitors have joined the proceeding.

In any proceeding under section 552(a) of title 5 to obtain information which the Administrator has refused to release on the basis that disclosure is prohibited by section 14(a) of this Act, the Administrator may not rely on section 552(b) (3) of title 5 to sustain the refusal to disclose the information. Thus the Administrator will have to show that the information falls within section 552(b)(4) of title 5. Of course, section 552 of title 5 is the vehicle through which the public can obtain information from the Federal government, and all the provi-

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sions of that section will apply to requests for information obtained under this Act.

The conference substitute specifically provides that disclosure of any health and safety study or information from such a study on any substance or mixture which is already being distributed or for which testing is required under section 4 or for which notification is required under section 5, is not prohibited. Data in such a study which discloses manufacturing processes or the proportions of a mixture may not be disclosed if such processes or proportions would otherwise be entitled to protection from disclosure. However, any restriction on the release of such data will not apply to the health and safety study in which it is contained or from which it is derived. To comply with such restriction the Administrator need only to exclude such data when releasing such study.

If a request is made to the Administrator for health and safety study information which is not entitled to protection, the Administrator may not deny a request under section 552 of title 5, United States Code, on the basis that such information is included in the exceptions to mandatory disclosure enumerated in subsection (b) (3) or (b) (4) of such section. It is also intended that the Administrator not use exception (b) (7) of section 552 of title 5, relating to matters under investigation, in an excessi[^] manner as a device for withholding information submitted under this Act. In order to be withheld under that exception, the information must be the subject of an ongoing, active investigation.

In submitting data, a person may designate data which the person believes is entitled to confidential treatment under this Act and submit it separately. If the Administrator proposes to release for inspection designated data, the Administrator must give 30 days notice to the person who submitted the information. Thirty days advance notice need not be given when information is to be released under one of the mandatory exceptions described above or when disclosure is not prohibited because the information is health and safety data. When disclosure is proposed because it is necessary to protect health and the environment from an unreasonable risk, the Administrator shall provide the person submitting the data written notice by certified mail of the proposed release at least 15 days prior to the release. The purpose of this provision is to provide the person submitting the data an opportunity to seek to stop the proposed release if that person disputes the Administrator's determination. The conferees recognize that there may arise emergency situations in which the Administrator determines that earlier release is necessary. In such cases, where the occurrence of the unreasonable risk is imminent, the Administrator need give notice only 24 hours prior to release. The required notice need not be given in writing but may be made by some

other means such as telephone or telegraph.

The criminal penalties for wrongful disclosure contained in the House bill have been included in the conference substitute.

PROHIBITED ACTS

Senate bill {section 15)

The Senate bill makes it unlawful for any person to fail or refuse to comply with any rule or order promulgated under section

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4, 5, or 6, or any requirement prescribed by section 5 or 6. It also makes it unlawful for any person to use or dispose of a chemical substance or mixture which the person knew or had reason to know was manufactured, processed or distributed in commerce in violation of section 5 or a rule or order under section 6, Failure or refusal to establish or maintain records, submit reports, notices, or other information or to permit access to, or copying of, records is also unlawful. Finally, the Senate amendment makes unlawful the failure or refusal to permit entry or inspection as required by section 11.

House amendment {section 15)

The House amendment makes it unlawful for any person to fail or refuse to comply with any rule or order promulgated under section 4, 5 or 6 or any requirement prescribed by section 5. It also makes it unlawful for any person to use for commercial purposes a chemical substance or mixture which the person using such substance or mixture knew or had reason to know was manufactured, processed or distributed in commerce in violation of section 5, a rule or order under section 5 or 6 or an order issued in an action brought under section 5 or 7. The House provisions respecting maintenance of records, submission of reports, entry, and inspections are identical to the Senate bill.

Conference substitute {section 15)

The conference substitute incorporates the provisions of the House bill with a conforming amendment making violations of the provisions of section 6 relating to poly chlorinated biphenyls an unlawful act.

PENALTIES

Senate bill {section 16)

This section outlines the penalties and procedures for assessing penalties against persons who violate section 15. Subsection (a) provides for civil penalties of up to \$25,000 per day per violation. Taking relevant factors into account, the Administrator shall assess the amount of such civil penalties in an order made on the record after the opportunity for an adjudicative hearing and proper notification of the person in violation of this Act. Such person may file a petition for judicial review of an order assessing civil penalties in U.S. Court of Appeals within thirty days ; however, if a person fails to pay such assessment after it has become a final and unappealable order or after the Court of Appeals has found in favor of the Administrator, then the Attorney General shall recover the amount assessed.

Subsection (b) provides for criminal penalties of up to \$25,000 per day or up to one year's imprisonment, or both, per violation for any person who knowingly or willfully violates this Act.

House amendment {section 16)

The House amendment follows subsections (a) and (b) of the Senate provision. In addition, subsection (c) of the House Amendment provides that the Administrator may require a person who has manufactured, processed, or distributed a chemical substance or fixture in violation of regulations issued under paragraphs (1) or (2) of section 6 (a) to give notice of the risk associated with that substance to any person who may be exposed to it and to the public at large.

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The Administrator may also require such person to either replace or repurchase the substance found to be in violation. The Administrator may choose any or all of the remedies set forth in subsection (c) ; however, in each case the order must be made on the record with full opportunity for an agency hearing.

Conference substitute {section 16)

The conference substitute adopts the provisions found in both bills concerning civil and criminal penalties for violations of this Act. Under subsection (a), the Administrator shall assess the amount of

civil penalties up to \$25,000 per day per violation; however, the Administrator must take into account such factors as the gravity and extent of the violation, the ability to pay of the person held in violation, and any prior history of violations under this Act.

Criminal penalties may be imposed on persons who "knowingly or willfully" violate any provision of section 15, which sets forth unlawful acts.

SPECIFIC ENFORCEMENT AND SEIZURE

Senate HUL {section 17)

The Senate bill grants the United States district courts jurisdiction, upon application of the Administrator or the Attorney General, to restrain any violation of section 15, to restrain any person from manufacturing or processing a chemical substance before the expiration of the notification period under section 5, and to restrain any person from taking any action prohibited by a requirement prescribed under section 5 or 6 or rules or orders issued under section 5 or 6. In addition, the courts are granted jurisdiction to direct any manufacturer or processor of a chemical substance or mixture who is not in compliance with any order issued under section 5(e) or any rule issued under section 4 or 6 to give notice of such fact to persons within the chain of distribution and to the public, and to either replace or repurchase the substance or mixture. The Senate provision also authorizes the district courts to compel the taking of any action required by or under the Act. In addition, the Senate bill provides that any substance or mixture manufactured or processed or distributed in commerce in violation of the Act or any rule or order promulgated under the Act shall be liable to be proceeded against for seizure and condemnation.

House amendment {section 17)

The House amendment grants jurisdiction to the district courts to restrain any violation of section 15, to restrain any person from manufacturing or processing a substance before the expiration of the notification period under section 5, and to restrain any person from taking action prohibited by section 5 or a rule or order under section 5 or 6. Jurisdiction is also granted to compel the taking of any action required by or under this Act. The seizure authority in the House amendment is similar to that found in the Senate bill, except that seizure and condemnation of articles containing chemical substances or mixtures manufactured, processed or distributed in commerce in violation of the Act or any rule or order promulgated under the Act is specifically authorized.

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Conference substitute

The conference substitute grants the district courts of the United States jurisdiction to restrain any violation of section 15, to restrain any person from manufacturing or processing a substance before the expiration of the notification period under section 5, and to restrain any person from taking any action prohibited by section 5 or 6 or a rule or order under section 5 or 6. The provision also grants such courts jurisdiction over actions to direct any manufacturer or processor of a chemical substance or mixture manufactured or processed in violation of any order issued under section 5 or any rule or order issued under section 6 to give notice of the risk associated with the substance or mixture to persons in the chain of distribution and to the public. The courts also have jurisdiction to require manufacturers or processors to either replace or repurchase the substance or mixture, whichever the person to whom the requirement is directed elects. The conference substitute also grants jurisdiction to compel the taking of any action required by or under the Act. The seizure authority in the conference substitute is identical to that contained in the House amendment.

PREEMPTION

Senate hill {section 18)

This section outlines the relationship between State authority and the authority under this Act to regulate chemical substances or mixtures. Subsection (a) asserts the State's authority to regulate, with certain limitations. No State may require testing which duplicates testing required by the Administrator under a section 4 testing rule. Further, if the Administrator has prescribed a requirement under section 5 or 6 to protect against a particular risk associated with a chemical substance or mixture, a State may not prescribe any different requirement (other than a total ban) with respect to that risk unless the State obtains permission from the Administrator to do so.

The Administrator may, by rule, grant such permission if the Administrator finds that compliance with the State requirement would not result in a violation of this Act, would result in a significantly

higher degree of protection, and would not unduly burden interstate commerce.

House amendment {section 18)

The House amendment is similar to the Senate bill. However, rules promulgated under section 6(a) (5) do not preempt State laws. Moreover, rules promulgated under other Federal authorities such as the Clean Air Act, are not preempted by requirements under this Act.

Like the Senate bill, the House amendment authorizes the Administrator to exempt, by rule, States from prohibitions under subsection (a) in the same manner as the Senate bill.

Conference substitute {section 18)

The conference substitute provides that no State or political subdivision may establish similar requirements for the testing of a substance or mixture after the Administrator has issued a rule under section 4 respecting the substance or mixture. Nor may any State regulate any risk associated with a substance or mixture if the Administrator has prescribed a rule or order under section 5 or 6, which is

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designed to protect against the risk to health or the environment, unless the rule (A) is identical to that issue under this Act, (B) is adopted under the authority of another Federal law, or (C) prohibits the use of such substance or mixture other than in its use in the manufacture or processing of other chemical substances or mixtures.

In addition to the specific exemptions from the preemption provision, the conference substitute provides a means whereby a State or political subdivision may seek an exemption from the preemptive effects of a Federal requirement in order to provide a higher degree of protection for their citizens than that provided by a requirement under this Act. The Administrator may, by rule, grant an exemption if compliance with the State or local requirement will not cause a violation of the applicable requirement under this Act, if the State or local requirement will provide a significantly higher degree of protection from the risk, and if the State or local requirement will not unduly burden interstate commerce.

JUDICIAL REVIEW

Senate bill {section 19)

The Senate's provision authorized pre-enforcement judicial review of any rule under the Act or an order issued under section 5(e). Any rule promulgated under section 3(b), 5 or 6 shall not be affirmed unless supported by substantial evidence on the record taken as a whole.

House amendment {section 19)

The House provision authorizes pre-enforcement judicial review of rules issued under section 4, 5 or 6(a). Such rules shall not be affirmed unless supported by substantial evidence based on the record taken as a whole.

Conference substitute {section 19)

Section 19 of the conference substitute provides for judicial review in the courts of appeals of the United States for certain rules promulgated under the Act. The jurisdiction for pre-enforcement review and review of determinations of the Administrator relating to cross-examination is exclusively vested in such courts. Not later than 60 days after the date of promulgation of a rule under section 4(a), 5(a) (2), 5(b)(4), 6(a), 6(e), or 8 any person may file a petition for judicial review of the rule in the appropriate U.S. court of appeals.

The section specifically defines the rulemaking record to include the rule being reviewed (which would include the statement of basis and purpose pursuant to section 553(c) of title 5, United States Code) , any transcript required to be made of an oral presentation, any written submission of interested parties, and any other information which the Administrator considers to be relevant to the rule and with respect to which the Administrator published a notice in the Federal Register identifying the information on or before the date of the promulgation of such rule. In addition certain findings and statements required to be made with respect to specific rules must also be included in the rulemaking record. In the case of a rule under section 4(a), the finding required by that section must be included in the record. In the case of a rule under section 5(b) (4), the finding required to be made

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by that section must be included in that record. In the case of a rule under section 6(a), the finding required by section 5(f) or section 6(a), as the case may be, and the statement required by section 6(c) (1) must be included in the rulemaking record.

The section includes authority for the submission of additional data and oral or written views and for the modification of the rule being reviewed.

Generally section 706 of title 5, United States Code, applies to review of a rule under this section. However, in the case of review of a rule under section 4(a), 5(b) (4), 6(a) or 6(e), the bill provides that the courts shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rule-making record taken as a whole. This provision is in lieu of paragraph 2(E) of section 706 of title 5. It is the intent of the conferees that the traditional presumption of validity of an agency rule is to remain in effect. The conferees recognize that in rulemaking proceedings such as those contained in this bill, which are essentially informal and which involve both determinable facts and policy judgments derived therefrom, the traditional standard for review is that of "arbitrary and capricious". However, the conferees have adopted the "substantial evidence" test because they intend that the reviewing court focus on the rulemaking record to see if the Administrator's action is supported by that record. Of course, the conferees do not intend that the court substitute its judgment for that of the Administrator.

Further, in the case of review of a rule under section 6(a) , the court shall set the rule aside if it finds that action by the Administrator in excluding or limiting cross-examination or rebuttal submissions precluded disclosure of disputed issues of material fact necessary for a fair determination of the rulemaking proceeding taken as a whole. Also, in review of such rules, section 706(2) (D) will not apply with respect to review of the Administrators actions respecting limitations or exclusions of cross-examination or rebuttal submissions, and review of such actions can occur only during preenforcement judicial review.

Section 19 also provides that the court may not review the contents and adequacy of any statement required to be made pursuant to section 6(c)(1) or any statement of basis and purpose required by section 553(c) of title 5 of United States Code to be incorporated in the rule except as part of a review of a rulemaking record taken as a whole.

Section 19 provides that in a judicial review proceeding under this section the court may award the costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an

award is appropriate. In addition, in any review of such an action the Supreme Court may also award such costs of suit and reasonable fees.

The section also provides that the remedies provided in section 19 shall be in addition to, and not in lieu of, any other remedies provided by law. This provision should not be construed, however, to negate the provision in this section Avhich specifically provides that the United States courts of appeals shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) if any district court of the United States would have had jurisdiction of such an action but for the provisions of this section.

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citizen's civil actions

Semite hill {section 20}

Subsection (a) authorizes any person to commence a civil action in specified district courts against (A) any person including the United States or any governmental agency or instrumentality alleged to be in violation of this Act or any rule or order prescribed under sections 4, 5, or 6(a). Such suits may also be brought to compel the Administrator to perform any nondiscretionary act or duty.

Subsections (b), (c), and (d) specify certain procedural provisions. No action may begin until the Administrator and the alleged violator have received proper notice of the alleged violation. If the Administrator has instituted a civil action against an alleged violator to compel compliance, then no action may be brought under this section. However, if the Administrator does not commence such action until after the person bringing the citizen's civil action has notified the alleged violator of intention to sue under this Act, then the person who gave such notification may intervene in the suit brought by the Administrator. The Administrator may intervene in any civil action under this section to which the Administrator is not a party. The court may award the costs of the suit and reasonable fees for attorneys and expert witnesses. The court may also consolidate two or more civil actions involving the same defendant, the same issues, or the same alleged violations when appropriate.

Home amendment {section 20}

The House amendment contains the same provision as the Senate bill.

Conference substitute {section 20}

The conference substitute contains the provision included in both the Senate bill and the House amendment with a clarification that citizen's civil actions may also be brought for violations of an order under section 6 or 6.

citizens' petitions

Senate bill {section 21}

Section 21 of the Senate bill authorizes any person to petition the Administrator to issue a rule or order or to take other action for the purpose of protecting against an unreasonable risk of injury to health or the environment. If the petition is denied or not acted upon within 90 days, the petitioner may bring a civil action in a United States district court to compel the Administrator to initiate the requested action. If the petitioner demonstrates by a preponderance of the evidence in a de novo proceeding that the action requested in the petition conforms to the applicable requirements of the Act, the court shall order the Administrator to initiate the requested action.

House amendment {section 21}

The House amendment authorizes any person to petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 4, 5 (c) , or 6 (a) . If the petition is denied, the petitioner may file a civil action to compel the Administrator

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to initiate the rulemaking proceeding. If the petitioner requests the issuance of a rule under section 4, 5(c), or 6(a) (as opposed to the modification or repeal of such a rule) the petitioner has an opportunity for a de novo proceeding before the court. If the petitioner makes the requisite showings for the applicable provision, the court must order the Administrator to initiate the requested action unless the court finds that the failure of the Administrator to initiate the re-

requested action was not unreasonable.

Conference substitute {section 21)

The conference substitute authorizes any person to petition the Administrator to initiate a proceeding for the issuance, amendment or repeal of an action under section 4, 5(e), 6, or 8 of the Act. It should be noted that a petition under this section may be used to initiate a proceeding under section 5(f) since a proceeding under that section is for the issuance of a rule under section 6(a). The Administrator must grant or deny any petition under this section within 90 days after it is filed.

The conference substitute thereafter provides for different judicial review of the Administrator's denial of a petition, depending upon whether such petition seeks the issuance of a rule or order or the amendment or repeal of an existing rule or order.

The substitute affords greater rights to a person petitioning for the issuance of a rule or order because in such a situation the Administrator will not previously have addressed the issue by rule or order. If the Administrator denies or fails to respond to a petition for the issuance of a rule or order, the petitioner may commence a civil action in a United States district court to compel the Administrator to take the action requested in the petition. In the court, the petitioner is entitled to a de novo proceeding. If the petitioner demonstrates to the court by a preponderance of the evidence that there is an adequate basis for the issuance of the rule or order requested, the court shall order the Administrator to initiate the requested action.

The court may defer requiring the Administrator to take the requested action if it finds that the extent of risk of injury to health or the environment alleged by the petitioner is less than those risks of injury which the Administrator is addressing under this Act and there are insufficient resources to do both. If a deferral is granted, the conferees anticipate that the Administrator may seek extensions as needed.

The conference substitute provides different treatment for review of petitions for amendment or repeal of rules or orders, because the Administrator already will have addressed the general subject matter in an existing rule or order and the Administrator's determination will have been subject to review under section 19 of this Act. Therefore, the conferee's main interest is to make certain that any such petitioner receive timely consideration of such petition. By requiring the Administrator to act on any such petition within 90 days, the conferees will facilitate such a petitioner's right to seek judicial review should the Administrator deny the petition. Otherwise, the Administrator could avoid any judicial review simply by failing to take any action.

The conferees believe that a petition for amendment or repeal of an existing rule or order should contain newly discovered, noncumulative

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material which was not presented for the Administrator's consideration in promulgating the rule or order. Failure to include such information would be an adequate basis for denying the petition.

At the same time, the conferees do not intend that the Administrator be subjected to constant petitions challenging rules or orders for which adequate judicial review is provided under section 19. Therefore, if the Administrator denies a petition to amend or repeal an action under section 4, 5(e), 6, or 8, the conference substitute permits review of such denial only under the Administrative Procedure Act.

NATIONAL DEFENSE WAI\rER

Senate bill {section 22)

The Senate bill directs the Administrator to waive compliance with any provision of this Act upon the request of the Secretary of Defense and a determination by the President that the interest of national defense requires such a waiver. The Administrator shall maintain a written record of the basis for the waiver. In addition, the Administrator shall publish notice of the waiver in the Federal Register, unless the Administrator determines, upon request from the Secretary of Defense, that such publication is contrary to national defense interests, in which case, the Administrator shall notify the Armed Services Committees of the Senate and the House of Representatives.

House amendment {section 22)

The House amendment is similar to the policies and procedures of the Senate bill except that only the President, not the Secretary of Defense, is authorized to request a national defense waiver from the Administrator and to request that publication of the waiver not be placed in the Federal Register for national defense reasons.

Conference substitute {section 22)

The conference substitute includes the provision of the House amendment.

EMPLOYEE PROTECTION

Senate bill {section 23)

Section 23 of the Senate bill provides protection for employees who cooperate with the Administrator in carrying out the Act. The provision prohibits any employer from discharging any employee or otherwise discriminating against the employee with respect to compensation, terms, conditions, or privileges of employment because the employee commenced, caused to be commenced, or is about to commence a proceeding under the Act. Protection is provided for employees who have testified or are about to testify in any proceeding under the Act or who have assisted or participated in a proceeding or any other action to carry out the purposes of the Act. The Secretary of Labor shall conduct investigations of alleged violations and issue orders to require any person who violates the prohibitions to take affirmative action to remedy any such violation. Any person adversely affected by an order of the Secretary may obtain judicial review of the order in the United States court of appeals for the circuit in which the violation allegedly occurred. The Secretary is authorized to enforce the orders in the dis-

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trict court of the United States for the district in which the violation occurred.

House amendment {section 23)

The House amendment contains an identical provision.
Conference substitute {section 23)

The conference substitute adopts the provision found in both the Senate bill and House amendment.

EMPLOYMENT EFFECTS

Senate bill {section 23 {f))

The Administrator shall conduct continuing evaluation of the effect on employment of rules or orders under this Act. Any employee who is discharged or whose employment is threatened or who is otherwise discriminated against as a result of any action under this Act may request investigation of the matter by the Administrator. The Administrator shall investigate the matter. If any interested party requests a hearing, the Administrator shall conduct a public hearing in accordance with section 554 of title 5, United States Code, at which the parties are required to present information on any employment effects.

Upon receipt of the investigation report, the Administrator shall make findings of fact as to the employment effects and shall make appropriate recommendations which shall be available to the public.

House amendment {section 2^)

The House amendment is similar to the Senate bill. The House provision differs from the Senate's primarily as to whether and how a hearing requested by an interested person shall be conducted.

Upon request, the Administrator must hold a public hearing unless the Administrator determines that there are no reasonable grounds for such hearing. The hearing need not be a formal adjudicative hearing under 5 U.S.C. 554. Provision is made for subpoenas, oaths, and payment of witness fees in connection with any investigation or public hearing conducted under this section.

Conference substitute {section 24)

The conference substitute follows the House amendment with two modifications. First, if the Administrator determines that there are no reasonable grounds for holding a hearing, the Administrator must so find, by order, within 45 days of the date within which time such hearing is requested. Second, if a hearing is held, it shall be in accordance with the requirements of section 6(c) (3) of this Act.

STUDIES

Senate bill {section 24)

The Senate bill requires the General Accounting Office to conduct a study of all Federal laws administered by the Administrator to determine whether and under what conditions, if any, indemnification should be accorded any person as a result of action taken by the Administrator under such' laws. The Senate bill also requires the Council on Environmental Quality to coordinate a study of the feasibility of

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establishing a standard classification system of chemical substances and related substances and a standard method for storing and obtaining* rapid access to information respecting such substances.

House amendment {section 25)

The House amendment contains a similar provision except that the indemnification study shall be conducted by the Administrator and reviewed by the General Accounting Office.

Conference substitute {section 25)

The conference substitute includes the House provision.

ADMINISTRATION OF THE ACT

Senate bill {section 26)

Subsection (a) gives authority to each federal department and agency to cooperate with the Administrator, upon request, by sharing services of personnel, facilities, and information in order to carry out the purposes of this Act.

Subsection (b) provides that the Administrator may, by rule, require payment from any person submitting data pursuant to section 4 or 5 to help defray administrative costs, provided that no such fee exceeds \$2,500.

Under subsection (c), the Administrator may act with respect to categories of comical substances or mixtures. For purposes of this section, a category includes chemical substances or mixtures grouped by virtue of similarity of chemical structure, physical, chemical, or biological properties, use or mode of entry into the human body or environment, or some other suitable grouping.

Under subsection (d) , any proposed or final rule or order under this Act shall be accompanied by a statement of purpose and justification,

which identifies the basis for the action. This statement shall become part of the "record of the proceedings" for purposes of judicial review under section 19(a).

SubvSection (e) directs the President to appoint by and with the advice and consent of the Senate, an Assistant Administrator of the Environmental Protection Agency to administer this Act. The Assistant Administrator shall be qualified to direct a program concerning the effects of chemicals on health and the environment by reason of background and experience.

House am-endment {section 26)

The House amendment contains provisions similar to the Senate bill concerning cooperation among federal agencies and fees to be paid by persons submitting data under section 4 or 5 to defray administrative costs, except that no small businesses shall be required to pay administrative fees exceeding \$100. The House amendment also includes a provision on categories similar to that in the Senate bill.

No provision is made in the House amendment for appointment of an Assistant Administrator for Toxic Substances. However, the House amendment establishes an office within the Environmental Protection Agency to provide technical and other nonfinancial assistance to manufacturers and processors of chemical substances and mixtures concerning the requirements and application of this Act.

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The House amendment does not contain a specific provision requiring that each proposed or final rule or order be accompanied by a statement of purpose or justification.

The House amendment in section 29 provides that each officer and employee of the Environmental Protection Agency and the Secretary of Health, Education, and Welfare who perform any function or duty under the bill and who has any known financial interest in any person subject to the bill or in any person who applied for or received any financial assistance pursuant to the bill must, beginning February 1, 1977, annually file with the appropriate agency or department a statement concerning all such interests during the preceding calendar year. Such statement must be available to the public.

The House amendment also directs the Administrator and the Secretary, within 90 days after enactment, to define "known financial interest" and to establish methods to monitor, enforce, and review the filing of such statements. They are also directed to report each year to Congress on June 1 regarding such disclosures and actions taken concerning them during the preceding calendar year.

Officers or employees in designated positions of a nonregulatory or nonpolicy-making nature may be exempted, by rule, from the requirements of this section.

The House amendment states that any officer or employer who is subject to, and knowingly violates, this section or any regulations issued thereunder is to be fined not more than \$2,500 or imprisoned for not more than one year, or both.

Conference substitute {section 26)

The conference substitute incorporates provisions from both the Senate bill and the House amendment. Subsection (a) gives authority to each federal agency and department to cooperate with the Administrator to carry out the purposes of this Act.

The Administrator is authorized to require, by rule, payment of reasonable fees from any person required to submit data under sections 4 and 5 in order to defray the costs of administering this Act. In no case shall such fees exceed \$2,500, or \$100 in the case of a small business. In all cases when setting such fees, the Administrator shall take into account the ability to pay of persons submitting data.

The conference substitute includes the House provision concerning categories in subsection (c). The conferees expect that the Administrator will find the authority to categorize especially helpful promulgating rules under section 5(a)(2) concerning what constitutes significant new use of chemical substances.

The conference substitute adopts the provision from the House amendment which establishes an office within EPA to provide technical and other nonfinancial assistance to manufacturers, processors of chemicals, and others. The purpose of the office is to help manufacturers and processors understand the requirements of the Act in order to assist in its efficient implementation and to avoid unnecessary confusion, which might prove detrimental to the chemical industry and the public interest. . . . ,

The conference substitute adopts the House provision on financial disclosures for which the Senate bill had no comparable provision.

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The procedures and penalties are designed to make sure that persons who perform regulatory functions under this Act divulge any known financial interest such persons may have in any person subject to this Act.

Subsection (f) of the conference substitute modifies the requirement in the Senate amendment that each proposed or final rule or order be accompanied by a statement of basis and purpose to apply only to final orders.

The conference substitute includes the provision found in the Senate bill that the President appoint, with the advice and consent of the Senate, an Assistant Administrator for Toxic Substances who shall direct a program concerning the effects of chemicals on human health and the environment and perform other duties and responsibilities under this Act.

While the Assistant Administrator for Toxic Substances will be assigned responsibilities pursuant to this Act, the Administrator may assign additional duties. Of course this position will be in addition to the existing five assistant administrator positions established by Reorganization Plan No. 3 of 1970.

DEVELOPMENT AND EVALUATION OF TEST METHODS

Senate bill

The Senate bill contains no provision respecting development and evaluation of test methods.

House amendment {section 27)

The House amendment authorizes the Secretary of Health, Education, and Welfare, in consultation with the Administrator and acting through the Office of the Assistant Secretary for Health, to conduct projects for the development and evaluation of inexpensive and efficient methods for determining and evaluating the health and environmental effects of chemical substances and mixtures.

Conference substitute {section 27)
The House provision is included.

STATE PROGRAMS

Senate hill {section 25)

Section 25 authorizes the Administrator to assist up to three states in the establishment of demonstration programs to complement federal efforts under the Act. Subsection (a) describes the functions of such programs. Subsection (b) requires the Administrator to submit annual reports to the Congress on the demonstration programs. Subsection (c) authorizes appropriation of funds to assist the states in funding the demonstration programs. Grants shall not exceed 75 percent of the cost of any demonstration program. Subsection (d) provides that assistance shall be available to those states which can establish a priority need for such assistance. The Senate bill authorizes a maximum appropriation of \$2 million for the fiscal year ending September 30, 1977, \$2 million for the fiscal year ending September 30, 1978, and \$2 million for the fiscal year ending September 30, 1979.

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House amendment {^section 28)

The House amendment is similar to the Senate bill, but differs in that grants are authorized only to assist states in addressing risks associated with substances and mixtures which the Administrator is unable to address.

The House amendment does not restrict the number of programs which the Administrator may approve. The House amendment authorizes an annual appropriation of \$1 million for the fiscal years ending September 30, 1978, September 30, 1979 and September 30, 1980.

Conference substitute {section 28)

The conference substitute generally follows the House amendment with some modification. The Administrator may make grants to States to establish programs to prevent or eliminate unreasonable risks associated with chemical substances or mixtures against which the Admin-

istrator is not able or not likely to take action under this Act. The conferees agreed to a compromise on the authorization for such programs of \$1.5 million for each of the fiscal years 1977 through 1979.

ATJTHORIZATIOX FOR APPROPRIATIONS

Senate bill {section 27)

Section 27 of the Senate bill authorizes to be appropriated to the Administrator \$11,100,000 for the fiscal year ending June 30, 1976, \$2,600,000 for the period beginning July 1, 1976 and ending September 30, 1976, and \$10,100,000 for the fiscal year ending September 30, 1977. This section prohibits using funds for construction of research laboratories.

Section 27(b) of the Senate bill requires that the Administrator submit concurrently to the Congress any budget requests, supplemental budget estimates, legislative recommendations, prepared testimony for Congressional hearings, or comments on legislation to the President or to the Office of Management and Budget connected with this Act.

House amendment {section 30)

The House amendment authorizes to be appropriated \$12,625,000 for the fiscal year ending September 30, 1978, \$16,200,000 for the fiscal year ending September 30, 1979, and \$17,350,000 for the fiscal year ending September 30, 1980. The House amendment contained no provision relating to simultaneous submissions.

Conference substitute {section 29)

The conference substitute authorizes to be appropriated to carry out the purposes of this Act as follows : \$10,100,000 for the fiscal year ending September 30, 1977; \$12,625,000 for the fiscal year ending September' 30, 1978; and \$16,200,000 for the fiscal year ending September 30, 1979. . . ,

The conference substitute contains no provision for simultaneous submission of materials to Congress and the Office of Management and Budget.

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ANNUAL REPORT

Senate bill (section 28)

The Senate bill requires the Administrator to submit to both the President and the Congress a comprehensive annual report. The report shall include (1) a list of the testing required under section 4 and an estimate of the costs incurred by the person required to perform the tests; (2) the number of notices received under section 5, the number of notices received under section 5 for chemical substances subject to a section 4 rule, and a summary of any action taken during the premarket notification period; (3) a list of rules issued under section 6; (4) a list, with a brief statement of the issues, of completed or pending judicial actions under the bill ; (5) a summary of major problems encountered in administration of the bill; and (6) such recommendations for additional legislation as the Administrator deems necessary to carry out the purposes of the bill.

Home amendment (section 31)

The House amendment is almost identical to the Senate bill. The only difference occurs with respect to the date that the Administrator must submit the first annual report. The House amendment specifies that the Administrator shall submit the first annual report on or before January 1, 1979.

Conference substitute (section 30)

The conference substitute generally follows the provision of the Senate bill. The first submission is due on or before January 1, 1978.

REVIEW

Senate bill

The Senate bill contained no rule review provision.

House amendment (section 32)

Section 32 of the House amendment provides that either House of Congress may veto a rule issued by the Administrator, the Secretary of the Treasury, or the Secretary of Health, Education, and Welfare under this Act, by adopting a resolution of disapproval within 60 days.

Conference substitute

The House recesses.

EFFECTIVE DATE

Senate bill

The Senate bill contained no specific provision specifying an effective date ; therefore, the legislation is to take effect upon enactment.
House amendment (section 33)

The House amendment provides that the legislation shall take effect October 1, 1977.

Conference substitute

The conference substitute establishes the effective date as January 1, 1977, except that section 4(f) shall not become effective for two years.

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Harley O. Staggers,

JOHN M. Murphy,

W. S. Stuckey,

Bob Eckhardt,

Ralph H. Metcalfe,

WILLIAM Broidhead,

James H. Scheuer,

Samuel L. Devine,

James T. Broyhix,

Matthew J. Rinaldo,
Managers on the Part of the House,

Warren G. Magunson,

Vance Hartke,

Phh,!? a. Hart,

John A. Durkin,

John V. Tunney,

Howard Baker,

T. E. Stevens,
Managers on the Part of the Senate,

SENATE CONSIDERATION OF CONFERENCE REPORT

[Excerpt from the Congressional Record, Sept. 28, 1976, Senate, pp. S16802-S17597]

Toxic Substances Control Act – Conference Report

The Presiding Officer (Mr. Stone). Under the previous order, the Senate will now proceed to the consideration of the conference report on S. 3149, which will be stated by title.

The assistant legislative clerk read as follows :

The committee of conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 3149) to regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses this report, signed by all of the conferees.

The Presiding Officer. Without objection, the Senate will proceed to the consideration of the conference report.

Mr. Magnuson. Mr. Prevsident, today the Senate will take final action on S. 3149. the Toxic Substances Control Act. This legislation is, in my opinion, the most important environmental legislation to come before the 94th Congress.

In 1971, the Council on Environmental Quality in a report entitled, "Toxic Substances," concluded that regulatory mechanisms to control

toxic chemicals were seriously inadequate. This report was the impetus for the original legislation on toxic substances that was introduced in the 92d Congress.

In the 6 years since the introduction of this original legislation, over 16 days of hearings and literally thousands of hours have been spent refining this legislation. The need for this legislation has been increasingly clear as ever-growing lists of chemical substances such as vinyl chloride, arsenic, asbestos, mercury, lead, PCB's, PBB's, fluorocarbons, BC] \IE, sulfuric acid, and many others have been shown to pose potential dangers to man and the environment.

Dr. David Rail, Director of the National Institute of Environmental Health Science of the National Institute of Health, stated :

Man is assaulted by these compounds alone and in combination from multiple sources. This problem constitutes possibly the major health hazard of this decade.

An important aspect of the growing concern with the lack of control of chemicals entering our environment stems from the estimates of the National Cancer Institute and the World Health Organization that from 60 to 90 percent of cancer is environmentally induced.

Mr. President, it is no accident that a comprehensive study carried out by the National Cancer Institute throughout this country found that the so-called hot spots for cancer are in close proximity to those locations where the chemical industry is most highly concentrated, and

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it is at these locations that the greatest incidence of bladder, lung, liver, and other cancers have been found. In fact, during the past 5-year period, there have been in excess of 1 million deaths in this country from cancer, and the cost of cancer in the United States is now in excess of \$18 billion per year.

It is the goal of this legislation to provide a means of preventing suffering, death, and environmental damage rather than merely reacting to it. It is my view that the conference has done an excellent job of meeting this goal. This legislation is strong, fair, and comprehensive. It closes many significant gaps in our environmental laws.

For example, in the past, the primary stumbling block to agreement between the House and Senate on the Toxic Substances Control Act in the Committee on Conference has been in regard to the question of premarket notification [Sec. 5]. I am extremely pleased to state that the conference has now agreed on a strong premarket notification provision which requires that 90 days prior to marketing of new chemicals or existing substances for a significant use, manufacturers must supply EPA with information in order that EPA can assess the safety of these chemicals. None of the other environmental health statutes, except pesticides, drug and food additives, and fuel additives, provide for premarket notification by appropriate regulatory officials. In my view, this provision is the heart of the act. This provision ends once and for all the present situation where chemicals can be marketed without notification of any governmental body and without any requirement that they be tested for safety. Thus, this provision would no longer allow the public or the environment to be used as a testing ground for the safety of these products.

It is important to note that we have gained these important benefits without placing an unreasonable financial burden on the chemical industry. The chemical industry in this country has grown to the point where its annual sales exceed \$100 billion a year. In light of the potential for protecting the health and environment of the American public the costs are extremely reasonable.

In the key provisions of the bill, costs are not to be incurred unless the Administrator determines that they are offset by benefits of at least the same magnitude. Obviously it is not feasible to match these kinds of determinations just on the basis of quantitative comparisons. The burdens of human suffering and premature death are extraordinary. However, this legislation has been fully dealt, as I stated before, with the economic aspects of the act. In order to delineate the effects of this act, I will now describe some of the important provisions of the Toxic Substances Control Act.

TESTING OF CHEMICALS AND MIXTURES [Sec. 4]

The conference substitute grants broad authority to be Administrator of EPA to require testing of chemical substances and mixtures. The conference substitute requires the Administrator to establish testing rules in either of two instances. First, if the manufacture, distribution, or processing, use, or disposal of the chemical substance presents an unreasonable risk of injury to health or the environment and other findings are made, the Administrator must require testing. Second, if a substance is or will be produced in substantial quantities

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lies and it either enters or may be reasonably anticipated to enter the environment in substantial quantities or if there is or may be significant or substantial human exposure, the Administrator must also require testing if the other additional findings are made.

An exemption procedure is provided to avoid the submission of duplicative data on a person subject to a testing requirement. In those instances, a cost-sharing procedure is also provided.

An interagency advisory committee is established to assist the Administrator in establishing testing priorities.

MANUFACTURING AND PROCESSING NOTICE [Sec. 5]

Ninety days prior to first manufacture, manufacturers of new chemical substances must give notice to EPA. In addition, manufacturers or processors of chemical substances for a use which has been identified by the Administrator as a significant new use must also give notice. A variety of information is required to be submitted with the notice, including such data as the identity of the chemical, categories of proposed use, estimates of the amount to be manufactured or processed, a description of byproducts, any test data in the possession or control of the person giving notice, and a description of any other data known by the person or reasonably ascertainable.

The requirement that manufacturing and processing notices be given for significant new uses of chemical substances is extremely important. As chemical substances frequently are not manufactured in large volumes or for a large number of uses initially, the authority to require notification for these substances as uses mount or as volumes increase is extremely important. A key element in the Administrator's determinations of significant new use is the requirement that he consider health or environmental threats that may arise through the manufacture, processing, distribution in commerce, or disposal of the chemical substance.

Thus, notification will occur with respect to significant new threats arising from any of these activities if it is associated with a different use. Of course, changes in the types of exposure, volume of the substance manufactured or processed, and other factors will obviously go into determination by the Administrator of what is a significant new use. The Administrator is expected to promulgate rules concerning significant new uses by categories in order to avoid a multiplicity

of rulemaking proceedings.

Determinations of what is or is not a new chemical substance is made through the establishment of an inventory of chemical substances under section 8(b). If a substance does not appear on the inventory, then it must go through premarket notification 90 days prior to first manufacture.

As chemical substances are rarely manufactured in an entirely pure state, it is intended that references to chemical substances include contaminants thereof. The statement of management states explicitly that the Environmental Protection Agency is to establish guidelines on how the contaminant question is to be treated for purposes of the different sections of the act. With respect to the Section 8(b) inventory and its relationship to premarket notification, EPA must be careful not to define contaminants too broadly with respect to substances

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on the section 8(b) inventory. If EPA were to do so, then there would be no premarket notification for chemical substances with new or different contaminants than those which appear on the section 8(b) inventory.

While it may be appropriate to include all contaminants within the requirements of a rule under section 6(a) or other provisions along with the principle chemical substance, it may be inappropriate to do so insofar as it relates to the premarket notification provisions of section 5.

EPA is required to take action against a chemical substance under section 5 if there is an insufficient amount of data available and the substance either may present an unreasonable risk of injury or results in substantial environmental exposure or significant or substantial human exposure. The procedure for prohibiting or limiting a chemical substance on this basis is the same as the procedure now in existence under section 701(e) of the Federal Food, Drug, and Cosmetic Act. Under that procedure as it will be applicable to this act, the Administrator is required to issue a proposed order prohibiting or limiting the manufacture, processing, distribution in commerce, use, or disposal of the substance. If he makes the finding within the last 45 days of the premarket notification period, or an extension he is required to seek an injunction to prohibit or limit the substance.

If a proposed order is issued prior to the last 45 days of the notification period, the manufacturer or processor is authorized to file, within 80 days after the manufacturer or processor has received notice, specific objections with the Administrator. If those objections are filed, then the Administrator must seek an injunction in order to halt or limit the substance.

The objections filed with the Administrator must be specific and must state with particularity the provisions of the order deemed objectionable. As the entire procedure is similar to that contained under section 701(e) of the Federal Food, Drug and Cosmetic Act, the provision will operate in the same manner.

For example, under the case law developed pursuant to that section—Pfizer Inc. v. Richardson, C.A.2, 1970, 484 F. 2d 586— as it applies to this act, the Administrator may require that reasonable grounds be stated by a manufacturer or processor as a condition for recognizing that objections have been filed. Thus, under the procedure adopted by the conference, the Administrator may indeed exercise flexibility in determining whether or not objections have been filed and thus whether or not his order is rendered ineffective.

If the Administrator determines that valid objections have been filed, then he is required either to seek an injunction or to dismiss the order. If he decides the objections are not reasonable, then the proposed order becomes effective upon the expiration of the premarket notification. Any manufacturer who disagrees with the Administrator's determination that the grounds are not reasonable is entitled to judicial review under chapter 7 of title 5, United States Code.

The conference substitute also provides a means for the Administrator to take immediate action against those substances for which there is a reasonable basis to conclude that a substance presents, or will present, an unreasonable risk of injury to health or the environment. The Administrator must either make a rule immediately effective

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five which limits the manufacture, processing, or distribution in commerce, or which imposes use or disposal requirements of a chemical substance or he must seek an injunction in court. If he wishes to completely prohibit the manufacture, processing, or distribution in commerce of a substance, he must follow the procedure outlined above as it relates to situations where there is an insufficient amount of data.

Thus, the goals of the Senate bill, which were to provide the Administrator wide flexibility during the pre-market notification period to halt or limit chemicals, has been preserved. This is the heart of the bill.

In each instance described above where the Administrator must give notice to a manufacturer or processor of a proposed order, actual notice in writing must be provided. As a manufacturer or processor may refuse to receive written notice of the proposed order and thereby thwart the actual notice requirement, if such a situation arises, and the Administrator has made a reasonable attempt to give notice, the notification procedure should be deemed to be fulfilled.

The conference substitute contains a requirement that the Administrator respond during the premarket notification period if the Administrator declines to take action during it to halt or limit a chemical substance. This was included in the Senate bill and has been retained for the most part in the conference substitute.

It is intended that the response as outlined in the report of the Senate Committee on Commerce be utilized not only for responses during the premarket notification period but the required response of the Administrator to designated chemicals under the section 4 interagency advisory committee list as well. In the context of premarket notification, it is anticipated that the Administrator's response must be, if action is not taken, that no unreasonable risk exists or that a testing need does not exist. In the context of the section 4 advisory committee list, the response should be, if the Administrator does not initiate a testing requirement rule, that none is necessary.

PROTECTION FROM UNREASONABLE RISKS [Sec. 6]

The conference substitute, as did the Senate bill, require the Administrator to impose restrictions on a chemical substance or mixture if the Administrator finds that such substance or mixture presents, or will present, an unreasonable risk of injury to health or the environment. A variety of regulatory tools are available, ranging from complete prohibitions to mere labeling requirements.

The conference substitute also contains an important provision relating to the controls of PCB's [Sec. 6(e)]. Within 1 year, PCB's may not be used in any manner other than in a totally enclosed manner unless the Administrator makes specific exceptions. Within 2 years, manufacture is to cease and within 2 1/2 years, processing and distribution in commerce. Again, exceptions are provided.

The conference substitute also contains the authority to act against

imminent hazards, which is defined as an unreasonable risk of serious or widespread injury to health or the environment.

It should be noted' that a specific reference is made in the imminent hazard authority and in the authority to take action under section b that articles containing substances or mixtures may be reached as

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well. While this is meant to ease the burden on the Administrator and the court in reaching such articles, it should in no way be interpreted as a limitation on the authority of the Administrator or the court to act against chemical substances and mixtures, as clearly defined in section 3 of the conference substitute.

IMMINENT HAZARDS AUTHORITY [ScC. 7]

The conference substitute requires the Administrator to seek action either in court or through administrative action when imminent hazards exist. An imminent hazard is defined as an unreasonable risk of serious or widespread injury to health or the environment which is likely to result before a final rule under section 6 can protect against the risk.

REPORTING [Sec. 8]

A vital provision of the conference substitute is section 8, which describes the authority of the Administrator to require recordkeeping and reports from manufacturers or processors, and in some cases other persons, with respect to information concerning chemical substances. The authority will be vital in determining what substances are being produced, what they are being produced for, and other information.

The general reporting requirements generally reach manufacturers or processors of chemical substances. Manufacturers or processors of mixtures or chemicals produced in small quantities for research purposes are to maintain records and submit reports to the Administrator as the Administrator determines is necessary for the effective enforcement of this act. Used in this context, the phrase "effective enforcement of this act," and elsewhere in the bill as well, should be used broadly. It is not meant to imply that such records and reports may only be required in order to effectively bring an enforcement action under section 16. Rather it should be interpreted to mean requiring records

and gathering reports so that the authorities of the act may be indeed invoked, if necessary.

JUDICIAL REVIEW [Sec. 19]

Among the more important provisions is the section calling for judicial review of certain rules promulgated under the act. Of importance is the fact that certain of them receive "substantial evidence" review by reviewing courts. While the "substantial evidence" review extends to rules under section 4(a), it is not anticipated that this review standard will unduly hinder the Administrator. As testing requirements under section 4(a) will frequently be based on an insufficiency of data, it would ordinarily not be appropriate for the Administrator to develop "substantial evidence" of that insufficiency.

Nonetheless, if a reasonable effort to find data which indicates that the health or environmental effects of a chemical substance may be determined and does not find such information, the Administrator should be deemed to have fulfilled the substantial evidence requirement. With respect to substances for which premarket notification is required, the Administrator should not be required to look beyond the notification documents.

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attorney's fees

Under the judicial review procedures, as well as those relating to citizens' petitions, citizens' suits, and the rulemaking procedures under section 6, provide for the award of attorneys' fees. A brief discussion of those provisions would be appropriate.

The conference substitute before us contains important provisions relating to the award of attorneys' fees. These provisions, including the judicial review provisions of section 19, the citizens' suit provisions of section 20, and the citizens' petition provisions of section 21, allow a court to award costs of suit and reasonable fees where appropriate. So that the legislative history accompanying these provisions is consistent, I ask unanimous consent that a discussion of these provisions by the distinguished Senator from California (Mr. Tunney) which appeared in the Congressional Record of March 26, 1976, be printed in the Record at this point.

There being no objection, the excerpt was ordered to be printed in

the Record, as follows :

Legislative History To Accompany Model Attorneys' Fees Provision

Mr. T. NEE. Mr. President, attorneys' fees provisions appear in a number of places throughout this legislation. These provisions allow a court to award costs of suit and reasonable fees where "appropriate." These provisions are very important to the proper vindication of rights under this legislation. I would like to offer some explanation which in my opinion will clarify the operation of those provisions.

Until recently, the courts often provided for effective actions by private citizens through the award of costs and fees, even in the absence of specific statutory authorization, under the "private attorney general" rationale. However, in a recent decision, *Alyeska Pipeline Service Co. against Wilderness Society*, the Supreme Court held that -

"Court lacked discretionary power to award attorneys' fees to petitioners who sought to vindicate 'important statutory rights for all citizens' . . . unless there was specific statutory authorization for such awards . . . The circumstances under which attorney's fees are to be awarded and the range of discretion in the court for making those awards are matters for Congress to determine."

In light of that decision, the fees and costs provisions of this legislation follow the precedent of over 50 Federal statutes in permitting fee shifting by the courts.

This provision would allow an award of fees and costs to any party when "appropriate," a word which should be liberally construed to effectuate the purposes of this act. Thus, in typical circumstances, the court should follow prevailing case law which holds -that a successful plaintiff "should ordinarily recover in attorneys' fee unless special circumstances would render such an award unjust." *Newman v. Piggic Park Enterprises, Inc.*, 390 U.S. 400, 402 (1968) (per curiam). "Plaintiff" in the sense is used to mean the parties seeking to enforce the rights granted by this section and can include an intervenor, or a defendant in some cases. See e.g., *Shelby v. Jyranicr*, 334 U.S. 1 (1948).

In exceptional circumstances, fees and costs might also be awarded to defendants where they must "defend against unreasonable frivolous, meritless or vexatious actions * * * *Unifed States Steel Corp. v. United States*, 385 F. Supp. 340, 318 (W. D. Pa. 1974). Where plaintiff's proceeding is brought in good faith or on the advice of competent counsel, fees and costs would ordinarily be denied to a prevailing defendant. *Richardson v. Hotel Corporation of America*, 332 F. Supp. 519 (E.D. La. 1971). *aff'd*, 408 F. 2d 951 (5th Cir. 1972). The standard for awarding fees and costs to a prevailing defendant is not the same as for a plaintiff because, if it were, the risk, to the average citizen of bringing suit under this section would be so great it would discourage such suits.

Fees and costs would be awarded to a "successful plaintiff" under this provision

where there was a final court order granting the relief requested by plaintiffs, or as a matter of interim relief pending the outcome of the case. The provision does not require the entry of a final order before fees or costs may be recovered. See

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Bradley v. School Board of the City of Richmond, 416 U.S. 606 (1974) ; Mills v. Electric Auto-Lite Co., 396 U.S. 375 (1970). Such awards are especially important where a party has prevailed on an important matter in the course of the litigation even where he does not ultimately prevail on all the issues. See Bradley, supra, and Mills, supra. For purposes of the award of fees and costs, it is "appropriate" to make awards where the parties have vindicated rights through a consent judgment or without formally obtaining relief, or where such award is in the public interest without regard to the outcome of the litigation. Kopet v. Esquire Realty Co., 523 F. 1095 (2d Cir. 1975) ; Parham v. Southwestern Bell Telephone Co., 433 F. 2d 421 (8th Cir. 1970) ; Richards v. Griffith Ruhler Mills, 300 F. Supp. 338 (D. Ore. 1969) ; Thomas v. Honeybrook Mints, Inc., 428 F. 2d 931 (3d Cir. 1970).

By specifying a general rule for the amount of fees to be awarded, this provision requires the method of calculating fees be no different than that now being utilized in other fields of law as, for example antitrust and securities regulation litigation. The "actual time" spent is that reasonably calculated to advance the client's interest. The Stanford Daily v. Zurcher, 64 F.R.D. 680 (X.D. Cal. 1974). and the amount can be adjusted for factors including inter alia, the contingent nature of the success or the quality of the work performed. Lindy Bros. Builders v. American Radiator and Standard Sanitary Corp., 477 F. 2d 161 (3d Cir. 1973), on remand, 382 F. Supp. 999 (E.D. Pa. 1974), or benefits to the public from the suit. Davis v. County of Los Angeles, S.E.P.D. 9444 (CD. Cal. 1974). Fees should not be reduced merely because the attorneys are salaried employees of public interest and or foundations-funded law firms.

Fees and costs awarded under this provision may be assessed against the United States, including any of its agencies and officers acting in an official capacity, the same as against a private party.

Finally, since expert witnesses are often needed to make an adequate presentation to a court such fees are also provided for in this statute. They would be in addition to those now provided in 28 U.S.C. 1920 and 28 U.S.C. 1821.

The policy outlined above should apply to the procedures under section 23 to the extent applicable.

Mr. Magusox. In addition, so that the legislative history may be

consistent in both the House and the Senate with respect to the costs of participating in a rulemaking proceeding under section 6, I ask unanimous consent that a portion of the report of the House Interstate and Foreign Commerce Committee - report No. 9-1:-1341 - regarding the award of the costs of participating in a rulemaking proceeding under section 6 be inserted in the record at this point.

There being no objection, the excerpt was ordered to be printed in the Record, as follows:

Excerpt of Report

In order to provide to the extent possible that all relevant interests be represented in rulemaking proceedings so that the rules adopted best serve the public interest, the Administrator is authorized to provide compensation for reasonable attorneys fees, expert witness fees, and other costs of participating in the rulemaking proceeding. Such fees and costs may be provided to any person who represents an interest which will substantially contribute to a fair determination of the issues to be resolved in the proceeding if the economic interest of the person is small in comparison to the costs of effective participation by that person in the proceeding or if the person demonstrates to the satisfaction of the Administrator that the person does not have sufficient resources to participate in the proceeding in the absence of compensation. In determining if a person represents an interest which will substantially contribute to a fair determination of the issues, the Administrator is to take into account the number and complexity of the issues and whether representation of such interest will contribute to widespread public participation and to representation of a fair balance of interests for the resolution of the issues.

In determining whether compensation should be provided and the amount of such compensation the Administrator shall take into account the financial burden which will be incurred as a result of participation. However, the Committee does not intend to imply that in all instances a person must be able to

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demonstrate a financial burden. Before the Administrator may provide the person with compensation demonstration of financial burden is required unless a person has an economic interest which is small in comparison to the costs of effective participation in the proceeding. Thus when the economic interest is small, no showing of financial burden is required. However, in light of the possibility that there may be competing requests for assistance in connection with proceedings under this section, a consideration of financial burden will be relevant in determining who should be the recipients of compensation and the

amount of compensation. In considering the financial burden to be incurred, the Administrator should not look solely at the costs of participating in the section 6 proceeding, but should instead view such costs in light of the overall activities of the person applying for compensation and the person's resources. For example, a person requesting compensation could show that such person represents interests which may require participation in other judicial or administrative proceedings and that such participation might have to be curtailed or limited because of a commitment of resources to the proceeding with respect to which such request made and the Administrator should consider such information.

A determination reasonable attorneys' and expert witnesses' fees should not be influenced by the fact that a person is a salaried employee of a public interest or foundation funded organization. The Committee intends that reasonable fees be those which are commensurate with those at which such professionals would normally be compensated for performance of similar services. The fact that attorneys or experts may be employed by citizens' groups or foundations at salaries or hourly rates which may be below the standard commercial rates such professionals might normally receive is not relevant to any computation of the rate of compensation under the bill. Even in situations where a lawyer or expert initially renders services without expectation of receiving any compensation, fees are to be awarded at prevailing market rates. It may well be that an attorney will agree to provide representation of an interest in a proceeding because of a belief that such representation furthers a public interest. Representation of such interests should not have to rely upon the charity of counsel. This intent reflects the well-settled judicial rule that fee awards are to be made without reference to the fee arrangements that exist between an attorney and client. As the court stated in *Miller v. Amusement Enterprises, Inc.*, 426 F. 2d 532, 38-130 (5th Cir. 1970) :

"What is required is not an obligation to pay attorneys' fees. Rather what - and all - that is required is the existence of a relationship of attorney and client, a status which exists wholly independently of compensation."

Similarly, the United States Court of Appeals for the District of Columbia Circuit has ruled that fee awards in litigation undertaken to further the public interest must be computed so as to bring the attorneys' rate of compensation up to that of the prevailing market rate. See *Wilfloss, Society v. Morton*, 495 F. 2d 1026, 1037 (D.C. Cir. 1974), reversed on other grounds, sub nom. *Aljaska Pipeline Co. v. Wilderness Society*, 421 U.S. 240 (1975), and *National Treasury Employees v. Nixon*, 521 F. 2d 317, (1975). Provision is made in section 19 (judicial review), section 20 (citizen's civil action), and section 21 (citizens' petition) for the award of reasonable attorneys' and expert witnesses' fees in actions under such sections. The considerations enumerated here respecting a determination of the reasonableness of a fee also apply to those sections.

Mr. Waxson. As the award of attorneys' fees under section 6, and the provisions of sections 19, 20 and 21 is not restricted to plaintiffs or to successful parties, an additional explanation of what is intended with respect to these provisions is also appropriate.

It is not the intention of these provisions to provide an award for an individual or a group if that individual or group may stand to gain significant economic benefits through participation in the proceeding. It is also intended to discourage individuals who may stand to benefit economically from the proceeding from joining with other individuals for the purpose of forming an organization to obtain compensation for participation in an agency proceeding under this act. A group or organization that has members who may have some economic interest in a proceeding would not necessarily be excluded, particularly if that

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interest cannot be said to have motivated those members' involvement in that group or organization.

It is not intended that the provisions support participation of persons, including corporations or trade associations, that could otherwise afford to participate or whose economic interest in the outcome of a proceeding is not insubstantial. Whether or not the person's resources are sufficient to enable participation would include consideration of the person or group's potential utilization of tax deductions for participation in litigation as a business expense, his current financial condition, and assessment of the likelihood that the person would seek to participate in the proceeding whether or not compensation was available.

AVAILABILITY OF INFORMATION [Sec. 14]

The provisions of section 14, concerning the release of information to the public obtained by the Administrator under the act, generally follows other statutes of this nature. Some important distinctions arise, however. Under the conference substitute, for example, the Administrator is required to release information to the public if necessary to protect against an unreasonable risk of injury to health or the environment.

Moreover, with the exception of process data and mixture com-

position, the statute states clearly that health and safety studies and information bearing on them are not prohibited from disclosure and, under the terms of the Freedom of Information Act, must be disclosed if requested. Moreover, this kind of information is required to be made public when it is received by the Administrator under the provisions of section 4, concerning the testing of chemical substances and mixtures, and section 5, premarket notification.

A procedure is provided for the designation by persons submitting data which is entitled to confidential treatment under the provisions of section 14. Before releasing data so designated the Administrator must give 30 days notice to the person submitting it.

The designation authority does not extend to data from health and safety studies. Moreover, if the Administrator proposes to release information if necessary to protect against unreasonable risk of injury to health or the environment, a 15-day notification will suffice. If it is necessary to protect against an imminent, unreasonable risk of injury to health or the environment, a 24-hour notice will suffice.

While the notice is to be made in writing by certified mail – unless it is necessary to protect against an imminent, unreasonable risk – this procedure should not prove onerous to the Administrator when desiring to release. As the requirement that notification be in writing by certified mail, it is obvious that by refusing to accept a certified letter from the Administrator, a person may effectively thwart this procedure. Thus, it is intended that the notification will be deemed to be satisfied if reasonable attempts have been made to deliver the notification to the person submitting information. A return receipt is not required.

Mr. President, the Toxic Substances Control Act represents over 5 years of work by the Congress. It is high time that this program got underway without further delay. I urge the acceptance of the Conference report.

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Mr. Hartke. Mr. President, it is rare that the Senate has the opportunity to establish a program for the protection of health and the environment which enjoys the wide support as does the Toxic Substances Control Act. The conference report which is now before the Senate is supported not only by environmentalists and organized labor, but is also supported by many elements of the chemical

industry.

This is especially significant given the bitterness and divisiveness which has surrounded this issue through its 6-year history in the Congress. The differences between the Senate position and the House position were extraordinary in the early years of this bill's history. Nonetheless, in this Congress, as evidence of the chemical threat has continued to grow, the principles for which the Senate has fought so long have become a reality.

While the struggle has continued on this bill, approximately 5,000 new chemical substances have reached commercial fruition. Moreover, the hazards associated with existing chemicals like heavy metals, vinyl chloride, PCB's, PBB's, and BCME have all dramatically come to the public's attention. From the slaughter of cattle in Michigan due to PBB contamination to the condemnation of large quantities of fish from Lake Michigan because of PCB contamination, the environmental and health threat due to chemical substances has continued to be etched in our consciousness.

During this period, there have been in excess of 1 million deaths from cancer. Over a million infants have been born with birth defects of one type or another. In fact, approximately 7 percent of all infants born in this country have some sort of physical or mental impairment.

While I hold some reservations with respect to this legislation when it was originally introduced in the first session, I am happy to lend my enthusiastic support for it now and was pleased, along with the distinguished Senator from California, to be an original cosponsor of the bill as it passed the Senate.

The essential elements of the program which were contained in the Senate bill have been preserved in the conference substitute. Broad authority to require testing of known and existing substances is provided as is appropriate authority for the Administrator to act during the premarket notification period with respect to new substances and significant new uses of existing substances.

Authority is given to the Administrator, with sufficient safeguards against administrative abuse, to take action against substances found to pose unreasonable risks.

Importantly, the Administrator will have clear direction as to when this statute is to be used as opposed to the other authorities or authorities possessed by other agencies. While the direction is clear in the statute, safeguards have been incorporated which will prevent endless litigation on this point. Reporting authority is authorized so that the Administrator may require that records be kept and reports made with respect to the full range of activities associated with

the manufacture and processing of chemical substances. . ^

Health and safety data generated by manufacturers, processors, or distributors in commerce shall be retained and listed with the Administrator. This is designed to prevent data available to the industry from being buried as it was alleged in the case of vinyl chloride. Records must be kept of any significant adverse reaction to health or the environment caused by a chemical substance and submitted to the Administrator upon request. . a • f

Citizens are authorized to bring suit against violators of the act and against the Administrator for nonperformance of mandatory duties. Citizens petitions

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are authorized which will force the Administrator to be more responsive to the needs of citizens in the establishment of rules under the act.

Protections have been built in which will prevent undue burdens on small business. For example, the reporting requirements of section 8 of the conference substitute may not be involved for small businesses unless the small business is covered by a proposed or a final rule or order under various sections of the act. While EPA must have access to reporting information from small business for the purpose of developing appropriate restrictions and requirements under the act, this provision will ensure that EPA not do so arbitrarily.

Moreover, the Administrator is given the authority to exempt persons from the premarket notification requirements applicable to new chemical substances if the Administrator determines that a substance will not present an unreasonable risk of injury to health or the environment. So that manufacturers or processors do not have to submit duplicative test data under section 4, an exemption procedure is also provided. Two explicitly stated bases for determining what amount of reimbursement will be required is the market shares of the company seeking the exemption, and its competitive position. Thus, a small manufacturer or Processor will not be unduly burdened by testing costs.

The broad acceptance that this legislation has now received is an indication that the rather outlandish estimates of the costs of this legislation made last year by the chemical industry have been largely discounted. While estimates from Dow Chemical ranged up to \$2 billion per year, and the estimates of the Manufacturing Chemists Association ranged from \$340 million to \$1.4 billion per year, EPA estimated that the cost would range from \$80 to \$140 million per year. The General Accounting Office, at the request of the Committee on Commerce, agreed largely with EPA's estimate and stated that the cost would

probably run between \$100 and \$200 million per year. This cost is obviously very slight when compared to the tremendous benefits not only in direct expenditures in health care, but with respect to pain and suffering as well.

And while this legislation has gained acceptance by the mainstream of the chemical industry, it is also acceptable to environmental, public health, and labor groups, such as the AFIO, the Sierra Club, Environmental Action, Congresswatch, and others.

It is rare that this kind of combination of support exists behind any program, let alone a program designed to protect against chemical threats to health or the environment. It would be a great disservice to the people whom we in the Senate serve to do anything other than approve this conference report by a resounding majority. I urge my colleagues to do so.

Mr. Moss. Mr. President, I support my chairman, the chairman of the Committee on Commerce, in his remarks concerning the Toxic Substances Control Act.

Mr. Magxusox. Mr. President, if the Senator will yield just a moment, I wish to add that the Senator from Utah, the Senator from California (Mr. Tunney) , and the Senator from Indiana (Mr. Hartke) have played a very important role not only in the hearings on this bill, but in carrying this bill through the Senate and the conference. As I say, there were many, many meetings of the conferees and they were stalwarts in keeping the Senate bill as intact as possible. We did have to make some concessions, but had it not been for them, I do not think we would have the kind of a conference report that we have before the Senate today.

I ask unanimous consent, since he is necessarily absent, to have printed in the Record a statement from the Senator from California (Mr. Tunney) on this conference report.

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There bein[^] no objection, the statement was ordered to be printed in the Record, as follows :

Statem^lnt of Senator Tuxney .

Oftentimes we in the Senate are tempted to place labels on legislation such as

"landmark", "historic", or some other suitable adjective.

While those words are obviously overworked in this great body, I nonetheless feel that they fit the Toxic Substances Control Act very well.

As the Senate today considers the conference report on the Toxic Substances Control Act, it would be well to reflect just for a few moments on the tortuous path this legislation has followed in getting to this point.

The legislation was first introduced in the spring of 1971 as a result of a report from the Council on Environmental Quality which indicated that there was not at that time (and there still isn't), a statutory authority in existence which would deal comprehensively with chemical substances such as phosphates in detergents, mercury and other heavy metals, asbestos, and so on. The proposal at that time was viewed largely as an environmental bill designed to plug gaps that existed in the environmental control framework.

It soon became readily apparent that this authority had a far greater utility. Most importantly, it can serve as the vehicle for establishing whether or not a new chemical substance (or a significant new use of an existing substance) has been adequately tested prior to first manufacturing and if a sufficient amount of data exists to take appropriate regulatory action. It is at this point in the life of a chemical substance that appropriate controls may most easily be imposed. It is at this time that the costs in terms of occupational danger, damage to the environment, and capital outlays are at their very lowest. We have found time and time again, as is the case with chemicals like vinyl chloride, that the imposition of necessary controls when a substance is in place in the channels of commerce is extremely difficult.

It is around this key provision that much of the controversy has raged over the life of this legislation. In 1972, the Senate passed the legislation with a strong pre-market notification provision. Unfortunately, the House bill did not contain a similar provision, and the bill died because time ran out in the 92nd Congress.

The provision also was the subject of extreme controversy in the 93rd Congress. Again, the Senate passed a strong provision and the House did not. That bill remained before a committee of conference for approximately one and one half years, without resolution.

In this Congress, there has been significant movement on the part of the House of Representatives which has resulted in the agreement we have before us today.

The many tragedies which have come to light within the past 3 years indicate that while it has been a long and difficult task to get a strong pre-market notification provision, it has been worth it. Scientific journals and the popular press have been filled with accounts of how chemicals like vinyl chloride, BCME, PCB's, and asbestos are causing far graver threats to human health than we had previously thought. All of these chemicals have now been implicated as causing cancer and

other grave health effects. Nonetheless, all of them are also used in very large quantities and have become so intertwined with the economic fabric of this country that control now is extremely difficult.

While many of the health effects to which human beings are at risk has declined in recent years, cancer has not. In fact, cancer incidence has been estimated in 1975 to be some two and a half percent above the previous year. That much of the increased incidence in cancer is due in major part to the use of chemicals in this country is largely beyond debate. The National Cancer Institute has estimated that from 50 to 90 percent of all cancers are environmentally caused. While much of this is due to cigarette smoking, much is not.

Had this statute been in existence when chemicals now known to cause major health effects began production or as their uses mounted, we could well have avoided much of the pain and anguish that accompanies occupational disease and public health and environmental threats generally. It is extremely important to recognize that the conference substitute before the Senate today contains the authority for the Administrator to require premarket notification before manufacture or processing of substances for significant new uses is begun [Sec. 5j]. Thus, as the volume of a chemical substance mounts, or as its uses change, EPA will have the authority to make sure that test data is available and that appropriate restrictions are imposed prior to the exposure taking place.

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I am happy to say that I have been a principal sponsor of this legislation since my joining the Committee on Commerce nearly four years ago. During that time, I have chaired day after day of hearings during which the grim tale of the kinds of human suffering that chemicals may cause has unfolded. Statistics concerning disease and death suddenly take on very clear meaning when one is seated across a hearing table from the surviving family of workers who have died from chemically induced cancer.

The essential elements of a strong toxic substances control program are included in the conference substitute. It provides for premarket notification for all new chemical substances, and it provides for adequate authority during that period to take action. If the Administrator finds that there is insufficient data or experience with respect to a chemical and the substance may present an unreasonable risk or if he finds merely that a substance will result in substantial environmental or significant or substantial human exposure, the Administrator must issue proposed orders to halt or restrict the chemical pending the development of the data. While the Administrator must go to court to get an injunction if objections are filed by the manufacturer or processor, it is clear that the Administrator will have a great deal of flexibility to determine whether or not the objections are

valid.

Moreover, if the Administrator finds that a substance presents or will present an unreasonable risk of injury to health or the environment, the Administrator must act to prohibit or limit the chemical substance during the pre-market notification period.

Importantly, the conference substitute contains adequate provision for citizen input to the administrative process. Citizens may bring suit against violators of the Act if EPA has not acted against them and to force EPA to act with respect to nondiscretionary duties. In addition, citizens may petition EPA for the issuance of certain rules and orders under the Act. If EPA does not respond within 90 days, or responds in the negative, citizens may bring suit to force the Administrator to initiate the action. All of us have an interest in ensuring that agencies of the Federal Government are more responsive to the needs of citizens. The provisions contained in the Toxic Substances Control Act should be an effective means to ensure that bureaucratic lethargy does not prevent the appropriate administration of this vital authority.

I am delighted that the Senate today will take final action on an authority which Russell Train, Administrator of EPA, has called the most important environmental measure before this Congress.

I could not agree more.

Mr. Moss. Mr. President, as was pointed out by the Senator from Washington, this is a complicated and difficult bill to write and on which to reach an agreement with the House of Representatives. But it is of immense importance to the health and welfare of our people and to the environment in which we live. Each day's newspapers carry some additional story about problems that we have with chemicals and toxic substances that, in various ways, impinge upon the health of our people and contaminate our water supply, our food supply, and create other health and environmental threats.

This bill will now establish a control mechanism, so that we can be sure that we are not exposing humans and the environment to toxic substances before we can determine whether or not they have deleterious effect and before effective action can be taken.

Ave live in an age of chemistry and technology. We do so many good things with chemistry and technology, but we have been quite oblivious to what the total effect of these new chemical processes may be. We are now attempting to be certain that nothing is loosed upon our people in the way of cliemical or toxic substances without our knowing what the fallout will be. If it is going to be damaging, then, of course, it m[^]ist be prevented.

I wanted to add just that brief comment because this has been a long and difficult process. The conference was lengthy, but the conference report which is before the Senate represents a reasonable compromise with the House of Representatives, and I urge its adoption.

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Mr. Magxusox. Locally, of course, we have been reading a great deal about the disaster involving Kepone. It is precisely this type of disaster that this bill is designed to prevent.

Mr. Moss. Right.

Mr. ^\AGxrsox. >.o question about it. That is why the law is so important. In the future things like this almost unbelievable disaster, will not happen.

Mr. Pkarsox. Mr. President, agreement by the Senate and House conferees on a compromise Toxic Substances Control Act marks a major achievement of the 94th Congress. For nearly 6 years, legislation regarding the control of toxic substances has been before the Congress ; during the 93d Congress, Senate and House conferees were unable to agree on a compromise bill. During that same time period, an estimated 5,000 new chemicals have been introduced into the commercial marketplace and have served to increase the number of known different chemicals to over 2,000,000. Final congressional action on the Toxic Substances Control Act comes at a time when the need to protect the American public from the harmful effects associated with toxic chemical substances has never been greater.

As my colleagues will recall, the Senate passed S. 3149, the Toxic Substances Control Act, on March 26, 1976, by a vote of 60 to 13. Final House passage on a very similar bill, H.iR. 14032, occurred on August 23, 1976, by a 319 to 45 vote. The conference report that we are now considering was then forged by the respective Senate-House conferees and represents a compromise that has been unanimously agreed to by all conferees.

The vast majority of commercially available chemicals have served to enormously increase our standrad of living and have been in large measure responsible for dramatic improvements and advances in agricultural production, medical research and technology, and a myriad of new and innovative products available to the consumer. There are also, however, a small number of highly toxic chemical substances that

have been commercially produced and marketed that have been responsible for enormous damage. The tragic human suffering and environmental degradation associated with such chemical substances as Kepone, vinyl chloride, mercury, and PCB's are well known. To a large degree, our continued failure to adequately test and regulate chemical substances, both during the premarket period and after the chemical is in commercial production, has been responsible for such tragedies. Enactment of the Toxic Substances Control Act will enable this Nation to gain the type of control necessary to adequately and effectively deal with this problem.

Enactment of this bill would:

Provide the means by which adverse effects on human health and the environment can be ascertained and appropriate action taken before chemical substances are first manufactured commercially and introduced into the marketplace.

Provide for an ongoing mechanism that would ensure that the EPA Administrator would continually have access to new information developed regarding adverse health or environmental effects associated with chemical substances. Appropriate action necessary to adequately protect against unreasonable risks associated with chemical substances could then be taken.

Provide for specific prohibitions regarding the manufacture, use, and disposal of PCB's, a widely used and long-lived toxic chemical substance.

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Require the Administrator to balance the various costs, risks, and benefits associated with chemical substances in determining adequate measures to regulate such substances.

Highlight the need to adequately protect against adverse human health or environmental effects resulting from the manufacture, distribution, use, and disposal of chemical substances.

Provide for both citizens law suits and petitions to ensure adequate and viable public input with respect to the effective administration of the bill.

Mr. President, the Toxic Substances Control Act as agreed upon

by Senate and House conferees has received widespread and overwhelming support from all major environmental and consumer protection groups and major and small chemical manufacturers. The compromise bill provides for far reaching and much needed controls over the manufacture, distribution, use and disposal of chemical substances, both at the critical premarket stage as well as during subsequent production stages, while at the same time requiring that the EPA administrator carry out the provisions of the act in a reasonable and prudent manner. In addition, and a point emphasized by the conferees, the Administrator is to use the least burdensome means of regulating a chemical substance consistent with providing adequate protection to human health and the environment from unreasonable risks associated with the manufacture, distribution, use, and disposal of chemical substances. Thus, adequate and meaningful regulatory controls are available to the EPA Administrator to protect against unreasonable risks associated with toxic chemical substances while at the same time insuring that such regulations take into consideration the enormous benefits associated with the manufacture and use of safe chemical substances.

Mr. President, this legislation is long overdue. I strongly urge my colleagues to accept the Toxic Substances Control Act as agreed upon by the Senate-House conferees.

Mr. DuRKTN. Mr. President, for the past 8 years, the Nixon-Ford administration has waged an intensive effort to prevent enactment of meaningful toxic substance control legislation. Their partner in this effort has been the mammoth petrochemical industry, which has sent legions of pin-striped lawyers to Capitol Hill to squash any interest in controlling harmful chemical production. The industry dangled the threat of thousands of unemployed chemical workers should such legislation be passed.

Not unrelated, during those same 8 years, at least 1,000 new chemicals were introduced into the environment each year with little or no knowledge of their long-term health or environmental effects, either for those working and living near chemical plants, or far away.

Today, we are on the verge of enactment of a toxic substance control bill in the Congress. The bill is a watered-down version of what I would call meaningful control on the production of new chemicals. It does not require premarket testing of all new chemicals. It does not provide for simple administrative mechanisms which the Environmental Protection Agency will need to effectively keep potentially harmful chemicals off the market. And it fails to authorize sufficient funds to assure full implementation even of the bill as written, let alone more strenuous enforcement and testing.

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Still, it is a stait, and represents years of effort by Senators Magnuson, Tunney, and Hartke to obtain enactment of the strongest possible legislation. The bill which came out of the House-Senate conference contained everything that could be squeezed from the chemical companies and the Republican administration. Despite the advice of his own Council on Environmental Quality, President Ford may still consider a veto of the bill.

Before going any further, we ought to put one myth to rest : that toxic substance control legislation threatens the jobs of chemical workers. In fact, passage of the current bill would not have been possible without the vigorous and uncompromising support of the Nation's labor unions, who have argued rightly that their members have far more to fear from the production of harmful chemicals than legislation designed to control them. It is the chemical workers and their families who suffer the highest rates of cancer, diseases, and disabilities if a toxic substance is introduced into the environment. And it is the chemical workers who eventually would be the first to suffer from multimillion-dollar damage suits leveled against their companies in the event that another Kepone is thrust upon the market without so much as a peep from the EPA.

The last 8 years of Nixon-Ford rule have been a disaster for the environment, and for environmental health. Tons of PCB's were dumped into our water, our air, and many of the commonplace articles of daily life - the same PCB's which experts at the National Institutes of Health now fear may threaten the health of babies who are breast fed. For the last 8 years, millions of tons of asbestos were produced without control. The result will be 400,000 asbestos workers dead during the next 50 years from asbestos-caused cancer.

This legacy of environmental recklessness will be visited upon us, upon our children, and upon our grandchildren. Toxic substances introduced into the environment today may have disastrous effects on our health, our life expectancy, and the biological development of the species for decades to come. Today's profitmaking chemical may be tomorrow's birth defect or disease.

Will Lepkowski wrote in the Washington Post earlier this month about how vital our social and environmental policy is to our children :

What is really at issue is not the ethics of protecting the least among us.

That's an obvious truth. It is the need for ethics covering the entire system to determine whether the current system is the optimal one for nurturing biological and social evolution. If the children are getting hurt, it needs a lot of questioning. The hopeful thing is that, thanks to scientific ways of understanding nature, we have the knowledge to start figuring out how to make the system work better for us. One might call it the ethics of adulthood.

Assuming that no one is safe might make it inconvenient at first for a lot of chemical companies. But if a fear epidemic of cancer or birth defects materializes, Lepkowski said, we will certainly regret not having done something about it while we could have. This is not an issue that can be put off for another Congress, another set of committee hearings, another round of bargaining with the chemical company lobbyists and another round of veto threats with a Republican White House.

Perhaps my concern seems extreme to some. Yet as someone who takes pride in the relative clean state of his home environment, I am also extremely concerned that New Hampshire has one of the highest

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cancer death rates in the country – sixth highest for women, eighth highest for men. My obligation is to help find out what is causing this disproportionate death rate, and what we can do about it. It is not an obligation to any company, to any industry, but to the children and future children of New Hampshire.

There can no longer be any question of the impact that chemicals have on health or the environment. No one knows for sure the causes of cancer. But we are reasonably sure that between 60 and 90 percent of cancer is induced by substances in the environment which we eat, breathe, or touch in some manner.

Chemicals are the No. 1 villain, and have been linked time and time again to gene mutations and birth defects, cancer, and various heart and lung diseases.

As a result, we can no longer blind our eyes to a policy which allows chemical companies to produce chemicals first and ask questions later. We ought to have all the answers in hand before we allow tons of unknown substances to be dumped willy-nilly into our environment. If there has to be a risk taken, then it ought to be by the chemical companies and their stockholders, not our children and grandchildren

still to be born. Chemicals should be tested first in the laboratory, not in the environment, and the results should be complete and conclusive.

Of course, we in the Congress could enact the most stringent and meaningful toxic substance control law, and there still would be no assurance of good faith execution by the administration, especially an administration which has danced an 8-year jig with the oil companies which control the bulk of chemical production in this country. A look at the EPA enforcement record under the Ford administration is discouraging. It came as no surprise that in January of this year, three lawyers with the EPA resigned because of the continued failure of the EPA to take effective action to regulate possible cancer-causing and other toxic chemicals in our air, food, and water.

The American voter concerned about his health and his environment does himself little good electing a Democratic Congress committed to controls and a Republican President dedicated to a free market in harmful chemicals. In the long run, perhaps we should consider altering our Government structure so that the Congress and the President are pulling in the same direction, to avoid the stalemate over this and hundreds of other issues during the past 8 years. In the short run, I hope the American voter will see the wisdom in electing both a Democratic Congress and a Democratic President, to carry on the work that still has to be done in this area.

Toxic substance control legislation will be before Congress next year. So far, we have enacted a ban on PCB's. We have required that EPA be notified of all new chemicals that are produced, and given EPA the authority to stop production of those substances which it can determine to pose a risk to the health and environment. Hopefully next year, with the cooperation of a Democratic President the Congress will put the shoe where it really belongs, and require the chemical companies to prove all their products are safe for future generations of Americans before proving they are safe for this generation of stockholders.

Mr. Magnuson. Mr. President, I move the adoption of the conference report.

The Presiding Officer. The question is on agreeing to the conference report.

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Mr. Allex. I call for the yeas and nays, Mr. President.

The Presiding Officer.* Is there a* sufficient second? There is a sufficient second.

The yeas and nays were ordered.

The Presiding Officer. The question is on agreeing to the conference report. On this question, the yeas and nays have been ordered, and the clerk will call the roll.

The legislative clerk called the roll.

Mr. Robert C. Byrd. I announce that the Senator from Texas (Mr. Bentsen), the Senator from Nevada (Mr. Cannon), the Senator from Florida (Mr. Chiles), the Senator from Michigan (Mr. Philip A. Hart), the Senator from Minnesota (Mr. Humphrey), the Senator from Wyoming (Mr. McGee), the Senator from Minnesota (Mr. Mondale), the Senator from New Mexico (Mr. Montoya), the Senator from Georgia (Mr. Talmadge), and the Senator from California (Mr. Tunney) are necessarily absent.

I further announce that the Senator from Ohio (Mr. Glenn), the Senator from Montana (Mr. Mansfield), and the Senator from South Dakota (Mr. McGovern) are absent on official business.

I further announce that, if present and voting, the Senator from Minnesota (Mr. Humphrey) would vote "yea."

Mr. Griffix. I announce that the Senator from Maryland (Mr. Beall), the Senator from New York (Mr. Buckley), the Senator from Nebraska (Mr. Curtis), the Senator from Kansas (Mr. Dole), the Senator from Arizona (Mr. Goldwater), the Senator from Wyoming (Mr. Hansen), the Senator from New York (Mr. Javits), and the Senator from Oregon (Mr. Packwood) are necessarily absent.

I further announce that, if present and voting, the Senator from Maryland (Mr. Beall) would vote "yea."

The result was announced – yeas 73, nays 6, as follows:

[Rollcall Vote No. 656 Leg.]

YEAS– 73

Abourezk

Allen

Baker

Bayh

Bellmon

Biden

Brock

Brooke

Bumpers

Biirdick

Byrd, Harry F., Jr.

Byrd, Robert C.

Case

Church

Clark

Cranston

Culver

Domenici

Durkin

Eagleton

Eastland

Fong

Ford

Garn

Gravel

Griffin

Hart, Gary

Hartke

Haskell

Hatfield

Hathaway

Hollings

Hruska

Huddleston

Inouye

Jackson

.Johnston

Kennedy

Laxalt

Leahy

Long

Magnuson

Mathias

McClellan

McIntyre

Metcalf

Morgan

Moss

Muskie

Nelson

Nunn

Pastore

Pearson

Pell

Percy

Proxmire

Randolph

Ribicoff

Roth

Schweiker

Scott, Hugh

Sparkman

Stafford

Stennis

Stevens

Stevenson

Stone

Symington

Taft

Thurmond

Weicker
Williams
Young

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NAYS- 6

Bartlett
Fannin

Helms
McClure

Scott, William L.
Tower

NOT VOTING- 21

Beall
Bentsen
Buckley

Glenn

Goldwater

Hansen

Hart, Philip A.
Humphrey
Javits

Mansfield

McGovern

Mondale

Montoya

Packwood

Talmadge

Tunney

McGee

Cannon

Chiles

Curtis

Dole

So the conference report was agreed to.

Mr. Magnuson. Mr. President, I move to reconsider the vote by which the conference report was agreed to.

Mr. IxouYE. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

[Subsequently, on 1 October 1976, Senator Magnuson made the following comments concerning S. 3149 as reported from conference and passed by the Senate :]

Mr. Magnuson. Mr. President, on Tuesday, September 28, both the House and the Senate approved the conference report on S. 3149, the Toxic Substances Control Act. That act is now before the President.

One of the key provisions of the act concerns the premarket notification procedures of section 5. They are extremely important as they form the basis by which threats to health or the environment will be-

come known and responded to prior to first manufacture of a new chemical substance or manufacture or processing of an existing substance for a significant new use. Apparently, some confusion still exists over the meaning of the conference report with respect to the responsibility of manufacturers or processors to submit notice of proposed manufacture or processing of new substances or significant new uses of existing substances and the notice of objections that a manufacturer or processor may file with the Administrator after the Administrator has issued a proposed order to halt or limit the substance.

With respect to the first point, it has been stated that the 90-day pre-market notification provision begins running when EPA receives notice from the manufacturer, regardless of whether or not the information submitted is in conformance with the requirements of the statute. This is clearly not so. Section 5 (d) of the statute explicitly states that the notice must include certain specific information. This includes the name, identity, and molecular structure of the chemical; proposed categories of use ; amount to be manufactured or processed ; a description of byproducts ; the number of individuals exposed ; and the manner or method of its disposal. In addition, any test data in possession or control of the person is to be submitted, in such form and manner as the Administrator prescribes and a description of any other data concerning the environmental and health effects of the substance.

The requirements of the act are clear. If this information is not properly submitted, then the notification requirements of the act have not been complied with. Manufacture or processing may not begin until 90 days - or 180 days, if extended - after proper notification has been given.

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In addition, there seems to be some misunderstanding on the manner in which a proposed order of the Administrator to prohibit or limit manufacture of a substance during the notification period could be rendered ineffective by the filing of objections by the manufacturer or processor. The act states explicitly that the objections must specify "with particularity the provisions of the order deemed objectionable and stating the grounds therefor [Sec. 5(e)(1)(C)]." Any objection not meeting these requirements will not be considered as filed. Moreover, as the entire procedure is borrowed from section 701(e) of the Federal Food, Drug, and Cosmetic Act, the interpretation of this provision is the same as it is under that provision. In fact, the statement of managers accompanying S. 3149 states that -

The conference substitutes borrows the procedure from section 701(e) of the Federal Food, Drug, and Cosmetic Act.

As was stated on the Senate floor when the conference report was approved on September 28, the case law developed pursuant to section 701(e) of the Federal Food, Drug, and Cosmetic Act applies to the procedure under this act as well. That case law - Pfizer v. Richardson[^] C.A. 2, 1970, 434 F. 2d 536- as applied to this act, authorizes the Administrator to require that reasonable grounds be stated by a manufacturer or processor as a condition for recognizing that objections have been filed. Thus, the Administrator will determine whether or not objections have been filed on the basis of whether or not the objections conform with the requirements of the statute, as interpreted under the case law developed pursuant to section 701(e) of the Federal Food, Drug, and Cosmetic Act.

Mr. President, it is my hope that this explanation will clear up any misunderstanding that might have occurred on the requirements of the section.

HOUSE CONSIDERATION OF CONFERENCE REPORT

[Excerpt from the Congressional Record, Sept. 28, 1976, House, pp. H11343-H11347]

CoxFERExcE Report ON S. 3149, Toxic Substances Control Act

Mr. MrRPiiY of New York. Mr. Speaker, I call up the conference report on the Senate bill (S. 3149) to regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes, and ask unanimous consent that the statement of the managers be read in lieu of the report.

The Clerk read the title of the bill.

The Speaker pro tempore. Is there objection to the request of the Gentleman from Ohio?
There was no objection.

Mr. Staggers. Mr. Speaker, the Toxic Substances Control Act is legislation which first passed the Senate in March 1976 and then passed the House on August 23, 1976 by a vote of 319 to 45. The House language differed from that of the Senate and a conference was needed. The conferees have met and filed their report.

The conference report essentially preserves the structure of the House provisions. I will summarize very briefly the resolution of the

differences between the two versions.

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First, the EPA Administrator is authorized to act against chemical substances or mixtures which present an unreasonable risk of human health or the environment.

Second, if there is inadequate information to evaluate the health or environment effects of a new chemical substance the EPA Administrator can ask for an immediately effective order before the end of the premarket notification period to halt or limit its manufacture. The manufacturer can then file objections to the administrative order with EPA. If the Administrator does not agree with the manufacturer, he is authorized to seek a court injunction to halt or limit the manufacture of the new chemical substance pending the receipt of adequate information on the new chemical substance [Sec. 6].

Third, the provisions in the House version protecting the small chemical manufacturer from burdensome reporting and filing fee requirements are retained [Sec. 8].

Fourth, the language of the House version is retained regarding the Administrator's authority to use the Toxic Substances Control Act as opposed to other existing Federal laws, and the Administrator's decision is committed to his decision [Sec. 9].

Fifth, the following sums are authorized to be appropriated [Sec. 29].

[In millions]

Fiscal year 1977 \$10.1

Fiscal year 1978 12.6

Fiscal year 1979 16.2

Sixth, the effective date is January 1, 1977 [Sec. 31].

Mr. Speaker, we fully expect this legislation to be signed by the President. This is a good conference report and I urge its enactment.

Mr. Broyhill. Mr. Speaker, the toxic substances control legislation

gives the Administrator of the Environmental Protection Agency extensive and wide-ranging authorities to regulate all aspects of the chemical industry. Briefly stated, this legislation would authorize the Environmental Protection Agency to require that manufacturers of chemical substances perform testing, would require that manufacturers of new chemical substances or existing substances being put to significant new uses provide EPA with certain information 90 days prior to manufacture, and would authorize EPA to impose various kinds of regulations on substances which the Administrator has found pose an unreasonable risk to health or the environment. The general standard for taking action under the legislation is that the substance may present an unreasonable risk. The conferees intend to limit the Administrator to taking action only against unreasonable risks because to do otherwise assumes that a risk-free society is attainable, an assumption that Congress does not make.

Although the authorities granted to EPA are extremely broad, the conferees have made a concerted effort to include in the conference report safeguards against arbitrary action on the part of EPA. As is stated in section 2 of the conference substitute, the conferees intend that the Administrator of the Environmental Protection Agency carry out this legislation in a reasonable fashion, taking into consideration not only the environmental effects, but also the economic and societal impact of its regulatory actions. As section 2(c) makes clear, action

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should be taken in an informed and responsible manner based upon knowledge, information and facts. To do less is to act in an irresponsible, imprudent and overly cautious manner. Further, any legislation falls more heavily on this country's small business community and the conferees expect that the Administrator of the EPA will consider the impact which his actions may have on the small businesses regulated under this legislation.

One of the most far-reaching and controversial provisions of the legislation is section 5 setting out the premarket notification requirements for manufacturers and processors of new chemical substances and of existing chemical substances which are being put to significant new uses. This section requires that those manufacturers and processors submit information specified in the legislation to EPA at least 90 days prior to manufacture. This 90-day period may be extended for an additional 90 days for good cause. If the information available about a substance is inadequate, the Administrator may

issue a proposed order to prohibit or limit production of the substance to go into effect upon the expiration of the premarket notification period. The proposed order would have to be issued at least 45 days prior to the expiration of the premarket notification period. If the manufacturer or processor of a substance files objections to the proposed order, or if the notice period will expire in less than 45 days, the Administrator may seek a court injunction to prohibit or limit the manufacture of the substance. The procedure I have just described would also be available to the Administrator if he had adequate information about the substance indicating that it poses an imminent hazard and he wishes to ban the particular substance.

The legislation states that a manufacturer or processor may file objections with the Administrator "specifying with particularity the provisions of the order deemed objectionable." The purpose of this provision is to put the Administrator on notice as to the objections of the manufacturer or processor. However, the Administrator could not put the proposed order into effect because he determined that the objections of the manufacturer were either unmeritorious or not of sufficient specificity. It is enough that the Administrator be on notice that objections do lie against the proposed order. Similarly, with respect to the 90-day premarket notice provision, this period would begin running when EPA receives the notice and information specified in the bill. EPA could not stop the tolling of the period by alleging that the information submitted by the manufacturer or processor was incomplete.

In section 6 of the conference substitute, we have given the Administrator authority to promulgate a number of different kinds of regulations ranging from the total ban of a substance to requirement that a substance be marked with warnings or instructions with respect to its use or disposal. However, I wish to emphasize that the conferees intend that the Administrator impose the least burdensome requirements necessary to adequately protect against the risk.

The conference substitute' includes a provision regulating PCB's similar to the provision included in the House bill [Sec. 6(e)]. This provision sets out a timetable for regulating PCB's culminating in a ban on the processing or distribution in commerce of PCB's 21/21 years

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after the effective date of this act. The purpose of this ban is to preclude the manufacture, processing or distribution in commerce of new

PCB's or new equipment containing PCB's in 21/2 years after the effective date of this act. It should be noted, however, that equipment now in existence containing PCB's is clearly exempted from this ban. Similarly, any PCB substance in existence would also be exempted from the ban on processing and distributing in commerce if sold or used to maintain existing equipment or transported for purposes of disposal.

]Mr. Speaker, the conference report now before us vests awesome, new responsibilities in the Environmental Protection Agency. However, I am confident that if the legislation is regulated in a prudent and reasonable manner, as the conferees intend, it will not prove to be overly burdensome to those regulated by it. Therefore, I support the passage of this conference report.

^Mr. Skubitz. Mr. Speaker, yesterday the House passed the Resources Conservation and Recovery Act, which sets out a detailed plan for regulating the disposal of hazardous wastes. I note, however, that section 6 of the toxic substances conference report gives the Administrator of the Environmental Protection Agency authority to promulgate regulations with respect to the manner or method of disposal of toxic substances. I am concerned that we may be setting up two different regulatory schemes to regulate the same kinds of substances. Would the gentleman from North Carolina care to comment on that ?

Mr. Broyhill. Mr. Speaker, I will be glad to comment on that. Perhaps the gentleman from West Virginia also would want comment on this.

Of course, I share the gentleman's concern about this. It is my understanding of what the conferees intend here is that, in this particular case, EPA would use the authorities that are granted to it in the Resource Conservation and Recovery Act. If those authorities can be used to regulate the potential problem, then we would expect those authorities would be used, rather than immediately going to the provisions of the Toxic Substances Act. I believe that section 9 of the conference report would require this result since it was the intent of the conferees that the Toxic Substances Act not be used, when another act is sufficient to regulate a particular risk.

Mr. Skubitz. I thank the gentleman.

Mr. Broyhill. The Administrator of EPA is to use authorities in the Toxic Substances Act if he cannot regulate potential hazards under other acts.

Mr. Skubitz. I thank the gentleman.

Mr. Staggers. I would agree with the statement of the gentleman from North Carolina that this is the intention of the conferees. Section 9(b) of the conference report states that if the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be reduced to a sufficient extent by acting under other EPA-administered laws, the Administrator must use those other laws unless he determines, in his discretion, that it is in the public interest to protect against the risk by using the Toxic Substances

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Control Act. Therefore, I would agree completely with the answer the gentleman from North Carolina gave the gentleman from Kansas.

Mr. Moore. Mr. Speaker, Members of the House, I am very disappointed in this conference report for several reasons, but the most important one is that on August 23, 1976, when we considered this bill, I offered an amendment [Sec. 32 of H.R. 14032 as passed by the House] which the House passed by a recorded vote of 210 to 157. At that time, that was the ninth instance the House had passed such an amendment. We know it now as the legislative veto amendment, wherein either House is given 60 legislative days to veto a regulation of an administrative agency ; in this particular case, the agency having administrative jurisdiction of this bill.

Since that time, an additional and tenth time, the House passed such an amendment. Again, I offered it, and then even more recently, just a week ago, the House considered under suspension a bill which would have made this veto blanket law. That bill passed clearly by a majority, and failed by only six votes of having a two-thirds majority of this House voting for this legislative veto as a necessary curb of the bureaucracy.

In every instance, we passed this amendment save one. the House conferees have crate red or give it up in conference. I think it is high time that we stop playing games with the public and stop playing games with the poor freshmen like myself, allowing us to pass these amendments, going to the public and saying, "We are making these reforms," and then going into the conference committee and cratering, letting them strip them off with no real attempt to liold them.

That is not the intent on the House floor. We voted on this amendment. We have thwarted the clear, distinct, overwhelming will of the

House by stripping that amendment off. I do not know what it takes to have certain Members of this House understand what the will of the House is, but it certainly has been thwarted in this particular instance.

I would offer a motion to recommit this conference report with instructions to reinsert that amendment if it were possible, but this being the second House to consider the conference report, it is not possible. Therefore, it seems to me that Members – some 265 by the last count – who believe that we need this kind of reform, ought to consider voting this conference report down. It would be an even clearer message, evidently, of what we have been saying that we are serious about this bureaucratic reform, and expect amendments like these passed by the House and to be held to by the House conferees when the bill goes to conference.

Mr. Levitas. Mr. Speaker, I would like to associate myself with the remarks of the gentleman from Louisiana. I am very disappointed that this congressional veto provision that was in the House bill was taken out of the bill by the conference committee. What disturbs me even more is the fact, according to information I have received, that the managers on the part of the House did not fight for the House position in this matter ; did not stand up for the expressed will of the House, but went into that conference committee with the understanding that they would cave in as soon as challenged. Indeed one proponent of this bill who opposed the congressional veto amendment when it was offered

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in the House said that it would be stripped off in conference and he later serA^ed on the conference committee. His prediction came true.

I think that this type of action is flying in the face of everything that this process stands for. The openly and freely expressed will of the majority should be respected.

It is interesting. I look at the ^Members of the House who are managers on the part of the House, and some of them are in the forefront of the leadership reform in the House. They speak of reform. But they act otherwise. I think one of the reforms we ought to institute is to have the managers on the part of the House stand up for the House

when they get into a conference committee. I think it is time to say, "Reformer, heal thyself because they ought to stand up for the expressed will of the House or else the democratic process is perverted.

There were 265 Members of this House who went on record in favor of the congressional veto by voting for H.R. 12048 just last week. An opportunity to carry out that will was lost by our conferees. They are supposed to represent our position and the position of the American people, but they cave in and surrender. I think we ought to change that. If we do not do it today, it certainly ought to be the highest order of priority in the next Congress.

Mr. Broyiill. Mr. Speaker, I support the concept upon which the amendment to which the Members refer is based. Unfortunately, the Senate would not go along with us on that.

Mr. Speaker, I would point out to the gentleman from Georgia and also to the gentleman from Louisiana that there is a good chance that a similar amendment offered by the gentleman from Louisiana to the Clean Air Act may be left in that act. So perhaps we are making some progress.

Mr. Murphy of New York. Mr. Speaker, the conference report before us today is one of the most important pieces of legislation to be considered by the Congress this year. It is legislation designed to protect our people and our environment from harmful chemical substances. It is the culmination of a legislative effort that spans three Congresses, and as recent incidents have indicated the legislation comes none too soon. The legislation is supported by such diverse groups as the National March of Dimes, the Manufacturing Chemists Association, the United Steelworkers, the Sierra Club, and the AFL-CIO.

Chemical substances have become an enduring part of our environment. They are in our air, our water, and our soil. They are used in our manufacturing processes and they are essential components for consumer and industrial goods. While society reaps enormous benefits from chemicals, we are learning that chemicals can also do tremendous harm. For example, contamination by polychlorinated biphenyls - PCB's - has resulted in closing some of our major water systems to fishing. Recent studies have linked this highly persistent, environmental poison to human cancer, and we are now discovering troublesome levels of PCB's in mother's milk. Thousands of cattle have had to be killed in Michigan because of contamination by polybrominated biphenyls - PBB's. Asbestos, widely used in items ranging from talcum powder to brake linings to wallboard is now known to cause cancer and other debilitating illnesses. These examples make it quite clear that the country faces serious risk of harm to the health of its people and to its environment from the substantial use which is made of chemicals. Unfortunately,

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current Federal law is inadequate to deal with the risks presented by these substances. The legislation before us today will enable us to act to protect health and the environment from the pernicious effects of toxic chemicals.

The bill before us today is substantially similar to that which passed the House by a wide margin on August 23. Briefly, the bill will ; First, require manufacturers and processors of potentially harmful chemical substances and mixtures to test their products so that their effects on health and the environment may be evaluated; second, require manufacturers of new chemical substances for significant new uses to notify the EPA 90 days in advance of commercial production ; third, authorize delays or restrictions on the manufacture of new chemical substances which have been inadequately tested and which may be dangerous; fourth, authorize the EPA to adopt rules to prohibit or limit the manufacture, processing, distribution, use or disposal of chemical substances or mixtures which present an unreasonable risk to health or the environment ; fifth, authorize the Administrator to take immediate action to protect the public and the environment from an imminently hazardous chemical substance or mixture; and sixth, ban the manufacture, processing, and use of PCB's within 21¹/₂ years.

The overriding purpose of the legislation is to provide protection of health and the environment through authorities which are designed to prevent chemical harm before it occurs, rather than merely reacting to harm after it has occurred. In addition, the legislation is designed to improve our abilities for dealing with hazardous chemicals after the harm has been manifested.

The legislation achieves these objectives through three major provisions. First, under the bill the Administrator of the Environmental Protection Agency is instructed to require manufacturers and processors to conduct testing on their chemical substances or mixtures if certain factors exist [Sec. 4].

Testing will be required in instances in which there is inadequate information to evaluate the health and environmental effects of the substance or mixture and when testing is necessary to develop data respecting the health or environmental effects. In addition, there must be some basis for concern about the substance. If there is information indicating that the substance or mixture may present an unreasonable risk

to health or the environment, testing is required. For example, if one substance is structurally similar to a second chemical with known adverse health or environmental effects, the Administrator could reasonably conclude that the first chemical may present an unreasonable risk and therefore require testing of it to determine its health and environmental effects. Or if there is reliable preliminary data indicating that a substance may be dangerous, again it would be reasonable to conclude that the chemical may present an unreasonable risk and that additional testing should be done. In addition, testing can be required in certain situations even though there is an absence of any information indicating that the substance or mixture per se may be harmful. This occurs when there is or will be substantial production coupled with substantial environmental or substantial or significant human exposure to a substance or mixture about which there is inadequate information. Thus, the legislation recognizes the importance in seeing that chemicals to

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which there is substantial human or environmental exposure be adequately tested to see that they are safe.

In the case of mixtures, the legislation encourages the Administrator to first look at the substances which comprise the mixture to determine whether the mixture's health and environmental effects may not be reasonably and more efficiently determined or predicted by testing the substances comprising the mixtures rather than the entire mixture. This is intended to reduce unnecessary or duplicative testing, since the assessment of safety of a mixture may well be based on the toxicity of particular components, and tests of the entire mixture with its varying component ratios may be unnecessary or unrewarding.

The testing authorities in the bill will enable us to find out about the chemical substances and mixtures which are already out in the environment as well as those which are just coming on to the market.

The second major regulatory provision which will enable us to protect against the occurrence of chemical harm is the premarket notification provisions of the legislation [Sec. 5]. Under the bill, manufacturers of new chemical substances and manufacturers and processors of existing chemical substances for significant new uses must give EPA 90 days' notice before commercial production begins. Because the conference report adopts the House definition of "chemical substance," the Administrator will receive advance notice not only

of new synthetic chemicals, but also of naturally occurring substances which are produced or manufactured commercially for the first time. The notification requirements are intended to provide the Administrator with an opportunity to review and evaluate information with respect to the substance to determine if manufacture, processing, distribution in commerce, use or disposal should be limited, delayed, or prohibited because data is insufficient to evaluate the health and environmental effects or because the substance or the new use presents or will present an unreasonable risk of injury to health or the environment.

Because the damage which can be done by a chemical substance or mixture is oftentimes irreparable, our experience indicates that the most desirable time to determine the health and environmental effects of a substance, and to take action to protect against any potential adverse effects, occurs before there is human or environmental exposure to the substance. This is the only practical means of avoiding human and environmental harm. In addition, the cost of any regulatory action in terms of loss of jobs and capital investment is minimized.

In addition to the testing and the notification requirements of the bill, the legislation empowers and directs the Administrator of EPA to take action to protect the public and the environment from chemical substances and mixtures which present an unreasonable risk of injury [Sec. 6]. If there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use or disposal of a substance or mixture presents an unreasonable risk, then the Administrator is to take regulatory action necessary to adequately protect against the risk. The Administrator can prohibit or limit the manufacture, processing, distribution, use or disposal of the substance or any combination of these requirements. To impose one of these require-

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ments, the Administrator must go through a rulemaking proceeding which allows all interested persons an opportunity for a hearing, and in certain instances an opportunity for cross-examination is also provided. However, if there is an imminent threat to health or the environment, the bill contains authority which allows the Administrator to take immediate action to protect health or the environment.

In addition to these major authorities, the conference report contains recordkeeping and reporting authority, and inspection authority

necessary for EPA to adequately administer the act. It also assures adequate citizen participation through provisions authorizing citizen suits and petitions. The conference report also provides for protection for employees who cooperate in the administration and enforcement of the act.

The bill also delineates the relationship between the Federal Government and State or political subdivisions in regulating chemical substances or mixtures. Generally the legislation provides that nothing in the bill shall effect the authority of a State or political subdivision to establish or continue in effect regulation of a chemical substance or mixture or article containing a substance or mixture. However, State and local regulation is preempted in certain instances. For example, if the Administrator establishes a testing rule under section 4, no State or local government may establish or continue in effect a testing rule for purposes similar to those for which the testing is required under section 4. Nor may any State regulate any risk associated with a substance or mixture if the Administrator has prescribed a rule or order under sections 5 or 6 which is designed to protect against the risk unless the State or local requirement is one identical to that issued under this act, is adopted under the authority of another Federal law, or prohibits the use of the substance or mixture other than its use in the manufacture or processing of other chemical substances or mixtures. This last exemption from the preemptive effect of a Federal regulation recognizes the interest of the State in adequately protecting its citizens and its environment from harmful chemicals while at the same time protecting the interest of interstate commerce in chemical substances and mixtures. The purpose of the provision is to enable States to totally ban a specific end use of a substance or mixture while not interfering with the manufacture or processing and distribution of substances or mixtures. For instance, a State could totally prohibit the use within its boundaries of a detergent containing a particular chemical substance. However, the State could not prohibit the manufacture or processing within the State of either the substance or the detergent, nor could it prohibit or limit interstate distribution of the substance.

The conference report retains many of the provisions in the House legislation designed to protect small business. These include partial exemptions from the general reporting provisions of the bill, establishment of a special office which will help small manufacturers understand the provisions of the bill, a requirement that the economic effects on small businesses be considered by the Administrator in taking regulatory action under section 6, and a maximum of \$100 for filing fees.

Mr. Speaker, the conference report will enable us to begin the very important task of protecting the public and the environment from

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harmful chemical substances and mixtures. It is legislation which is long overdue, and I urge my colleagues to approve the conference report.

Mr. Staggers. Mr. Speaker, I feel a little bit as I did when I first came to Congress and was on the Veterans' Committee. We held some hearings on one of the first bills that came to the floor on veterans' benefits. I thought the bill was certainly for the best interests of the veterans of this land, having been a disabled veteran in World War II, and having voted every time for every veterans' benefit that came on the floor.

Two gentlemen came to the well and said that this was not done and that was not done, and all I did was to say, "Were you there when we discussed this in committee?" Both of them said they were not. I said, "You do not have a right to judge what was done."

I say to the gentleman from Louisiana and to the gentleman from Georgia, who are fine gentlemen, who represent their districts well, and are, as I say, gentlemen in every sense of the word, that in conference we did try to uphold what was in the best interests of the House. I have always tried to do that. I have never gone to a conference with my mind made up that I am going to give in on anything the House has done.

The Senate did not have a similar provision in their bill, and they said, "We will not have it in the conference report." They said not only that, but that a bill was vetoed recently that had such a provision, the pesticides legislation. The President gave that as his reason for vetoing that bill. That is one of the reasons that it did not come back to the House floor.

Mr. Speaker, I would like to see the provision in the bill. However, I see reality, too. As often we go to conference we are a coequal branch, and we have to listen to what the Senate says on their side. There are points they think are valid; and we think we have points that are equally as valid. We are in such a situation right now with the Clean Air Act. The Senate thinks they are going to get their way, and we think they are wrong. We may not get a bill. If two men come up against a stone wall and nothing gives, then we do not get a bill. That is not the way we make laws in this Congress, nor the way the con-

ference acts. When the House and Senate go to conference, they must compromise a little bit to try to get legislation approved by both sides.

This conference report passed the Senate this morning by a vote of 72 to 6. I think it ought to pass this House by the same majority, because this is the third time the toxic substances legislation has passed the House of Representatives, and it never has become law.

It is time now that this legislation is enacted, because we know that many chemical substances present serious risks to health and the environment in America. Problems of cancer or birth defects are serious ones. It is time that we remedy this situation. We have the opportunity as Representatives of the people to let them know we are trying to protect their health and provide a better environment.

Mr. Speaker. I urge the adoption of the conference report.

Mr. Staggers. Mr. Speaker, I move the previous question on the conference report.

The previous question was ordered.

The Speaker pro tempore (Mr. McFall). The question is on the conference report.

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The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

]Mr. Steigek of Wisconsin. Mr. Speaker, I object to the vote on the <jround that a quorum is not present and make the point of order that a quorum is not present.

The Spkakek pro tempore. Evidently a quorum is not present.

The Sergeant at Arms will notify absent Members.

The vote was taken by electronic device, and there were – yeas 360, nays 35, not voting 35, as follows :

[Roll No. 820]

YEAS- 360

Abdnor

Burlison, Mo.

Abzug

Burton, John

Adams

Burton, Phillip

Addabbo

Butler

Alexander

Byron

Allen

Carney

Ambro

Carr

Anderson, Calif.

Carter

Anderson, 111.

Chappell

Andrews, N.C.

Chisholm

Andrews, N. Dak.

Clancy

Annunzio

Clausen, Don H.

Aspin

Clay

AuCoin

Cleveland

Bafalis

Cochran

Baldus

Cohen

Baiiman

Collins, 111.

Beard, Tenn.

Conable

Bedell

Conte

Bell

Conyers

Bennett

Corman

Berjrland

Cornell

Bevill

Cotter

Biaggi

Coughlin

Blester

D' Amours

Bingham

Daniel, Dan

Blanchard

Daniel, R. W.

Blouin

Daniels, X.J.

Boggs

Danielson

Boland

Delaney

Boiling

Dellums

Bonker

Dent

Bowen

Derrick

Brademas

Derwinski

Breaux

Devine

Breckinridge

Dickinson

Brinkley

Dlgs

Brodhead

Dingell

Brooks

Dodd

Broomfield

Downey, N.Y.

Brown, Calif.

Downing, Va.

Brown, Mich.

Drinan

Brown. Ohio

Duncan, Oreg.

Broyhill

Duncan, Tenn.

Buchanan

du Pont

Burgener

Early

Burke, Calif.

Eckhardt

Burke, Fla.

Edgar

Burke, Mass.

Edwards, Ala.

Edwards, Calif.

Eilberg

Emery

Erlenbom

Eshleman

Evans, Colo.

Evins, Tenn.

Fary

Fascell

Fenwick

Findley

Fish

Fisher

Fithian

Flood

Florio

Flowers

Foley

Ford, Mich.

Ford, Tenn.

Forsythe

Fountain

Eraser

Frenzel

Frey

Fuqua

Gaydos

Giaimo

Gibbons

Gil man

Ginn

Goldwater

Gonzalez

Goodling

Gradison

Gude

Guyer

Hagedorn

Haley

Hall, 111.

Hamilton

Hanley

Hannaford

Harkin

Harrington

Harris

Harsha

Hechler, W. Va.

Heckler, Mass.

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Hefner

Helstoski

Henderson

Hicks

Hightowei*

Hillis

Holt

Holtzman

Horton

Howard

Howe

Hubbard

Hughes

Hungate

Hyde

Jacobs

Jeffords

Johnson, Calif.

Johnson, Colo.

Johnson, Pa.

Jones, Ala.

Jones, N.C.

Jones, Okla.

Jones, Tenn.

Jordan

Karth

Kasten

Kastenmeier

Kazen

Kemp

Kindness

Koch

Krebs

Krueger

LaFalce

Lagomarsino

Landrum

Latta

Leggett

Lehman

Lent

Levitas

Lloyd, Calif.

Lloyd, Tenn.

Long, La.

Long, Md.

Lott

Lujan

Lundine

McClory

McCloskey

McCormack

McFall

McHugh

McKay

McKinney

Madden

Madigan

Maguire

Mahon

Mann

Martin

Mathis

Mazzoli

Meeds

Melcher

Metcalf

Meyner

Mezvinsky

Michel

Mikva

Milford

Miller, Calif.

Miller, Ohio

Mills

Mineta

Minish

Mitchell, Md.

Mitchell, N.Y.

Moakley

Moffett

Mollohan

Moorhead, Calif.

Moorhead, Pa.

Morgan

Mosher

Mottl

Murphy, 111.

Murphy, N.Y.

Murtha

Myers, Ind.

Myers, Pa.

Natcher

Neal

Nedzi

Nichols

Nolan

Nowak

Oberstar

Obey

O'Brien

O'Hara

O'Neill

Ottinger

Patten, N.J.

Patterson, Calif.

Pattison, N.Y.

Perkins

Pettis

Peyser

Pickle

Pike

Poage

Pressler

Preyer

Price

Pritchard

Quie

Quillen

Railsback

Randall

Rangel

Rees

Regula

Reuss

Rhodes

Richmond

Rinaldo

Roberts

Robinson

Rodino

Roe

Rogers

Roncalio

Rooney

Rose

Rosenthal

Rostenkowski

Roush

Roybal

Ruppe

Russo

Ryan

St Germain

Santini

Sarasin

Sarbanes

Satterfield

Schneebeli

Schroeder

Schulze

Seiberling

Sharp

Shipley

Shriver

Sikes

Simon

Sisk

Skubitz

Slack

Smith, Iowa

Smith, Nebr.

Snyder

Solarz

Spellman

Staggers

Stanton, J. WilliaD

Stanton, James V.

Stark

Steed

Steiger, Wis.

Stephens

Stokes

Stratton

Studds

Sullivan

Symington

Talcott

Taylor, N.C.

Thone

Thornton

Traxler

Treen

Tsongas

Udall

Uuman

Van Deerlin

Vander Veen

Vanik

Vigorito

Walsh

Waxman

753

Weaver

Whalen

White

Whitehurst

Whitten

Wiffsrins

Wilson, Bob

Archer

Armstrong

Ashbrook

Burleson. Tex.

Cederberg

Clawson. Del.

Collins. Tex.

Crane

Davis

de la Garza

English

Evans, Ind.

Ashley

Badillo

Baucus

Beard. R.I.

Conlan

Esch

Flynt

Green

Hawkins

Hayes. Ind.

Hubert

Heinz

Winn

Wirth

Wolfe

Wright

Wydler

Wylie

Yates

NAYS 35

Grassley

Hall. Tex.

Hammersehmidt

Hansen

Hutchinson

Ichord

Jenrette

Kelly

Ketchum

McDonald

Montgomery

Moore

NOT VOTING- 35

Hinshaw

Holland

Jarman

Keys

McCoUister

McDade

McEwen

Matsunaga

Mink

Moss

Nix

Passman

Yatron

Young. Alaska

Young, Fla.

Young, Ga.

Young, Tex.

Zablocki

Zeferetti

Paul

Risenhoover

Rousselot

Runnels

Sebelius

Shuster

Spence

Symms

Taylor. Mo.

Vander Jagt

Waggonner

Pepper

Riegle

Scheuer

Steelmau

Steisrer, Ariz.

Stuckey

Teague

Thompson

Wampler

Wilson. C. H.

Wilson, Tex.

Mr. Abdnor, changed his vote from '*iiay"' to ''yea.''

So the conference report was agreed to.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on tlie table.

[Subsequently, on October 1, 1976, Congressman Murphy of Xew York made the following comments concerning S. 3149 as reported from conference and passed by the House :]

Mr. Mi'RPHY of Xew York. Mr. Speaker, I should like to say a few words about the intent of the conferees on a matter not made explicit in the Conference Report on the Toxic Substances Control Act. The conferees recognize that the requirements prescribed by the Administrator under section 6(a) of the Toxic Substances Control Act may provide protection for employees in the workplace. For example, by prohibiting the manufacture of a substance, risks to employees involved in the manufacturing of the substance would be eliminated. Or by requiring a manufacturer of a hazardous chemical or an article

containing such a chemical to provide warning labels regarding use, persons using the substance or article in the workplace will be alerted to any potential risks. However, the conferees do not intend to vest in the Administrator authority to issue workplace standards directly regulating such matters as the airborne concentrations of a substance to

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which employees may be exposed or issue rules regarding personal protective equipment for employees, or work practices in operations hazardous to employees. Such direct regulation of the workplace falls under the jurisdiction of the Occupational Safety and Health Act, not under this bill. Of course, if the manner in which a substance is handled in the workplace presents a risk, not to the worker, but to the public or to the environment, the Administrator could use the authorities in the Toxic Substances Control Act to protect against that risk.

APPENDIX I

COUNCIL ON ENVIRONMENTAL QUALITY REPORT- TOXIC SUBSTANCES (1971)

1

TOXIC SUBSTANCES

Prepared

by the Council on Environmental Quality
April 1971

(757)

Preface

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In the spring of 1970, shortly after the Council on Environmental Quality came into being, we turned to the question of metals and synthetic organic chemicals which might endanger human health and the environment. It seemed that new controls were probably necessary to deal with the problems raised by such substances, but the scope of the problem, the lack of a central source of knowledge to deal with questions raised, and the great uncertainty about a number of key aspects of the whole area of toxic substances led us to the conclusion that extensive staff work would be necessary prior to a decision about the desirability or content of possible legislation. This report is the result of that work.

The data collection, analysis, and much of the writing of the report were substantially complete by December 1970. However, the process of formulating the President's legislative

program overtook the task of finishing the report. Thus the proposed Toxic Substances Control Act of 1971 became public before the study upon which the legislation was based.

The Council is grateful to the many individuals who contributed to preparation of this study. We are particularly indebted to Dr. John Buckley and Dr. Edward Burger of the President's Office of Science and Technology, Dr. Henry Kissman of the National Library of Medicine, and Dr. Douglas Worf and Dr. Delbert Barth of the Environmental Protection Agency. We hope that this report will help to shed light on the President's proposed legislation and that it will contribute to under-

standing of a major environmental problem.

Russell E. Train, Chairman

'Robert Cahn

Gordon J. MacDonald

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Findings and Recommendations

The Council on Environmental Quality has examined the problems associated with toxic substances in the environment and has reached the following conclusions:

Toxic substances are entering the environment

About 2 million chemical compounds are known, and several thousand new chemicals are discovered each year. Most new compounds are laboratory curiosities that will never be produced commercially. However, several hundred of these new chemicals are introduced into commercial use annually. Of particular concern because of their rapidly increasing number and use are the metals, metallic compounds, and synthetic organic compounds.

U.S. consumption of metals with known toxic effects has increased greatly in the last 20 years. The data on use underestimate the increasing pervasiveness of metals in our environment because many new metallic compounds are being formulated and used in an ever widening variety of new products.

Similarly, use of synthetic organic chemicals is growing rapidly. Over 9,000 synthetic compounds are now in commercial use in amounts

of over 1,000 pounds each per year. In 1968, they totaled nearly 120 billion pounds – a 15 percent increase over 1967' and a 161 percent increase over 10 years ago.

Although many of these substances are not toxic, the sheer number of them, their increasing diversity and use, and the environmental problems already encountered from some indicate the existence of a problem.

These substances enter man's environment – and man himself– through complex and inter-related pathways. "Present in air, water, soil, consumer products, and food, they pervade our environment. They often become concentrated through the food chain – with minute quantities being magnified thousands of times as they are consumed by higher forms of life. Increasingly,

all forms of life are being exposed to potentially toxic substances.

These substances can have severe effects

The environmental effects of most of the substances discussed in this report are not well understood. Testing has largely been confined to their acute effects, and knowledge of the chronic, long-term effects, such as genetic mutation, is inadequate. Although far from complete, available data indicate the potential or actual danger of a number of these substances.

Many serious effects, including those resulting in cancer (carcinogenicity), genetic mutations which cause permanent and transmissible change in the genes of offspring from those of the parent (mutagenicity), and production of physical or biochemical defects in an offspring (teratogenicity) can occur from metals, their compounds, and synthetic organic compounds. In general, we do not know which chemicals cause such effects or the levels that a given chemical must reach before the effects occur.

The problem is complicated by the chemical changes which may occur once toxic substances enter the environment. They can become more toxic through modification in the ecosystem or as a result of synergistic actions with other substances.

Wildlife and fish populations are also being exposed to these substances, and some species have already been severely damaged by such exposure.

Existing legal authorities are inadequate

Existing Federal Government controls over the introduction of toxic substances into the environment are of two-types. The first is control over the initial production of a substance and its distribution. For example, under the Federal Insecticide, Fungicide, and Rodenticide Act, a manufacturer must register a pesticide with the Environmental Protection Agency

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(EPA) before it can be introduced in interstate commerce. EPA can prohibit distribution of a pesticide or require labeling of acceptable uses. This type of control, exercised at the point of manufacture, is also applied to drugs and food additives. Although this control technique can be very effective, current authorities cover only a small portion of the total number of potentially toxic substances and do not deal with all uses of a substance which may produce toxic effects. Most of the substances mentioned in this report are not subject to the legal controls necessary to protect man from the toxic effects noted.

The second type of control is media oriented

and thus is directed at air and water pollution from various sources. Federal authority derives primarily from the Clean Air Act and the Federal Water Pollution Control Act. Under the Federal Water Pollution Control Act, the Federal Government, in cooperation with the States, sets standards for the amounts of particular substances allowable in the water. Under the Clean Air Act, the Federal Government sets national air quality standards, allowing the States to set more stringent standards. Enforcement of standards depends on limiting the emissions of a substance from a given source.

In theory, this type of authority can be used to control the substances discussed in this report, but there are several limitations to the effective application of such controls. These media-based authorities are mainly concerned with pollutants which occur in large quantities. Controlling minute quantities of dangerous substances is difficult with this type of authority, in part because of the difficulty of detecting their presence in air or water. Control is also difficult because many toxic substances enter the environment through disposal of consumer products. If a product is disposed of by flushing into a municipal sewer line or by burning at an incinerator, it is almost impossible for the media-oriented controls to deal effectively with the toxic decomposition products which might re-

sult. For example, if there were a need to control a substance contained in a household detergent, under the media authorities the government could try to limit the amount of the substance emitted from municipal waste treatment plants. But such a limit would be effective only if the substance could be removed by existing treatment methods, and many toxic substances cannot be so removed.

Most toxic substances are not exclusively air or water pollutants but can be found in varying quantities in air, water, soil, food, and industrial and consumer products. The multiplicity of

ways by which man can be exposed to these substances makes it difficult for the media-oriented authorities to consider the total exposure of an individual to a given substance, a consideration necessary for the establishment of adequate environmental standards. Also, in the past no agency has considered itself completely responsible for all such substances in all media. The likely result is what happened in the case of mercury: Available knowledge on adverse effects was ignored and new data were not collected.

New legal authority is required

The Council's study indicates the high-priority need for a program of testing and control of toxic substances. Our awareness of environmental threats, our ability to screen and test substances for adverse effects, and our capability to monitor and predict, although inadequate, are sufficiently developed that we need no longer remain in a purely reactive posture with respect to toxic substances. We should no longer be limited to repairing the damage after it has been done; nor should we continue to allow the entire population or the entire environment to be used as a laboratory.

To assure this protection without handicapping desirable technological innovation or hindering interstate commerce, the Council on En-

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vironmental Quality recommended new legal authority.

In February 1971, the President submitted to the Congress a bill based on these recommendations. The Toxic Substances Control Act of 1971 calls for several major, new authorities:

- The Administrator of the Environmental Pro-

tection Agency would be empowered to restrict or prohibit the use or distribution of a chemical substance if such restriction were necessary to protect health or the environment. In imposing such a restriction, the Administrator would be required to consider not only the adverse effects of the substance but also the benefits to be derived from its use.

- If the Administrator believed that a substance were creating an imminent hazard, he could ask the courts to restrain use or distribution of the substance immediately.
- The Administrator would be authorized to issue standards for tests to be performed and for results to be achieved from such tests for various classes and uses of new substances. A new substance (excluding products covered by other regulatory authority) could be marketed only after it met these standards.
- The Administrator could request information from the manufacturers on potentially toxic substances - names, chemical composition, production level, uses, and results of tests conducted on their effects.
- The Council on Environmental Quality would be charged with coordinating efforts to establish a uniform system, for classifying and handling information on chemical substances. The proposed legislation also authorizes the

Administrator of EPA to carry on needed research on toxic substances and to develop an information system and prediction capability to deal effectively with these materials.

Such an information system would focus on the quantity, distribution, and flow of a particular substance throughout the environment. Focusing on the pollutant rather than on the

particular medium being polluted has two major advantages: First, a potential problem can

often be rapidly identified, perhaps before damage to health or the environment has occurred. Second, this approach can suggest the most efficient means of controlling a problem. If the analysis indicates that most of a substance is entering the environment through water, then the most efficient control may be through water pollution control laws. If an identified industrial or consumer use of a substance is responsible for the major amount of environmental contamination, then control of the distribution and use of the substance may be the most efficient strategy. In short, pollutant-focused monitoring is capable of giving the decision-maker the overall view necessary for making key enforcement decisions.

For the system of testing, monitoring, and control authorized in the proposed legislation to be most effective, the scientific basis of much of our research must be greatly improved. First, a broader view of the problem must be taken. In terms of human health, total exposure of a human being to a given substance from all parts of his environment - air, water, and food - must be considered, and the interactions of these substances both within and outside the body must be evaluated. Similar consideration must be given to other living organisms.

Second, testing substances for their effects on man and the environment must be expanded, and the scientific basis for interpreting such tests must be improved. Current scientific knowledge about data gained from experiments with animals is often inadequate to allow reliable interpretation of the data in terms of possible effects on man.

Much effort has already been devoted to toxic substances monitoring and research. Much more will be needed. The proposed legislation would improve the framework for such efforts, but by itself it would not bring them to fruition. The

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resources of the Environmental Protection Agency, the Department of Health, Education, and Welfare, industry, universities, and many others both within and outside the Government will be necessary to achieve a truly adequate system for assessing the hazards of toxic substances and for preventing damage from them.

SUMMARY

Recent incidents of mercury and other contamination of the environment and the diversity and quantities of toxic and potentially toxic substances entering the environment indicate the extent of this growing national problem. Action is needed to prevent damage to man's health and the environment. New regulatory authority, improved research, and better monitoring

systems have been recommended and must be implemented now if protection is to be provided.

The approach called for in the Toxic Substances Control Act is a new way of looking at environmental problems. Rather than dealing with pollutants as they appear in air, in water, and on land, it represents a systematic and comprehensive approach to the problem. It relies on understanding the flow of potentially toxic substances throughout the entire range of activity - from extraction to production to consumer use and to disposal. Only through such a comprehensive approach can we provide protec-

tion to man and his environment. In the last few years, we have identified the enormity of the problem; we have developed the institutional capability through the creation of EPA to look comprehensively at pollution of the environment. The time has come for an action program to control the use of toxic substances.

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CHAPTER I Scope and Magnitude of the Problem

Until recently, the public and the Government have been concerned with pollutants which appear primarily in one medium, usually air or water. These pollutants – such as suspended solids, particulates, and sulfur oxides – generally occur in large, measurable quantities. They can be readily identified with existing monitoring techniques, and legal authority for their control is available. Controlling their levels in the media in which they primarily occur protects human health and the environment. However, there are substances, such as radioactive materials and pesticides, for which research, monitoring, and control based on media are not adequate. In the case of radioactive materials and pesticides, needed regulatory authority and control procedures have been developed.

There are several types of substances for which no adequate control authority exists and for which a total environmental approach is lacking. Existing authority based on media control, although sometimes applicable, is not adequate to deal with such substances because they are present not only in our air, water, and soil but in all the products that we consume and use in our everyday lives. Further, control of a substance in one medium often shifts pollution to another medium. For the protection of man and his environment, all sources of exposure must be considered comprehensively. Chapter I examines major examples of the toxic chemical substances for which this comprehensive approach is needed and indicates the extent of the problem presented by them.

Everything in our environment is composed of chemical substances, and most of these pose minimal danger to man or the environment. However, some pose a serious danger – particularly those produced by man's activities. Those chemicals which damage the environment are usually called pollutants. Not all pollutants are of concern as toxic substances. Most common air and water pollutants, such as particulates and solids, are not included in the Council study

because existing regulatory authority and control programs adequately deal with them. For this reason, radioactive substances, drugs, food additives, and pesticides are also excluded.

Many other chemical substances are of concern here because of their potentially toxic effects at extremely low levels of exposure and their presence in many media. Rather than attempt to be exhaustive given our current incomplete knowledge, this report indicates the problem by using examples of what appear to be the most pressing areas of concern.

Selected metals, their compounds, and certain synthetic organic chemicals are perhaps the best examples of toxic substances which can adversely affect man and his environment. They enter the environment in a variety of ways, through air and water and through food and other goods. In this chapter, the magnitude and pervasiveness of the problem are indicated by the quantities of potentially toxic substances produced and the variety of products in which they are found. The pathways by which these substances enter the environment and their potential for adverse effects are outlined in Chapter II. Chapter III describes existing and proposed control measures for such substances.

METALS AND THEIR COMPOUNDS

Singly or in combination, the 105 known elements form the basis of all matter. Of these, 77 are metals. Simply stated, metals are elements generally characterized by ductility, malleability, luster, and conductance of heat and electricity. Of the 77 elemental metals, 52 can be considered "economic metals," that is, they are in sufficient industrial and commercial usage to warrant collection of statistical production data. The quantities used vary from millions of tons for iron and manganese to only thousands of ounces for iridium. (4-4)

Many, perhaps most, metals are prerequisite

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to life, usually in trace amounts. However, some metals and/or their compounds can and do adversely affect human health if ingested or absorbed in excessive quantities. A necessity of life at certain levels, they can be lethal at increased levels.

Serious adverse environmental and/or health effects, actual and potential, have been observed or indicated for roughly one-fourth of the metals in common economic usage today. Many of the troublesome metals are the so-called "heavy metals," of which lead and mercury are the most common examples. Table 1 shows the estimated U.S. consumption of selected metals for which adverse human effects have been documented. Not included in these estimates are data for production and release of metals from processes other than those used to produce the metals for consumption. For example, Table 1 does not include the amounts of vanadium released to the atmosphere from oil combustion or of mercury released from coal combustion.

TABLE 1. - Estimated U.S. Consumption of Selected Metals, 1948 and 1968 (44, 46)

Arsenic (As₂O₃)

Barium (barite)

Beryllium (beryl)

Cadmium

Chromium (chromite)

Copper

Lead

Manganese (ores, 35% or more

Mn)

Mercury

Nickel

Selenium

Silver'

Vanadium ...

Zinc

Total estimated
consumption > (in tons)

Percent
increase
1948-1968

1948

1968

24,000

25,000

04

894.309

1. 590. 000

78

1.438

8, 719

fxn

3.909

6,664

70

875,033

1,316.000

50

1.214,000

1,576,000

30

1, 133, 895

1.328,790

17

1,538.398

2.228,412

45

1,758

2.866

63

93,558

159,306

70

419

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82

3, 611

4,983

38

>N.A.

5,495

01,200,000

1,728,400

44

' Includes stocks released to the open market by the Federal Government and imports; does not Include exports.

' Consumption by industry and arts; monetary consumption not Included because much was stockpiled.

' Figures not available between 1946 and 1956; consumption in 1946 was about 748 tons, in 1955 about 1,700 tons.

After originally extracting metals from the earth, man reintroduces them into the environment directly in elemental form or in a wide variety of compounds. The compounds may have quite different effects from their elemental forms; some metals are more toxic as compounds.

The compounds of metals appear in larger number than do the metals themselves as intermediate and consumer products For example, at least 40 lead compounds and more than 45 cadmium compounds are currently in commercial use. {3, 23) The total number of variants for just two of these metals is thus more than five times the total number of metals for which

adverse effects have been identified. Most of the other metals are also used in a wide array of compounds.

Numerous manufacturing processes and products employ metals and their compounds.

Arsenic, for example, is used in the manufacture of glass, pigments, textiles, paper, metal adhesives, ceramics, linoleum, and mirrors. {39)

Its compounds are used in wood preservatives and paints, insecticides and herbicides, and electrical semiconductors. Beryllium is used in several of the above manufacturing operations as well as in electroplating and as a catalyst in organic chemical manufacture. Barium is used in paper manufacturing, fabric printing and dyeing, embalming, synthetic rubber production, and animal and vegetable oil refining. It is a component of fireproofing compounds, x-ray screens, water softening chemicals, enamels, lubricants, and photographic supplies. (^7)

These products exemplify the diversity of uses of metals and the almost, unending list of products in which they may be present. When metals are used in the manufacture of products, effluents from the operations often contain metallic compounds, which may contaminate the environment. Many metals are present in final products, direct human contact or environ-

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mental exposure is possible during use or after disposal.

The number of metals and related compounds for which serious environmental concerns arise will probably increase as technology continues to find new uses for existing metals and metal-

lic compounds. The increasing consumption of metals is shown in Table 1.

New products will require the development of new metal compounds and possibly the expanded use of metals which now have little, if any, commercial use. Iridium, once only a laboratory curiosity, is now used to make jeweler's platinum and to manufacture electric instruments, penpoints, surgical instruments, and needles. (40) Beryllium has been used experimentally in rocket fuels. These new variations and applications are certain to increase the potential exposure of man to metals.

SYNTHETIC ORGANIC COMPOUNDS

The Chemical Abstracts Service Registry Number System has registered some 1.8 million chemical compounds, and the list is growing by the addition of 250,000 chemicals each year. (3) Approximately 300 to 500 new chemical compounds are introduced annually into commercial use. {4^, 43) Of those which are or may be used commercially, synthetic (manmade) organic chemicals are of special concern because frequently they are alien to the natural environment, and in some instances their modification, redistribution, or persistence have already had some dangerous effects.

Approximately 9,000 synthetic organic compounds were in commercial use by 1968. (47) As shown in Table 2, production is increasing rapidly, from over 103 billion pounds in 1967 to nearly 120 billion pounds in 1968, an increase of about 15 percent. Compared to the 1957-1959 annual average of 46 billion pounds, production

Table 2. - U.S. Production of Synthetic Organic Chemicals, 1968 ' (47)

Chemical

1968 Production
(in millions
of pounds)

Percent
increase
over 1967

Intermediates

25, 014
226

20.3

Colorants:
Dyes

9.7
1.9

Pigments

54

Flavors and perfumes

117

16,360
1,331

4.6

18.6

5.4

18.6

11.6

7.6

13.1

Plastic products-
Plastics and resins

Plasticizers

Rubber products:
Processing chemicals

313

Elastomers

4,268

3,739

67, 525

Surfactant active agents

Miscellaneous.

Total

118, 947

15

' includes data on production measured at several successive steps in the manufacturing process and therefore reflects some duplication.

Public disclosure is not permitted by the data-collecting agency when only one manufacturer produces a chemical. When production of an item was below 1,000 pounds, or sales below \$1,000, a product is not included. Further, medicinals and pesticides are not included.

increased 161 percent in approximately 10 years. {47) With changes in industrial needs and technological knowledge, new and more complex compounds with new and different uses are constantly being developed.

The synthetic organic chemicals shown by classes in Table 2 are obtained from coal, crude petroleum, natural gas, wood, vegetable oils, fats, resin, and grains. Products are formed by such processes as thermal decomposition, synthesis, catalytic cracking, distillation, absorption, or fermentation. Intermediate products are sometimes consumed directly or may be further processed. The category of intermediates in Table 2 refers to those that are consumed directly.

Dyes and pigments are organic chemicals used to impart color to other materials. Approximately two-thirds of the over 1,000 synthetic dyes consumed in the United States per year is used in coloring natural and synthetic fibers

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or fabrics, and about one-sixth is used in coloring paper. {45) The remainder is used chiefly in the production of organic pigments and in dyeing plastics and leather. Pigments are used in paints and related products, in printing inks, and in plastics and resin materials.

In some cases, pigments contain metals in addition to their organic constituents. Dyes and pigments, a part of many everyday products, find their way into the environment from manufacturing operations as well as from ultimate disposal of consumer products.

Plastics and associated resins and additives, such as plasticizers, are another major type of synthetic organic chemical. Plasticizers are organic chemicals that are added to synthetic plastics and resin materials to improve workability during fabrication; to extend or modify the natural properties of these resins; or to develop new, improved properties not present in the original resins. They are present in plastic products in concentrations ranging from less than 5 to as high as 50 percent. Poly chlorinated bi phenyls (PCB's), a class of compounds formerly used in small amounts as plasticizers, are of considerable environmental concern.

Total U.S. production of plastic products in 1968 was 17.7 billion pounds, 103 percent more than in 1962. (47," 49) By 1980, total plastics production is expected to be well over 50 billion pounds, with production growth at about 10 percent per year through the coming decade. (4-1)

Plastics are used in ever increasing quantities to replace other materials. Packaging, previously dominated by glass, paper, and metals, now employs large quantities of plastics. In some cases plastics have replaced the traditional packaging materials. "When used with other materials, plastics have improved such features as strength and appearance.

Polyethylene, polyvinyl chloride, polystyrene, and ABS (acrylonitrile-butadiene-styrene) res-

ins were first used as packaging in the 1950's. Volume usage developed about 1960. By 1966, 2.2 billion pounds of plastics were used in packaging, and by 1976, the figure is expected to reach almost 6.3 billion pounds, a 185 percent

increase. (8) The use of plastics is also increasing dramatically in other areas. Relatively new is use in automobiles, shoes, handbags, coats, furniture, dishes, and insulation.

Rubber products can be manufactured from synthetic organic chemicals (elastomers) which are formulated with properties similar to natural rubber. Products made from natural rubber may contain synthetic organic chemical additives. Hence, these types of synthetic organics are commonly found in toys, tires, rain coats and shoes, carpet backing, garden equipment, tools, and numerous other products.

Surface-active agents, another category of synthetic organic chemicals, reduce the surface tension of water or other solvents and are used chiefly in detergents, dispersing agents, emulsifiers, foaming agents, and wetting agents. A major portion— about 550 million pounds— is used in detergents for both household and industrial use. (36) The remainder is employed in processing textiles and leather and in the manufacture of agricultural sprays, cosmetics, elastomers, lubricants, paints, pharmaceuticals, and many other products.

Organic chemicals can be tailored in structure and properties to fit almost any imaginable need. During 1968, production of chemicals in the miscellaneous category shown in Table 2 totaled 67,525 million pounds, over half of all synthetic organic chemicals produced. Examples of chemicals in this category are some of the halogenated hydrocarbons, which are used as solvents in dry cleaning and refrigerants, and aerosol propellants for hair sprays, paints, and deodorants. Alcohols, nitrogen compounds, acids and anhydrides, aldehydes, and ketones are also included in this category.

SUMMARY

Man's physical environment is now exposed to a myriad of potentially toxic substances. These substances are the constituents of nearly everything that man uses. In trace amounts in the human body, some are essential to life; yet in larger quantities these same substances may be toxic. The balance between these two extremes

is often unknown. And because of man's own activities, other substances not formerly present are now found in the human body.

The uses of chemical substances are growing rapidly, many new substances are being formulated, and new commercial applications are being found almost daily. As Chapter II indicates, many of this growing array of substances have already been found to have adverse effects on man and his environment.

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CHAPTER II Environmental Pathways and Effects

Chapter I discusses toxic substances, their quantities, and the diversity of products in which they are present. This chapter examines how these substances enter the environment, move within the system, and ultimately affect man and other organisms.

PATHWAYS OF ENVIRONMENTAL CONTAMINATION

Figure 1 is a simplified diagram of how potentially toxic materials reach man and his environ-

ment. It indicates several key processes: First,

materials are extracted from the environment in crude form and are successively refined, processed, and manufactured into more diverse and complex forms ("Manufacture" in Figure 1). These diverse processes may produce air and waterborne wastes to which man may be exposed at each intermediate step. The wastes can contain not only the original substance but also considerably modified and perhaps more toxic substances. The end products are consumed by man as food or are used as durable and non-durable goods. This consumption and use can result in man's further exposure to a substance. Consumption, however, is not the end of most

FIGURE 1.

PATHWAYS FOR TOXIC SUBSTANCES

mm

mm

MANUFACTURE

MAN

(CONSUMPTION)

- 0

■mm

DISPOSAL

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products, because after they have served their purpose, they must be disposed of. Except for direct recycling, disposal methods return material to the environment - but almost always to a different place and often in different chemical form. Thus, the disposal process alters the patterns of distribution and concentration of substances which naturally occur in the environment and may produce new chemical forms which may be more dangerous to man than the original substance. As a result of disposal processes, assimilation by biological organisms may be facilitated, interaction with other chemical substances may occur, and inherent toxicity may be enhanced. These possibilities are suggested

by "Interactions" in Figure 1.

There is a natural background of metal substances and compounds in the environment to which biological systems generally have adapted over the millenia. It is the redistribution and chemical alteration resulting from man's activities when he engages in economic exploitation and disposal which are considered here. Although some substances introduced by man into the environment may represent a net benefit, for example, small amounts of fluoride in water to reduce tooth decay, this report is concerned with possible adverse effects.

Both metals and synthetic organic chemicals are potential environmental hazards. However, significant differences exist in the ways in which the two types of substances enter the environment and affect man.

Metals are recovered from ore deposits either directly or as byproducts in the course of refining other metals. Pure cadmium, for example, is not found uncombined in nature in commercially usable quantities. Commercial quantities are obtained as a byproduct of smelting zinc.
(3)

During the mining and refining processes, dusts and gases enter the atmosphere. Metallic salts formed during these recovery and refining processes can escape as waste products into sur-

face and ground water. Undesirable concentrations of metals and metallic salts in the environment have been reported from such sources in a number of cases, including :

- High concentrations of cadmium salts in Missouri mine waters – in one spring the concentration was 1,000 milligrams per liter (25)
- High atmospheric vanadium concentrations near mining and refining operations (4.)

- Toxic levels of arsenic trioxide emissions from a gold mine and smelter in the western United States. (39)

Almost all synthetic organic compounds are manufactured from crude petroleum, natural gas, and coal rather than from raw ores. Although extraction and transportation of the raw materials cause some environmental damage, the more complex synthetic compounds produced by manufacturing operations are often the most toxic.

Waste effluents often result from the manufacture of synthetic organic chemicals. These effluents may be the compounds which remain unreacted in the production process or the unwanted byproducts of the operation. Sludges, gases, and liquid effluents of varying chemical complexity and toxicity may be produced. For example, thermal cracking of crude petroleum to obtain gasoline or fuel oils can yield phenols, sulfides, and other organic wastes. Ammonia, mercaptans, and waste oil effluents result when reforming is used to produce benzene, toluene, and other products.

Finally, the diverse end products reach man and are used. In the course of use, some toxic materials may inadvertently be introduced into the environment. One example is the unburned or partially burned hydrocarbons from gasoline. Eventually, most unused residues must be disposed of, and they enter the environment through sewage systems, incineration, or landfill.

Most sewage treatment plants are not capable of removing many of the toxic substances found

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in waste water. Secondan,' sewage treatment is capable of removing a large portion of the

metals, but many synthetic organic chemicals are unaffected by the biological treatment processes employed by municipalities. Even if the toxic substances are removed by treatment, their presence in sewage sludge may still pose a problem.

About 10 percent of all municipal solid wastes are incinerated. During combustion, organic and metallic materials are converted into a multitude of compounds. Some are partially oxidized or reduced and their structure and properties substantially changed. Some remain unaltered chemically, changing only physically, as from a solid to a gas. Some gaseous or particulate products of combustion are drawn off through the stacks; those that are not removed by stack gas cleaning reach the atmosphere. The solid residue from combustion is often quenched with water, which then enters the general environment. Eventually most airborne emissions return to earth and are deposited on land and in water.

Materials disposed of at some landfills also can present a problem. At landfills the volume of wastes is frequently reduced by open burning. The resultant particulate and gaseous emissions can cause the same pollution problems encountered in incineration. Even when the wastes are buried, leaching of toxic metals or organic compounds is possible, causing contamination of ground or surface water. For example, the plasticizers in plastics may be leached and thus contaminate ground water supplies, (i) Regardless of the pollution which may result, disposal of metals and some chemicals in landfills represents a waste of valuable resources which could be recycled.

Another possible method of disposal is to dump wastes in the ocean. The Council issued a previous report on this subject and concluded that available methods of land disposal are preferable to ocean dumping. (6)

INTERACTIONS WITHIN THE ENVIRONMENT

After substances enter the environment, they may be diluted or concentrated by physical forces, and they may undergo chemical changes, including combination with other chemicals, that affect their toxicity. The substances may be picked up by living organisms which may further change and either store or eliminate them.

The results of the interaction between living organisms and chemical substances are often unpredictable, but such interaction may produce materials that are more dangerous than the initial pollutants. One example is inorganic mercury, which was thought to settle safely into the bottom sediments when discharged into water. Anaerobic bacteria are now known to convert inorganic mercury into very toxic and soluble organic mercury compounds, such as methylmercury, which pass through the food chain by aquatic algae and by fish, eventually reaching man. (37)

DDT, another example, is nearly insoluble in water. It occurs in high concentrations among some fish-eating birds as a result of two factors : DDT's solubility in fats is much higher than in water, and plankton, shellfish, and fish generally pass successively higher concentrations of DDT on to the organism next in the food chain. Polychlorinated biphenyls (PCB's), which are chemically similar to DDT, have been found in similar association with marine food chains. Oysters exposed to one type of PCB for 96 hours accumulated the substance to a level 3,300 times that of the ambient water. (9)

Synergism is another complicating interaction. Two or more compounds acting together may have an effect on organisms greater than the sum of their separate effects. For example, the toxic effects of mercuric salts are accentuated by the presence of trace amounts of copper. (4[^]) Cadmium acts as a synergist with zinc and

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cyanide in the aquatic environment to increase toxicity. {W. 25. 32) Convei"sely, sometimes the presence of one substance lessens the effect of another substance on an organism. Arsenic, a toxic substance itself, counteracts the toxicity of selenium and has been added to poultry- and cattle feed in areas where animal feeds are naturally high in selenium. (38)

EFFECTS OF TOXIC SUBSTANCES

As noted earlier, inetals, unlike synthetic organic compounds, have always been present in the environment, and living organisms - including man - have evolved in their presence. Blood and body tissues are composed of a complex mixture of elemental substances, including the metals. Some metals are essential to life at low concentrations but are toxic at higher concentrations. Further, the form in which the metal occurs - as a pure metal, an inorganic metallic compound, or an organic metallic compound - strongly influences its toxicity. Thus the danger of metals to man depends on their concentration and chemical form.

Most synthetic organic substances are not essential to life, though many share with metals the characteristic of toxicity. As with metals, the concentration and type of exposure to a particular synthetic organic substance are key factors in determining its effects.

The total effect of all toxic substances on a single species, say, man, is impossible to quantify with accuracy because of our lack of know-

ledge about the effects of toxic substances. Although many substances in the environment can cause death or injury if man is exposed to them in sufficiently high concentrations, the effects of long-term exposure to low levels of such substances, singly or in combination, are generally unknown. A standard text on the dangers of commercial products rates the toxicity of more than 1,000 commercially used chemical

compounds, most of which are toxic to man at high levels of exposure. (IS) However, the long-term effects of low levels are known for only a few.

Although lack of effort partially accounts for this paucity of knowledge, our ignorance also stems from the many difficulties inherent in testing for adverse effects. The large number of chemicals that should be evaluated by long-term laboratory experiments requiring many test animals is a serious limiting factor. Extrapolation of data on dose effects obtained from animal studies to man must consider many species variations in response to exposure from toxic substances. Substances rarely occur in the environment in isolation, so that possible synergism or antagonism of two or more substances adds to the difficulty of adequate testing and of interpretation of field results.

Difficult choices must also be made in determining the effects or biological end points to be examined. Biological end points are often determined from such irreversible effects as carcinogenesis, mutagenesis, and teratogenesis¹.

Carcinogenesis is the ability of a substance to cause cancer. Chemical mutagenesis is the induction in protoplasm of genetic mutations by a substance. These can be permanent and transmissible changes in the genes of an offspring from those of the parents of earlier generations. Teratogenesis is the production of physical or biochemical defects in an offspring during gestation ; it is limited to a particular child. During

the last decade, there were many deformed infants born of women who had ingested the drug thalidomide during pregnancy – a vivid example of teratogenesis.

The effects of any given substance may vary among individuals and among species. Differences in effects are a function of age, sex, health condition and history, stress, different metabolic patterns in different species, and other less understood factors. Further, we often do not know how to apply to humans the results

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from experiments with laboratory animals. If a substance produces cancer in mice, will it produce human cancers? How do we extrapolate the level of a substance required to produce a given effect in mice to the level that will produce the same effect in man? If mice are not affected by a substance, is that substance also safe for humans?

All these difficulties contribute to the dearth of knowledge concerning the biological effects of many environmental contaminants and particularly the toxic substances discussed in this report. But we do understand enough to know that many substances may significantly threaten man and the environment.

Many useful data on health effects of toxic substances derive from studies of occupational exposure. Commonly, the levels of exposure are much higher at the workplace than in the total environment, and the data gathered on exposed groups of workers can contribute to understanding effects on the general population. However, even here caution must be exercised in interpreting the results for nonindustrial groups who are exposed to lower concentrations and whose level of health may not match that of the industrial worker.

A few examples will illustrate the ways in which toxic substances have become a part of our environment and have affected humans. These examples are not in any way intended to be exhaustive or definitive. All of the limitations cited above concerning data on effects apply to the examples, and the data given are used simply to illustrate, in a selective way, the basis for concern over toxic substances.

Metals and Their Compounds

The potential for dangerous metals' entering the environment is indicated by the consumption data in Chapter I. Studies of ambient conditions substantiate these data: Twenty-seven trace elements are found in the atmosphere. (33) A survey of eight heavy metals in U.S. waters

showed that these metals were distributed in low concentrations. (10) Their level in drinking; water generally did not exceed standards but did indicate potential problems in some areas.

Examples of the toxic effects of metals are readily found. Compounds of nickel and beryllium, which accumulate in the lungs, may cause fatal diseases. (33) If inhaled, barium can cause respiratory disease, or if ingested in sufficient quantities, it causes heart, intestinal, and nervous system disorders. (27)

Some laboratory experiments indicate that exposure to metals may interfere with vital chemical reactions. In a study of rats and mice living in a carefully controlled environment relatively free from metal contamination, the sample group lived 20 to 25 percent longer than the control group in its usual contaminated environment. (33) In addition, laboratory breeding mice exposed to concentrations of cadmium, lead, or selenium produced abnormal offspring. Long periods of arsenic and molybdenum exposure changed the sex ratios of mice and rat

offspring. Antimony, in low doses, shortened the lifespan of rats. (33)

Lead- Lesvd is one of the oldest known pollutants. In the second century B.C., the wealthy class of Rome was decimated by sterility, child mortality, and permanent mental impairment. {12) According to one theory, this decline can be traced to lead poisoning from wine and food vessels. The lower classes survived because they could not afford lead utensils.

Today lead is absorbed by humans in a more democratic way, because all social classes are exposed to lead in the atmosphere. Lead particles in the air eventually settle to land and water, mixing with other sources of the metal and following complex pathways in the environment. The increase in lead pollution is now global in scope. For example, between 1904 and 1964, lead concentrations in Greenland snow increased 16-fold. (28)

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A variety of industrial and mining effluents, disposal of consumer products such as automobile batteries, and various food products all contribute to both environmental and human accumulation of lead. However, these sources are small contributors to lead pollution compared with combustion of leaded gasoline. In 1968 alone, 180,000 tons of lead were omitted from leaded-gasoline combustion - 14 percent of all lead consumed in the United States that year. ill)

Although the acute toxicity of lead has been a health problem for 2,000 years, the effects of ambient levels are not known. Acute poisoning

is still a frequent problem, primarily among children who have eaten chips of lead-based paint in older dwellings. The use of lead-based paint is now restricted, but there are still many old houses whose walls are covered with lead paint applied years ago. Aside from this problem, the critical question today is whether the total body burden produced by inhaling air polluted with lead and by drinking water containing small amounts of lead is sufficiently large to produce any adverse effects. The data are not conclusive, but in the opinion of at least one recognized expert, "There is little doubt that at the present rate of pollution, diseases due to lead toxicity will emerge within a few years." {33)

Cadmium - Like most metals, cadmium is stable and does not degrade in the environment. Thus, as increasing amounts of cadmium are refined, more and more of it is circulated in the environment, and increasing amounts may reach man.

Only a fraction of the cadmium taken into the body is actually absorbed by the body. The cadmium which is absorbed accumulates in the kidneys and the liver, and because there appears to be an inefficient excretory mechanism in humans, accumulation tends to increase with increased absorption.

The effects of such accumulation vary according to the amount and time period of exposure. Some preliminary studies indicate that exposure to low levels of cadmium from sources present in the everyday environment may lead to hypertension and heart disease and perhaps to cancer. (5, 30[^] 34-)

Many sources contribute to the accumulation of cadmium in humans. The metal is found in concentrations of 50 to 170 parts per million in superphosphate fertilizers, and it is also used in some pesticides. (3) Cadmium becomes an air and water pollutant through a variety of

industrial processes, and it is being used in increasing amounts by the storage battery, plastics, plating, and petroleum industries. Additional amounts are introduced into the home by the pipes which carry drinking water. (33) Food is another major source of cadmium - it has been found in a variety of products, from dry cereal to vermouth. (29)

Mercury - Although poisoning from mercury has been recognized as an occupational hazard for years, concern with mercury as a general environmental contaminant in the United States is quite recent.

Metallic mercury was long thought environmentally inert. When discharged into a river, for example, it was believed to settle to the bottom and remain there. Then in 1960, it was reported that 111 persons had died or suffered serious neurological damage near Minamata, Japan, as a result of eating fish and shellfish which had been contaminated by mercury discharged into Minamata Bay by a plastics manufacturing plant. (J) In 1965, another poisoning incident was reported in Niigata, Japan, and in 1966, Swedish studies indicated that many species of birds were being poisoned by mercury. (18) Other Swedish studies pinpointed the critical facts that metallic mercury, previously thought inert, can be changed by bacteria into methylmercury - a compound that is far

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more toxic than metallic mercury - and that methylmercury can enter the food cycle through uptake by aquatic plants, algae, lower forms of animal life, and fish. (17, 21) Even more significantly, the studies showed that the con-

centration factor in the fish could be 3,000 or more to 1. (IS) Thus, harmless levels of mercury in water can be concentrated to hazardous levels in fish.

In 1967, large amounts of methylmercury were reported in fresh-water fish in Sweden. [21) A study submitted in the same year to the U.S. Public Health Service concluded : "From our review of mercury as an environmental chemical contaminant, it is obvious that a considerable amount of mercury has been cycled through our environment. . . . We have little or no information as to where the mercury that is being cycled through our environment is going." {2!t) The report recommended expanded monitoring and study of the health effects of mercury.

Finally, in the spring of 1970, high levels of mercury were discovered in fish in Lake St. Clair, on the Canada-U.S. border. Canada banned the .sale of fish from the Lake, and 10 days later Michigan followed suit. In succeeding months, there followed a series of bans, mostly of fish and seafood products containing, or suspected of containing, excessive mercury. These actions resulted in losses of millions of dollars to the food, canning, and tourist industries.

The concern over mercurj' is well founded. Some organic mercury' compounds are accumulated in humans, concentrating in the brain, the kidney, the liver, and the fetus. They can destroy the cells of the brain, cause tremors and mouth ulcers, and produce birth defects because of chromosome -breakage. [19)

The sources of mercury are numerous. It is used in a number of industrial processes and appears in such varied products as paints, electrical apparatus, thermometers and other in-

struments, and cosmetics. Primary concern has focused on mercury as a water pollutant, largely

because it is now known to reach the food chain by water, but the metal is also present in soil and in air.

Vanadium – Very little research has been done on the toxicity of environmental concentrations of vanadium. When the route of exposure is the respiratory tract, vanadium may accumulate in the lungs. High concentrations of the metal may damage human gastrointestinal and respiratory tracts. (4) Exposure to lower concentrations has resulted in inhibition of cholesterol synthesis in man. (^)

Trace amounts of vanadium are natural to all humans, but it is probably a recent addition to the atmosphere. There is no evidence that ambient levels of vanadium are toxic. But these levels have been increasing in recent years due to the burning of fuel oils containing vanadium and to increased industrial use of vanadium compounds. Eighteen compounds of vanadium are now used in a wide variety of commercial processes. (^4)

Synthetic Organic Chemicals

A vast number of synthetic organic chemicals is being introduced into the environment, and many of these chemicals have not been identified. A study prepared for the Water Quality Office of the Environmental Protection Agency reported that 496 organic chemicals were found or suspected in fresh water, but the chemical composition of only 66 of these was identified. (22) The disparity between the number recorded and the number identified indicates the need for better monitoring and analytical techniques. It also shows the difficulty of dealing with such substances once they have entered the environment.

Some organic compounds have been identified as tumor-producing in experimental animals.

A smaller number have been singled out as capable of causing cancer in humans. Research on teratogenic effects has been limited, but a few chemicals have been shown to be teratogenic in humans in doses corresponding to those which might be expected in the environment. So little testing has been conducted on the mutagenic effects of synthetic organic chemicals that almost nothing is known about such effects.

Discussed below are three examples of synthetic organic chemicals which have posed some hazard to human health or the environment.

NTA (Nitrilotriacetic Acid)- NTA recently came into extensive use as a substitute for phosphates in detergents. Until a couple of years ago, almost no NTA was used. NTA, a substance with which the consumer has suddenly come into direct contact, may enter the general aquatic environment in large quantities through flushing into sewers and septic tanks. If NTA proved safe, an estimated 600 million pounds would have been used annually in detergents by 1973. (36) Because of its concern with water pollution caused by detergents, the Federal Government studied the health and environmental effects of NTA and other phosphate substitutes. Preliminary results indicated that NTA may combine with cadmium, mercury, and other metals to enhance the toxicity of these metals. Therefore, the major detergent manufacturers recently agreed not to use NTA until completion of testing now underway.

ONCB (Orthonitrochlorobenzene) (26)- ONCB is an unusable byproduct in the manufacture of paranitrochlorobenzene, a chemical in wide commercial use. In 1958, this unique and persistent chemical was found at levels of .021 parts per million in water samples taken at mon-

itoring stations between St. Louis and New Orleans. Concentrations of 0.03 parts per million of ONCB were found in treated drinking water, indicating that ONCB survived normal potable

water treatment procedures. Few studies have been done on the effects of ONCB, but it was calculated that 5 to 50 parts per million would be lethal to humans and that 0.5 to 5 parts per million would cause clinical symptoms.

Although concentrations of ONCB in the water were not toxic, the Public Health Service concluded that the safety factor was not adequate, the chemical was remarkably persistent, and normal water treatment was inadequate. On the basis of this analysis, the source of the ONCB agreed to remove waste streams containing ONCB from the river.

PCB's (Polychlorinated Biphenyls)- The

molecules of plastics are generally inert and nonreactive. Problems arise because of certain types of plasticizers, dyes, oxidation retardants, and various stabilizers which are added to plastics. These additives are not always chemically bound to the plastic molecules and thus may be released into the environment. PCB's, also known as Aroclors, are such a group of additives.

PCB's are among the more persistent[^]organic chemicals - they degrade very slowly in the environment. In addition to their use as plasticizers, they have also been used in paint, electrical transformers, and lacquer resins and as lubricants, heat transfer fluids, and "carriers" for some insecticides. Structurally, PCB's resemble DDT, and like DDT, they are not soluble in water but are fat soluble and therefore can be absorbed by human tissue. The resemblance to DDT goes further. PCB residues have been found in fish and wildlife around the world. Normally used analytical methods find it difficult to differentiate between DDT and PCB's.

In April 1969, PCB's were first detected as residues in oysters in Escambia Bay, Florida. Further sampling indicated the presence of PCB residues in the water, sediment, fish, blue crabs, and shrimp. The substance was traced to a leak from an industrial plant 6 miles upstream

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from the Bay. PCB was being used there as a heat exchange fluid, and the leak was not known. The leak has been stopped, but PCB's are still present in the Bay. albeit in decreasing amounts, apparently leaching from river sediments. (9)

Tests with PCBs have shown that 0.1 parts per million were fatal to juvenile pink shrimp after a 48-hour exposure, and the same concentrations stopped oyster shell growth in 96 hours. In laboratory tests, shrimp, pinfish, and oysters all concentrated PCB. (9) U.S. Fish and Wildlife Service workers have correlated the lethal effects of PCB's on game birds directly with the chlorine content of PCB. (15)

PCB's have also been found in Great Lakes fish and in human fatty tissue. (31) A study of human tissue samples showed concentrations of from less than 1.0 parts per million to as high as 250 parts per million. Fifteen percent of the samples exceeded 1.0 parts per million PCB's. (31) Another study showed that over half the urban residents examined had traces of PCB in their blood. (11)

SUMMARY

This chapter discusses the many pathways by which toxic substances enter the environment. Such substances are found in air, water, soil, food, and a variety of consumer products. Once they enter the environment, complex changes can take place which can alter their chemical form and change the ways in which they affect man.

The effects of toxic substances on man vary according to the type of substance, the amount of the substance to which a person is exposed, the duration and method of exposure, and several other factors. There is ample evidence that many metals and synthetic organic chemicals can pose hazards to human health.

Effects on human health are the primary concern of this chapter. Effects on wildlife, agriculture, and other parts of the ecosystem pose additional problems, but the effects of toxic substances on ecosystems have been even less well explored by scientists than the effects of such substances on man.

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CHAPTER in Technological and Legal Controls

This chapter details methods for controlling the introduction of toxic substances into the environment. Technological controls are discussed as background for evaluation of institutional and legal authorities available.

Control of a product and its uses, including total prohibition of the product, and control of the effluents. The alternatives and their relationship to the pathways by which contaminants enter the natural environment are shown in

Figure 2. Each is discussed briefly.

TECHNOLOGICAL METHODS OF CONTROL

Several control strategies exist for almost all the substances included in this study because each enters the environment in numerous ways. The strategies are of two general types: con-

Product Control

Control of products ("1" in Figure 2) to reduce contamination of the environment can be effected by either reducing the input of the raw material of concern or changing the nature of the end products.

FIGURE 2.

CONTROL STRATEGIES FOR TOXIC SUBSTANCES

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From a materials balance analysis, reducing the amount of a contaminant that is initially used ultimately reduces the amount that can enter the environment from effluents, regardless of the number or complexity of intermediate steps. Also, to the extent that the total body burden for a given substance or its accumula-

tion in a target organ is important, this control point may be the easiest at which to determine the absolute reduction required.

For example, fuel oils contain varying concentrations of metals. In the future we may have to look to fuels with low concentrations of highly toxic metals, just as we look to low-sulfur fuels today. Fuel oil combustion is chiefly responsible for vanadium concentrations in the atmosphere. Residual oil imported from Venezuela has up to 63 percent vanadium pentoxide in ash, compared with 14 to 38.5 percent for oil from Iran and 0.4 percent, 1.4 percent, and 5.1 percent for oil from Kansas, Texas, and California, respectively. (35) Changing to low-vanadium fuel is a control that could be used to reduce atmospheric vanadium concentrations if such reduction were necessary.

Changing end products or prohibiting their production is an important control technique because man is directly affected by these products and by their disposal – through interaction with the environment and through further interaction with man. Simply changing an ingredient can also effect a desired change. For example, lead has been used in paint to accelerate drying; its harmful effects can be eliminated by removing it from the product formulation and substituting another less toxic or nontoxic material.

Certain plastic products have used plasticizers which were persistent and upon disposal could cause damage to wildlife. Replacing them with other materials has alleviated the disposal problem without robbing the product of desired physical characteristics.

Control over use of a product is often suc-

cessful in reducing or eliminating damage caused by the product. The circumstances under which products such as drugs or pesticides can be used are carefully regulated because of the

severe damage which can result if they are misused. Many toxic substances can be used safely if human exposure is prevented. For example, the manufacturer of PCB's agreed to limit their use to closed systems, thus preventing damage by preventing their entering the environment.

Effluent Control

A second method of controlling the introduction of pollutants into the environment is to change the production process to eliminate or to control the effluents.

Changes in production processes may, in some cases, significantly reduce the quantities of contaminants that are discharged as effluents or that become intermediate or final products. For example, improving the efficiency of synthetic organics production can reduce the volume of toxic or potentially toxic effluents. Yields of organic products are rarely, if ever, 100 percent. Remaining chemical constituents are usually wastes, which may be recovered, treated, or released to the environment. Hence, to the degree that production is made more efficient and more of the raw material is utilized, wastes released to the environment are reduced.

Similarly, changes in production processes can change byproducts or wastes to less toxic or less persistent compounds. Some carcinogenic organic compounds are produced by burning coal and refuse. Improving combustion efficiency lowers the concentration of the carcinogens emitted.

Controlling effluents from manufacturing processes and from end product disposal has been the most widely used technique for controlling pollutants. The processes used are re-

cycling, waste treatment, or other kinds of disposal.

When the contaminants are of high value, as some metals are, recycling not only protects the environment but may also be the major source of the mineral. For example, arsenic, cadmium, and selenium occur in such low natural concentrations that they are not mined for themselves but are recovered during the refining of lead and zinc, among other metals. Similarly, because mercury is expensive, much of it can be economically recovered from effluents for reuse.

Recycling synthetic organic chemicals is more difficult than recycling metals and their compounds due to their complex molecular structures and to the economics of recovery. However, recycling rather than disposal is sometimes possible. Instead of incinerating scrap plastics, some scrap can be remelted for reuse in fabrication.

Treatment of wastes is also useful in preventing the harmful interaction of contaminants and the environment. Arsenic, nickel, and vanadium are usually airborne contaminants resulting from smelting other metallic ores. These toxic substances are commonly emitted with particulates. Therefore baghouse filters, wet scrubbers, and electrostatic precipitators which remove substantial quantities of particulates also reduce emission of these toxic metals. The resultant ash and metals can then be carefully disposed of or recycled. For example, an electrostatic precipitator which effectively reduces particulate emissions also reduces arsenic concentrations from a range of 5 to 17 parts per billion before treatment to 4 parts per billion after treatment. (39)

Effluents can also be neutralized before final disposal. Metals converted to metallic salts or

sulfides can be disposed of more safely. Also, some potentially toxic synthetic organics can be treated. Before disposal, phenols - a byproduct of some synthetic organic processes - can be decomposed by biological action into carbon

dioxide and water, two harmless, natural chemical components.

EXISTING LEGAL CONTROLS

Legal authorities available to control pollution parallel the technical methods of control. A product is controlled by regulating the amount manufactured and the uses permitted. For some products the processes of manufacture are regulated. Effluent control has generally involved the establishment and enforcement of standards for levels of air or water pollutants.

Product Control

The Federal Government exercises some control over the manufacture and distribution of pesticides, drugs, food additives, consumer products, and radioactive materials. Each of these authorities differs somewhat from the other.

Pesticides are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 135-135k), enacted to protect the user and handler of pesticides by requiring registration, proper labeling, and in some cases coloring of pesticide products. The FIFRA regulates the marketing, in interstate commerce, of "economic poisons and devices," which includes insecticides, rodenticides, plant defoliants, and household disinfectants.

The FIFRA requires registration of pesticides with the Administrator of the Environmental Protection Agency (EPA). The manufacturer must submit data to establish the

safety and efficacy of a pesticide along with the label proposed for the product. This information is reviewed to determine that the label contains adequate directions for use and adequate warnings to assure that handling, storage,

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or use of the product will not result in injury or damage when used as directed. Through the registration procedure and its approval of labeling, EPA can control whether a pesticide will be marketed and, if marketed, the particular crops on which it will be used. There is no provision for control over application of the pesticide, but the Administration has submitted a new, comprehensive pesticides bill which would remedy this and other defects in the existing law. The Food and Drug Administration (FDA) also enforces pesticide regulations through examination of food to insure that the pesticide residues do not exceed allowable limits.

FDA. under the authority of the Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), regulates food labeling, food additives, food containers, drugs, and cosmetics. Particularly tight controls are exercised over drugs. Before they are marketed, drugs must be registered and approved by FDA. They must be properly labeled and must be safe and effective when used as directed or suggested. Drug producers must register their plants, which are subject to close inspection by FDA. Manufacturers and handlers of depressant or stimulant drugs must keep extensive records of the type, quantity, and disposition of such drugs.

Regulation of foods, food additives, and cos-

metics is less stringent. Food standards can be prescribed for identification, quality, and fill of containers. New food additives must be cleared prior to use. FDA can prohibit the use of particular food additives or establish tolerance levels for the amount to be used. Although pre-clearance is not required for cosmetics, they must, not contain poisonous or deleterious substances; they cannot be produced or held in unsanitary conditions or packaged in a container which renders the contents injurious to health; and they must be fairly and accurately labeled.

Radioactive materials are the most closely

regulated of all substances. Under the authority of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.), the Atomic Energy Commission (AEC) regulates almost the entire spectrum of activity associated with the handling, transportation, and disposal of radioactive materials. Specifically, the AEC licenses and maintains continuing surveillance over facilities utilizing, processing, or disposing of radioactive materials. It also prescribes procedures and standards for packaging and shipping such materials.

Effluent Control

There are two major statutory authorities for controlling the release of pollutants directly into the environment - the Federal Water Pollution Control Act (33 U.S.C. 466 et seq.) and the Clean Air Act (42 U.S.C. 1857 et seq.). Both have been extensively amended since enactment, and the Congress is now considering further major changes in the Water Pollution Control Act.

The Federal Water Pollution Control Act provides for establishment of Federal-State water quality standards for interstate and coastal waters. Standards for all States have been approved by the Federal Government, although standards for some interstate waters

and some measures of quality have not yet been established. These standards basically cover general parameters of the water— such as oxygen content, temperature, and turbidity — rather than specific substances in the water. Although the standards may be enforced directly by the Federal Government, primary responsibility for enforcement rests with the States.

Early in 1970 and again in 1971, the Administration submitted to the Congress amendments to the Water Pollution Control Act designed to broaden the Act's coverage and to simplify the enforcement process. The amendments would

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extend the coverage of water quality standards to all navigable waters, ground water, the contiguous zone, and the high seas with respect to discharges emanating from U.S. territory ; and they would authorize establishment of effluent standards for all such waters. The Government also recently announced a program based on the 1899 Refuse Act, which requires a Federal permit to discharge effluents other than municipal sewage. The Refuse Act authority will serve as the basis for a national system of controlling industrial pollution.

The Clean Air Act has provided for a system of Federal-State establishment of air quality standards. However, comprehensive amendments to the Act (Clean Air Amendments of 1970 (Public Law 91-604)) passed recently require the Federal Government to establish national air quality standards and require the States to submit emission standards for individual pollutants for Federal Government approval. Further, the amendments require Fed-

eral establishment and enforcement of emission standards for certain classes of new industry and for hazardous air pollutants.

In addition to air and water pollution control, the Federal Government is concerned with solid waste disposal. However, the Solid Waste Disposal Act (42 U.S.C. 3251-3259) and the amendments contained in the Resource Recovery Act of 1970 (Public Law 91-512) do not authorize Federal regulation but deal primarily with research and demonstration of improved methods of disposal. The Resource Recovery Act does require the formulation of a plan for a system of national disposal sites for the storage and disposal of hazardous wastes. Many State and local governments promulgate disposal regulations, but in the main the regulations are concerned with visible smoke, not with toxic substances. No laws or regulations are directed at the problems which may be created by the disposal of potentially toxic materials.

Toxic Substances

Existing law does not entirely ignore the types of substances dealt with in this study. Toxic substances are specifically dealt with in the Hazardous Substances Act (15 U.S.C. 1261-1273), section 12 of the Federal Water Pollution Control Act (33 U.S.C. 1162), the recent amendments to the Clean Air Act, and the authorities of the Department of Transportation relating to transportation of hazardous substances.

The Hazardous Substances Act covers household products and toys – but not the raw materials from which they are manufactured. Thus it does not deal directly with most of the toxic substances of concern in this report. Primarily the law authorizes the Secretary of Health, Education, and Welfare only to require how a product should be labeled. Although the Act does allow extremely hazardous products to be banned from interstate commerce, the definition

of a "hazardous substance" is quite restrictive, stating that a substance may be banned only if special labeling or packaging is found ineffective in preventing a hazard. Only three household products have been banned.

Section 12 of the Federal Water Pollution Control Act authorizes the President to designate hazardous substances and to recommend methods and means for their removal from water. Under the section (33 U.S.C. 1162(a)), "hazardous substances" is limited to "such elements and compounds which, when discharged in any quantity into or upon the navigable waters of the United States or adjoining shorelines or the waters of the contiguous zone, present an imminent and substantial danger to the public health or welfare . . ." The section is generally aimed at accidental discharges of such substances into water and thus does not cover either continuous discharges into water or release of hazardous substances into other media.

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The Clean Air Amendments of 1970 contain a section directed specifically at hazardous substances and also authorize the Administrator of EPA to regulate the use of fuel additives. Section 112 requires the EPA Administrator to publish a list of air pollutants which are not covered by air quality standards and which "may cause, or contribute to, an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness." The Administrator must then set and enforce national emission standards for these pollutants. A similar section has been included in the Administration's proposed amendments to the Water Pollution Control Act.

The Department of Transportation (DOT) regulates interstate transportation of hazardous substances under several authorities, including the Department of Transportation Act (49 U.S.C. 1651 et seq.), the Transportation of Explosives Act (18 U.S.C. 831-837), and the Hazardous Cargo Act (46 U.S.C. 170). DOT has defined several classes of hazardous materials (49 C.F.R. Parts 170-179), and its Hazardous Materials Regulations Board plans further classification based upon health hazard (35 Fed. Reg. 8831, June 6, 1970). Although some testing for effects of hazardous substances is involved in the implementation of these regulations, substances are classified primarily from the perspective of hazards involved in their transportation and possible spills from accidents. Most of the problems of toxic substances discussed in this report relate to aspects of their use rather than to transportation and spills.

Inadequacy of Authorities

It is clear that current laws are inadequate to control the actual and potential dangers of toxic substances comprehensively or systematically. The controls over manufacture and distribution

pertain to only a small percentage of the chemical substances which find their way into the environment. Almost all the effects described in Chapter II relate to substances not covered by present controls over manufacture and distribution.

Both controls over production and controls over effluents suffer from the limited focus of their authority. For example, the Food and Drug Administration carefully examines food containers for their effect on food but does not address the environmental and health effects of incinerating the containers. With the exception of radioactive materials, disposal is not a consideration in any programs controlling manufacture.

But the problems of focus are broader than specific examples. Setting rational standards for many pollutants under existing legislation is almost impossible. The key factors involved in setting standards are the total human exposure to a substance and its total effect on the environment. The focus must be on a particular pollutant and all the pathways by which it travels through the ecosystem. Controls over distribution approach this perspective, but most fail to consider important environmental factors adequately.

The obvious limitation of controls over effluents is that they generally deal with a problem only after it is manifest. They do not provide for obtaining information on potential pollutants before widespread damage has occurred.

More subtle but more serious limitations of effluent controls arise from their focusing on the media— air or water— in which the pollution occurs. This approach has several consequences : First, it leads to concern with those substances found in air or water in the greatest quantities. For example, the Air Pollution Control Office uses the gross weight of air pollutants as one indicator of the severity of air pollution. Gross weight is a valid indicator, but it disregards

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the degrees of danger of the various pollutants. As indicated in Chapter II, comparatively small amounts of some substances can cause severe damage, but media-oriented programs tend to overlook the importance of such substances. Another consequence of the media approach is that it cannot deal effectively with the fact that many, perhaps most, toxic substances find their way into the environment

through several media. They cannot be characterized strictly as water pollutants or as air pollutants, for they are found in air, in water, and often in soil, food, and other parts of the environment. The characteristic pervasiveness of toxic substances makes it difficult for the media-oriented programs to engage in adequate and efficient research, monitoring, and control activities for such substances. The need for such a comprehensive approach was a major rationale for the creation of the Environmental Protection Agency (EPA) .

The scope of EPA's authority provides a basis for an integrated approach to toxic substances. However, such an approach cannot be accomplished simply by coordinating the activities of existing media-oriented programs. The activities themselves must be conducted on an integrated basis. Testing to determine the health or environmental effects of a substance must be done in terms of total exposure to the substance, not simply exposure through air or through water. There must exist a capability for integrating the monitoring data from various media and for doing nonmedia analyses, for example, utilizing the materials balance approach. (This approach compares the total amount of a substance produced with the amount appearing in various end uses. A disparity between the two indicates the approximate amount escaping into the general environment.) Finally, there must exist authority to insure that the effects of a new substance are carefully examined before it enters the air, soil, or water.

A NEW SYSTEM

The shortcomings of the legal authorities described above, the effects of toxic substances outlined in Chapter II, their increasing number and amounts indicated in Chapter I, and the inadequate attention paid to such substances all support the need for a new legal and institutional system to deal with toxic substances.

Our awareness of environmental threats, our ability to screen and test substances for adverse effects, and our capabilities for monitoring and predicting, although inadequate, are now sufficiently developed that we need no longer remain in a purely reactive posture with respect to chemical hazards. We need no longer be limited to repairing damage after it has been done; nor should we allow the general population to be used as a laboratory for discovering adverse health effects. There is no longer any valid reason for continued failure to develop and exercise reasonable controls over toxic substances in the environment.

In February 1971, the Administration submitted to the Congress a bill developed by the Council on Environmental Quality in consultation with EPA and other agencies, entitled The Toxic Substances Control Act of 1971. The bill contains two new, major authorities:

- The Administrator of the Environmental Protection Agency would be empowered to restrict or prohibit the use or distribution of a chemical substance if such restriction were necessary to protect health and the environment. In imposing such a restriction, the Administrator would be required to consider not only the adverse effects of the substance but also the benefits to be derived from use of the substance, the normal circumstances of use, the degree to which release of the substance or its byproducts to the environment is controlled, and the magnitude of human and environmental exposure to the substance or its byproducts.

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- The Administrator would be authorized to

issue standards for tests to be performed and for results to be achieved from such tests for various classes and uses of new substances. A new substance could be marketed only after it met these standards. Consumer products (insofar as their household use is hazardous) , pesticides, drugs, and other kinds of substances which are already regulated would continue to be regulated under existing authorities rather than under the Toxic Substances Act.

In addition to these two authorities, the bill contains several other significant provisions. If the Administrator believed that a substance were creating an imminent hazard, he could ask the courts to restrain use or distribution of the substance immediately. The Administrator would be authorized to develop the resources necessary to predict introduction of new chemical substances into the environment and to assess the environmental consequences of their introduction. The Council on Environmental Quality would be charged with coordinating efforts to establish a uniform system for classifying and handling information on chemical substances. The bill would also establish an independent Toxic Substances Board to provide scientific advice to the Administrator of EPA.

EPA would also be given authority to collect information on potentially toxic substances, an authority vital to a successful program for deal-

ing with such substances. The Administrator could request information from manufacturers on the substances that they produce - names, chemical identities, amounts produced, uses, and results of tests conducted on their effects.

SUMMARY

Existing legal authorities are inadequate to deal with toxic substances. If a substance is

toxic, control must often be exercised at the point of manufacture and distribution because the variety of ways in which such substances enter the environment and the difficulties of detecting many of them make effluent controls an ineffective mechanism. Also, standard-setting, monitoring, and control can often be done more efficiently and rationally if attention is focused on the particular substance rather than on the medium in which it may appear.

The proposed Toxic Substances Control Act represents a significant step in dealing with problems that will become increasingly acute unless action is taken. The growing number and amount of substances produced commercially are an environmental problem of potentially great magnitude. The proposed legislation and accompanying administrative action would protect the public and the environment to a far greater degree than is now possible.

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HEARINGS

U.S. Congress. House. Committee on Interstate and Foreign Commerce. Subcommittee on Consumer Protection and Finance. Toxic Substances Control Act. Hearings, 94th Cong., 1st sess., on H.R. 7229, H.R. 7548, and H.R. 7664. Washington, U.S. Govt. Print. Off., 1975. 482 p. Hearings held June 6 . . . July 11, 1975. "Serial No. 94-41"

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♦U.S. Congress. Senate. Committee on Commerce. Toxic Substances Control Act; report on S. 3149 together with additional views. Washington, U.S. Govt. Print. Off., 1976. 90 p. (94th Cong., 2d sess. Senate. Report No. 94-698)

"To regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes."

♦U.S. Congress. Conference Committee, 1976. Toxic Substances Control Act; conference report to accompany S. 3149. Washington, U.S. Govt. Print. Off. 1976. 105 p. (94th Cong., 2d sess. House. Report No. 94-1679)

U.S. Congress. Conference Committee, 1976. Toxic Substances Control Act; conference report to accompany S. 3149. Washington, U.S. Govt. Print. Off. 1976. 105 p. (94th Cong., 2d sess. Senate. Report No. 94-1302)

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Vol. 122, pp. S4397-S4432 [daily ed.].

♦House considered and passed S. 3149, amended, in lieu of H.R. 14032, August 23,

1976: Congressional Record, Vol. 122, pp. H8803-H8863 [daily ed.].

♦Senate agreed to conference report, Sept. 28, 1976: Congressional Record, Vol. 122, pp. S16808-S16810 [daily ed.] ; also, October 1, 1976, pp. S17596-S17597 [daily ed.].

♦House agreed to conference report, Sept. 28, 1976: Congressional Record, Vol. 122, pp. H11343-H11348 [daily ed.].

SECTION-BY-SECTION INDEX

Notes on the use of the index -

1. The index is preceded by a comparison of the sections of P.L. 94-469, H.R. 14032, and S. 3149; the index follows the same order of sections as the comparison.

2. A dash (-) in place of a section number indicates "No Comparable Provision."

3. Bold figures in the index denote particularly significant references.

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