

Part A: Supporting Statement for Information Collection Request 2126.01

1(a). Title

ICR: Longitudinal Study of Young Children's Exposures in their Homes to Selected Pesticides, Phthalates, Brominated Flame Retardants, and Perfluorinated Chemicals (A Children's Environmental Exposure Research Study - CHEERS)

EPA ICR Number: 2126.01

1(b). Short Characterization/Abstract

The US EPA's Office of Research and Development's National Exposure Research Laboratory (ORD/NERL) proposes to conduct a two-year longitudinal field measurement study of young children's (aged 0 to 3 years) potential exposures to current-use pesticides and selected phthalates, polybrominated diphenyl ethers, and perfluorinated compounds that may be found in residential environments. The study will be conducted in Duval County, Jacksonville, Florida over a two-year period from 2004 to 2006. Sixty young children will be recruited into this study in two cohorts: (1) infants recruited into the study soon after birth, and, (2) children recruited into the study at approximately 12 months of age. The study involves up to six data collection events at each home during the two-year study period. During each event, environmental and biological samples will be collected to measure chemical concentrations and questionnaires will be administered to collect data that will be used to estimate aggregate exposures and to analyze the measurement data. Aggregate exposures will be estimated for the current-use pesticides and selected phthalates in the study. The data collected on the polybrominated diphenyl ethers and the perfluorinated compounds will be used to evaluate the potential magnitude for exposure and to determine the temporal and spatial variability of these chemicals in residences. The study will collect data to fill critical gaps in our understanding of very young children's exposure to chemicals in their residences. The study will help the Agency reduce uncertainty in exposure and risk assessments for children by providing data on exposure factors and validated tools for estimating children's exposure to contaminants, as well as providing much needed measurement data for model refinement. The exposure factors generated in this study will be included in the National Center for Environmental Assessment's (NCEA) Child Specific Exposure Factors Handbook. Additionally, the information will appear in the form of final EPA reports, journal articles, and will also be made publicly available in an electronic database for use by the scientific community, risk assessors, and risk managers.

2. NEED FOR AND USE OF THE COLLECTION

2(a). Need/Authority for the Collection

The U.S. Environmental Protection Agency (EPA) has pledged to increase its efforts to provide a safe and healthy environment for children by ensuring that all EPA regulations, standards, policies, and risk assessments take into account special childhood vulnerabilities to environmental chemicals. In evaluating environmental health risks to children, it is important to understand that children are not little adults. Children's exposures to environmental contaminants are expected to be different and, in many cases, much higher than older persons due to differences in their physiological function, surface to volume ratio, ratio of food consumption to body weight, and the way children intimately interact (e.g., eating from the floor, sitting, crawling, rolling or sleeping on the floor, putting toys and other objects into their mouths) with their environment. Furthermore, the hypothesis that young children's exposures to environmental chemicals vary as a function of their age and developmental stage needs to be tested.

Exposure and risk assessments for very young children's exposures to chemicals in the residential environment rely heavily on default assumptions based on sparse data. In 1999, the 10X Exposure Working Group produced the report, *Exposure Data Requirements for Assessing Risks from Pesticide Exposure of Children* (US EPA 1999). This report defined the components of a complete and reliable data set and described why these components are currently not available. Critical elements that are missing include an understanding of the most important pathways of exposure for young children, approaches for evaluating exposure for critical pathways such as dermal and indirect ingestion exposure, protocols for generating the exposure data, and exposure factor data. Concurrently, the EPA's Office of Research and Development (ORD) developed the *Strategy for Research on Environmental Risks to Children* to articulate the problems and research needs associated with children's exposure to environmental contaminants (US EPA 2000). Three specific objectives are articulated in this *Strategy* to (1) make use of existing information to develop improved risk assessment methods and models for children; (2) design and conduct research on exposure, effects, and dose-response that will answer questions about age-related differences in exposure and risks that will lead to better risk assessments for children; and, (3) explore opportunities for prevention and reduction of risks to children.

The Children's Exposure Research Program at the EPA ORD's National Exposure Research Laboratory (NERL) has been designed to meet these objectives. The first phase of the program was to use existing data to develop improved methods. A comprehensive, systematic approach is required to understand and adequately address all of the components of children's aggregate exposure assessments. To develop NERL's research strategy and approach, factors influencing children's exposure to environmental contaminants were reviewed and the quality and quantity of available data associated with default assumptions for exposure factors were evaluated (Cohen Hubal *et al.*, 2000a). A framework to systematically identify the important sources, routes, and pathways for exposure was developed (Cohen Hubal *et al.*, 2000b). This framework is based upon the development of a conceptual model for aggregate exposure and provides the basis

for developing a protocol to measure and assess aggregate exposures, as well as for developing sophisticated stochastic models. This framework also allows researchers to systematically identify the most critical research needs and data gaps associated with children's exposures. NERL researchers identified four priority research areas, including pesticide use patterns, spatial and temporal distribution of pesticides, dermal and indirect ingestion, and dietary ingestion exposures. Laboratory studies, small pilot field studies, and larger, collaborative studies were designed and implemented to address these research needs.

A Draft Protocol for Measuring Children's Non-Occupational Exposure to Pesticides by all Relevant Pathways (i.e., *Draft Protocol*) was developed by NERL researchers to provide guidance for generating data that can be used to improve exposure assessments for young children (US EPA 2003). Currently, standard protocols for conducting exposure field studies that provide data for measurement-based exposure assessments do not exist. Likewise, protocols for developing exposure factor data to be used for modeling assessments are not available. Although research on children's exposure to pesticides and other toxic chemicals has been performed within EPA, academia, industry, and other research organizations, protocols for specific studies have not always collected all of the data required for reliable exposure assessments. The *Draft Protocol* fills a critical need for standardization of the approaches and methods for collecting exposure concentration and exposure factor data. One of the objectives of the proposed study is evaluate and validate the *Draft Protocol*. Although it has been evaluated in a set of small pilot studies performed by NERL researchers, it has not been evaluated in a large field study. It is essential that the *Draft Protocol* is fully evaluated for estimating exposure of young children to pesticides and other environmental contaminants so that future exposure assessments are conducted with a systematic and standardized approach. Use of this standardized protocol will facilitate comparison of data collected in children's exposure studies conducted by different groups in government, academia, and other research organizations. This standardized approach will lead to better exposure and risk assessments.

The CHEERS study will also directly address questions about age-related differences in exposure and risks by designing and conducting research on exposure, effects, and dose-response as detailed in the ORD children's *Research Strategy*. The study has been designed with repeated data collection for the same participating children in order to estimate aggregate exposures and exposure factors at the different developmental ages defined by EPA's Risk Assessment Forum. These data are critical for improved exposure and risk assessments and required by the Agency's risk assessors.

Four classes of chemicals for which environmental and biological data are needed for assessing human exposures include current-use pesticides, phthalates, polybrominated diphenyl ethers, and perfluorinated organic compounds. These chemicals are found in a wide variety of consumer products that are used extensively indoors, have been identified in many environmental media, and are a concern for the potential for adverse human health effects. However, data on the levels of these compounds in the human environment are limited. More data are needed on the potential exposures of very young children to these chemicals in their environment. Longitudinal

exposure data are not available for many of these compounds. The proposed study has been specifically designed to collect data that will be used to evaluate temporal variability of concentrations of these chemicals in environmental and biological media.

Pesticides are chemicals for control of a wide range of pests in the environment. They are essential for use on crops; small amounts of residues are tolerated in our food supplies. Pesticides are also needed to control insects and other pests both outdoors and in indoor environments. The EPA's regulatory programs address the needs for these chemicals along with their potential risks. The pesticides used most frequently indoors are currently the synthetic pyrethroids. However, there are limited data on indoor concentrations of these chemicals. This study addresses potential exposures to these chemicals and the factors that may affect children's exposures to pesticides in their homes.

Phthalates are used in the manufacture of a wide range of plastic and non-plastic products, including medical packaging, cosmetics, children's toys, wood finishes, paints, upholstery, and insect repellents (Hoppin *et al.* 2002; Koo *et al.* 2002). However, the characterization of human exposure to phthalates is limited and the National Toxicology Program's Center for the Evaluation of the Risks to Human Reproduction concluded that more data regarding the potential for human exposure to phthalates are needed (Hoppin *et al.* 2002).

Polybrominated diphenyl ethers (PBDEs) are used primarily in electronic and upholstery foams because of their fire retarding properties. However, PBDEs are thought to volatilize from these products during use. European and Canadian researchers have been investigating the prevalence of PBDEs in soil, water, wildlife, fish, and human breast milk samples for the last couple years. Evidence in the literature suggests that PBDEs are ubiquitous in the environment (Rice *et al.* 2002).

Organic fluorochemical compounds are found in polymers, lubricants, fire retardants, pesticides, and surfactants (Hansen *et al.* 2002). One study has shown trace levels of certain fluorochemical compounds in the serum of non-occupationally exposed humans and tissues from wildlife samples (see ref. in Hansen *et al.* 2002). Although the manufacture of perfluorooctane sulfonate (PFOS), one of the major fluorochemicals used to treat upholstery and textiles, has been discontinued in the US, the chemical is of concern due to the number of potential sources present indoors. There are very limited data (most collected by the manufacturer) that are available to adequately evaluate the potential for human exposure to the organic fluorochemical compounds. There is also concern that perfluorooctanoic acid (PFOA) is a persistent bioaccumulative toxicant in animals and humans. The Agency and industry are currently addressing that concern. Measurements of the perfluorinated chemicals in this proposed study are important because they will provide data that is complimentary, but independent of industry-generated data for these chemicals.

Evidence in the literature has shown that longitudinal human exposure data for pesticides, PBDEs, perfluorinated compounds, and phthalates are extremely limited. This study will greatly

increase our understanding of young children's potential exposures to chemicals found in their everyday environment. Data will be available for the pesticides and phthalates to perform aggregate exposure estimates, to apportion exposure pathways, and to identify exposure factors as they relate to changes in age and developmental stage. For the BFRs and perfluorinated chemicals, the data on concentrations in the indoor environment will fill a critical data gap. This research will also provide much needed preliminary data for identifying research needs and designing future field studies targeting chemicals of interest.

2(b). Practical Utility/Users of the Data

The data generated from this study will:

- 1) validate the systematic approach for evaluating aggregate exposure described in the *Draft Protocol*, thus providing for a standardized approach for future exposure assessments
- 2) evaluate the variability in exposure based on the age and developmental stage of the child, thus answering questions about age-related differences in exposure and risks
- 3) estimate the aggregate exposures of a cohort of very young children to current-use pesticides in their residential environments, for which data are currently limited
- 4) evaluate the relationship between biomarker concentrations and exposure estimates based on measurements of current-use pesticides in environmental media and diet and information on activities that may lead to exposure, data which will be useful in interpreting results from programs such as the National Health and Nutrition Examination Survey (NHANES)
- 5) evaluate and apportion the exposure pathways for the current-use pesticides
- 6) estimate the aggregate exposures of a cohort of very young children to the selected phthalates in their residential environments
- 7) evaluate the relationship between biomarker concentrations and exposure estimates based on measurements of the selected phthalates in environmental media and diet
- 8) evaluate and apportion the exposure pathways for the selected phthalates
- 9) determine spatial and temporal variability of the PBDEs in residences and the potential for children's exposure based on concentrations in environmental samples and diet
- 10) determine spatial and temporal variability of the perfluorinated compounds in residences and the potential for children's exposure based on concentrations in environmental samples and diet

The primary users of the data generated in this study will be risk assessors and risk managers within and outside of the Agency. Within EPA, users of the data include exposure assessors, risk assessors, human exposure modelers, and scientists in ORD, OPP, and OPPT. In addition, NCEA will include the exposure factors generated from this study in the Child Specific Exposure Factors Handbook. EPA regions and state agencies who conduct risk assessments will also utilize the data. In the private sector, industry groups will be able to use this exposure factor data for their risk assessments and risk management programs. Furthermore, data generated in this study will be used to determine the need for additional research on exposures to these, or other, persistent chemicals. If additional research is required, results of the proposed study will be instrumental in efficient and effective study designs. The protocol and methods used and

evaluated in the proposed study will be available as validated and standardized procedures for future studies by the Agency and other researchers.

3. NONDUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a). Non-duplication

Data on children's exposures and exposure factors have been collected in a number of studies (Simcox *et al.* 1995; Zartarian *et al.* 1995, 1997, 1998; Loewenherz *et al.* 1997; Melnyk *et al.* 1997; Reed *et al.* 1999; Freeman *et al.* 1999, 2001; Quackenboss *et al.* 2000; Hore 2003; Shalat *et al.* 2003). However, these studies (1) did not use the systematic approach for exposure assessment proposed for this study, (2) focused on a limited number of environmental chemicals in a limited number of media, (3) generally did not include measurements for all routes and pathways of exposure including dietary, (4) could not be used to develop estimates of aggregate exposures, (5) included a small number of children in the study (usually less than nine), and, (6) focused on exposures of children older than 3 years of age. However, none of these studies have adequately addressed the impact of children's age and activities on differences in exposure. Furthermore, environmental, biological, and activity pattern data were not systematically collected in a way that allowed the relationships between environmental and biological measurements to be evaluated. None of these studies are longitudinal. EPA's Children's Total Exposure to Pesticides and Other Persistent Organic Pollutants (CTEPP) study attempted to address a number of the deficiencies identified in previous children's exposure studies by measuring young children's exposures to various environmental chemicals in child care and residential settings. Although CTEPP is providing a valuable database on children's exposures, it, like other prior studies, does not provide adequate data on children younger than three years of age and did not collect information that can be used to assess the impact of age-related changes in children's activities and their aggregate exposures to chemicals in their home. The proposed CHEERS study will allow EPA to collect longitudinal data on exposure concentrations and exposure factors using a systematic approach that will address the data gaps and provide the data needed to reduce the use of default assumptions in the risk assessment process.

3(b). Public Notice

EPA solicited public comment on its information collection plans by publishing a notice in the Federal Register (68 FR 57442) on October 3, 2003.

The EPA received one public comment concerning the proposed study. Listed below are the comments and EPA's response to the comments.

EPA's response to comments placed on the edocket by the American Chemistry Council's Phthalate Esters Panel on December 2, 2003

Docket ID Number ORD-2003-0011

Proposed Collection: Longitudinal Field Measurement Study of Infant and Toddler's Aggregate Exposure to Pesticides and Persistent Pollutants, EPA ICR Number 2126.01, 68 FR 57442 (October 3, 2003)

Comment: Phthalates are not persistent compounds and therefore cannot serve to meet EPA's objective of studying "persistent pollutants". Therefore, they should not be included in the proposed collection. If EPA nevertheless continues to propose to include phthalates, it should change the name of the study to avoid mischaracterizing phthalates as persistent, a characterization not supported by the science.

Response: EPA will change the title of the study to the following: Longitudinal Study of Young Children's Exposures in their Homes to Selected Pesticides, Phthalates, Brominated Flame Retardants, and Perfluorinated Chemicals (A Children's Environmental Exposure Research Study - CHEERS)

Comment: Inclusion of phthalates in the proposed collection would not meet the necessity and practical utility requirements of the Paper Reduction Act. Excellent data already exist on phthalate exposure factors, routes and pathways of exposure. Those data demonstrate that exposures to phthalates are well below levels that could be anticipated to pose health concerns, and therefore that no further regulation of phthalates, which are already well regulated by EPA, is needed. Furthermore, many meaningful risk assessments already exist for the phthalates and support the low health concerns and lack of need for further regulation. It is hard to find another class of compounds as well studied, evaluated and assessed as the phthalates. The existing data and risk assessments indicate that phthalates should be a low priority for further study and risk assessment by EPA. Therefore, the proposed collection is not necessary to proper performance of the functions of EPA and would have only marginal utility.

Response: EPA appreciates the compilation of citations listed by the Phthalate Esters Panel in their comments. However, the citations clearly show the need for a longitudinal study as proposed by the EPA.

- There is no data to show how young children's exposure to phthalates changes as a result of the age and developmental stages proposed by the EPA's Risk Assessment Forum. The CHEERS study has been designed with repeated data collection for the same participating children in order to estimate aggregate exposures at different developmental stages.
- The CDC citation does not provide metabolite levels for children younger than 6 years of age. Therefore, collection of metabolite data from children younger than 3 years will significantly expand EPA's and the scientific community's understanding of phthalate metabolite levels in very young children.
- The Phthalate Esters Panel relies heavily on a publication by Brock *et al.* 2002 to argue that EPA is conducting duplicative research. However, the publication by Brock *et al.* does not use a systematic approach to evaluate young children's exposure to phthalates.

The only samples collected in this study are one or two urine samples from the participating children which prevents an evaluation of the exposure factors as a function of age and developmental stage to phthalates in the residential environment. Furthermore, the Brock *et al.* study discusses the need for further research to (1) determine the sources of phthalate exposures in young children, and (2) to fully assess the exposures to phthalates multiple urine samples should be collected from each participating child. The CHEERS study will address both of these listed needs for further research.

- Table 1 shows the lack of data for phthalate exposures for very young children. As can be seen in the table, there is no data relating environmental and biological measurements; there are only 19 data points for young children in the age range of 12-18 months; and, there is no data for children younger than 12 months.

Table 1. Data outlining why CHEERS is a critically needed study.

Citation	Major Data Contributed by Citation	Need for CHEERS study
Blount <i>et al.</i> ; CDC references	Adult urine samples	EPA study will collect data from children younger than 3 years of age
Brock <i>et al.</i>	One or two urine samples from 19 children ranging in age from 12 to 18 months	EPA study will collect six urine samples during each monitoring event from children younger than 3 years of age; EPA study will also relate the environmental samples to the biological samples
Health Canada; Zaleski <i>et al.</i> ; Kavlock <i>et al.</i> ; Clark <i>et al.</i>	Model work; no measurement data generated	EPA study will generate environmental, biological, and activity pattern data and exposure factors critical to model validation and refinement
EPA CTEPP study	One time aggregate exposure assessment of children ranging in age from 3 to 5 years; urine metabolites were not measured	EPA CHEERS study is a longitudinal aggregate exposure study to numerous chemicals found in the residence

- EPA will collect environmental and biological samples during the monitoring period to

conduct an aggregate exposure assessment for the young children's exposure to phthalates. There is no published data that allows researchers to evaluate exposure to phthalates.

Comment: EPA's Study Design for the proposed collection was developed and peer-reviewed for scientific merit only with respect to the pesticide component. The Panel raises questions that indicate the study design may be inappropriate for collection of data on phthalates, resulting in biased data that will then lack utility because of its unreliability. Therefore, EPA should not include any other classes of chemicals in the information collection, including phthalates, unless and until the study design is modified and peer-reviewed with respect to those chemicals.

Response: The design for the proposed study was developed in consultation with both government and non-government experts in the field of exposure assessment. While the study was originally designed as a current-use pesticide exposure study, the exposure factors generated in this study will be applicable to any chemicals found in the residential environment. In addition, the EPA has formed an advisory committee that will provide technical guidance and review study procedures during the course of the study.

Comment: Are any phthalates (or other add-on chemicals) present in the pesticide formulations?

Response: EPA is evaluating the aggregate exposures of young children to pesticides and phthalates in their residential environment. EPA is collecting the environmental, biological, and activity pattern data needed to evaluate the exposure factors necessary for assessing aggregate exposure. EPA is not attempting to identify the source of the phthalates, but the young children's exposure to them. Therefore, the design of the study is adequate to collect the data needed to conduct an aggregate exposure assessment to any chemical found in the residential environment.

Comment: Are the questionnaires appropriately designed to collect exposure information relevant to sources of phthalates? For example, detailed information on use patterns and use timing in relation to exposure measurements would be needed to place results in a meaningful context.

Response: After consultation with many government and non-government researchers, the conclusion was reached that there are no validated questionnaires currently being used for exposure assessments to phthalates. However, EPA believes it critically important to use questionnaires that have been evaluated or used by other researchers. This helps in consistency of the analysis and interpretation of the data. Therefore, the questions relating to potential phthalate exposures have been taken from other researchers.

Comment: Do methods exist for urine collection from infants that would not result in possible sample contamination with phthalates?

Response: The Brock *et al.* study used urine collection bags. The same manufacturer of the urine collection bags also distributes other urine collection devices that could be applicable to the

collection of urine from young children.

Comment: Does EPA have appropriate analytical techniques for environmental media other than air and dust, and for aggregating the data?

Response: The Contractor for the EPA has extensive analytical expertise with a wide variety of compounds, including phthalates. As pointed out in the comments, the EPA has analyzed for phthalates in the CTEPP study. As discussed in the *Draft Protocol*, the EPA has methods for aggregating the data.

3(c). Consultations

The design for the proposed study was developed in consultation with many experts in the field of exposure assessment. Government and non-government individuals have been involved in the development of the peer-reviewed study design. Their expertise was critical in the planning of the collection and development of the approach necessary to minimize burden in a study of this type. The persons most closely associated with the design and review of the longitudinal children's study are given in Table 1.

Table 1. Peer-reviewers for the study design document.

Responsibility	Individual	Affiliation
2002 Peer-Review Panel	Mary Kay O'Rourke	Univ. of Arizona (520)626-6835
	Maria Morandi	Univ. of Texas SPH (713)500-9288
	Luke P. Naeher	Univ. of Georgia (706)542-2454
	Karen Hammerstrom	US EPA/NCEA
	Michael Firestone	US EPA/OCHP
	David J. Miller	US EPA/OPP
	Cathy Fehrenbacher	US EPA/OPPT
ACC Review Coordinator	Tina Bahadori	American Chemistry Council (703)741-5214

3(d). Effects of Less Frequent Collection

Repeated data collection is required to meet the objective to determine age-related differences in exposures to the chemicals and to collect data on exposure factors that can be used to reduce uncertainties in the Agency's risk assessment process for children of different ages. Any less frequent data collection will not allow for adequate evaluation of the developmental age bins as proposed by the EPA Risk Assessment Forum.

3(e). General Guidelines

All study activities will adhere to OMB's general guidelines for information collections. Data collection activities will not start before OMB approval. In addition, participation is voluntary. Informed consent will be obtained before the field technicians begin any data collection activities. Participants are free to withdraw their consent any time during the study.

Specifically, study participants are not required to do any of the following:

- Report information to the Agency more often than quarterly.
- Prepare a written response to a collection of information in fewer than 30 days after receipt of a request.
- Submit more than an original and two copies of any document.
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years.
- Participate in a statistical survey that is not designed to produce data that can be generalized to the universe of the study.
- Utilize a statistical data classification that has not been reviewed and approved by OMB.
- Receive a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use.
- Submit proprietary, trade secret, or other confidential information unless the Agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

3(f). Confidentiality

Assuring respondents of the confidentiality of their data is a key to obtaining participation and continued success in survey data collection. In addition to standard confidentiality procedures outlined below, the proposed study will obtain a Certificate of Confidentiality. Our standard procedures cover the following key concerns:

- Preventing disclosure of information containing personal or organizational identifiers

We require that all data be identified with unique participant identification numbers. Participant identification numbers are the only identifying information

that will be associated with the respondent's data, responses to questionnaires, or the results of the analysis of samples collected.

- Storing hardcopy files

The links between the identification numbers and personally identifying information, addresses, or names are maintained in locked file cabinets, with access limited to senior project staff. Questionnaires, consent forms, and compensation receipts will be stored by the Contractor in a locked file.

- Assuring computer data security

The computer data generated from the proposed study will be password-protected. Only authorized staff members will have access to the data. The paper document and hardcopies of the computer files will be secured in locked file cabinets in locked, limited-access rooms.

- Disposing of completed forms that are outdated

At the conclusion of the proposed study, the EPA Project Officer will authorize disposal of outdated, completed forms by a qualified commercial Contractor specialized in disposing of documents. A certificate will be provided by the Contractor to state that these documents were properly disposed of.

3(g). Sensitive Questions

The questionnaires prepared for the study do not contain any questions concerning sexual behavior or attitudes, religious beliefs, or other matters usually considered private.

4. RESPONDENTS AND INFORMATION REQUESTED

4(a). Respondents/SIC Codes

Participants in this study will be residents of Duval County in the greater Jacksonville, Florida area. Participants must meet certain eligibility requirements as outlined in the list below.

- Age of the child at the time of recruitment is a newborn or 12-months of age
- High pesticide use in the home
- Participant child will not attend day care outside the home
- Participant lives in a permanent residence (not transient housing)
- Participant is willing to advise field measurement team of planned pesticide applications
- Participant is willing to collect urine and diet samples, and,
- Participant is willing to participate in the study for two years.

The population ultimately selected will be a convenience sample based on the Duval County

Health Department's community-based approach.

4(b). Information Requested

(i) Data Items

The reporting items requested are contained in the attached copies of questionnaires. These include the questionnaires necessary to determine eligibility of the potential participants, to screen the potential participants prior to enrollment into the study, and to collect information during the data collection monitoring events. Questionnaires administered in the proposed study will collect information on sources of chemicals and participant activities. This information is needed to systematically evaluate aggregate exposures. The questionnaire data are needed in combination with measurements of chemical concentrations in environmental and biological media to perform calculations to estimate aggregate exposures, to determine the exposure factors, and to measure spatial and temporal variability of the chemicals. Additionally, the Vineland Adaptive Behavioral Scales will be administered twice during the study to evaluate the feasibility of collecting developmental data in exposure studies for future large studies. A copy of each questionnaire is included as an appendix to this document. In addition, a separate document explains the rationale and use for each question administered to the participants (titled Appendix to Part A).

In addition to the reporting items collected with the questionnaires, environmental and biological samples will be collected. The samples to be collected from the study participant or caregiver include urine samples, duplicate diet samples, a cotton pajama worn to collect chemical residues from surfaces contacted by the child, accelerometer measurements, and a short videotape of the child's activities. Six urine samples, collected with diapers or as voids, will be collected from each participating child during each data collection event. For children recruited under three months of age, there will be six data collection events for each of the 30 children in the cohort. Therefore, a total of 36 urine samples will be collected from each child during the two-year study. For each of the 30 children recruited into the study at one year of age, six urine samples will be collected during each of five data collection events for a total of 30 urine samples from each child during the two-year study. In addition to collection of urine samples from the participating children, the caregiver of the child will be asked to provide two urine samples during two data collection events during the study, for a total of 240 adult urine samples that can be compared to the children's urine sample results. The total number of urine samples for the study will be 2220. The samples will be analyzed for the metabolites of pyrethroid pesticides, diazinon, chlorpyrifos, and phthalates. During the last data collection event for 40 children, a request will be made for a blood sample from the child and from the caregiver that can be analyzed for perfluorinated chemicals and brominated flame retardants. This will be voluntary and the child and caregiver are not required to provide blood samples to participate in the study.

Duplicate diet samples will be collected by the caregiver during each data collection event for a 24-hour period. The duplicate diet sample consists of equal portions of foods that the child

ate during the period. The food samples will be analyzed for all of the chemicals in order to determine their intake of the chemicals during the period. Data on concentrations of the chemicals in the food are essential for estimating aggregate exposures because food may be the primary source of exposure to select chemicals. Duplicate diet samples have been collected in many previous exposure studies and the procedures for collecting duplicate diet samples have been developed to minimize the burden on the participant.

To determine if children are exposed to chemicals during the study due to contact with residues on the floor or other surfaces where the child plays, the participating child will be asked to wear a one-piece cotton garment (“pajama”) for approximately one hour during each data collection event. The cotton will then be analyzed to determine chemical concentrations on the material. This method for estimating dermal exposure to chemicals is similar to dosimeter methods used to measure occupational exposures. It has been evaluated in a number of pilot studies (Hore 2003). An approach has been developed that minimizes the participant burden. Participation in this activity is strictly voluntary. Participating children will wear an accelerometer during the data collection event so that their level of activity can be related to surface residue concentrations to estimate dermal exposure. Caregivers will also collect at least 12 minutes of videotape with a camera provided to them in order to classify the level of activity during indoor play, quiet time, eating, and play outdoors.

The field technicians for the technical support Contractor will collect the environmental samples at the study participant’s residence during each data collection event. The participant will not be involved in collection of these samples. The samples to be collected by the Contractor technicians include air samples, surface transferable residues, floor dust, dust on furniture, soil, and water. A summary of the samples to be collected in the proposed study is provided in the attached study design document. Environmental samples will only be analyzed for the compounds listed in Table 2. A multi-residue analysis method will be used to quantitate the pesticides and brominated flame retardants. Separate aliquots will be analyzed for the selected phthalates and perfluorinated compounds. Table 3 lists the target analytes for the biological samples.

The environmental and biological samples chosen for collection and analysis will be used to evaluate the systematic approach needed for an aggregate exposure assessment.

(ii) Respondent Activities

Of the six activities listed in the 1995 PRA Definition of Burden and nine activities listed in OMB’s Definition of Burden in OMB’s Final Rules (5 CFR1320.3(b)(1)), the following are relevant to the respondents:

- Reviewing instructions,
- Training personnel to be able to respond to a collection of information, and
- Completing and reviewing the collection of information.

The respondent activities specific to this study include the following:

- Screening and enrollment into the study
- Training of the respondents for data collection,
- Collection of samples to include urine samples, duplicate diet, cotton garment (“pajama”), videotaping segments, and the accelerometer, and
- Completion of the survey forms (questionnaires and reporting items).

1. Screening and Enrollment - The respondents will provide information to the Agency’s Contractor staff with the Eligibility Screening Questionnaire that will be administered at clinics, hospitals, and other community sites to determine potential participants for the study. Respondents that meet the basic eligibility criteria will be further screened. The Home Pesticide Inventory and Use Screening Questionnaire will be used by the Contractor technician to collect information that can be used to verify potential participant use of pesticides in their homes prior to final enrollment into the study.

2. Training - Individuals who agree to participate in the study will be trained for the following activities:

- Completion of survey forms during the study, and
- Collection of the duplicate diet, urine samples, cotton garment, videotaping segments, and the accelerometer.

3. Collection of Samples - Participants will collect some samples, such as duplicate diet, urine samples, cotton garment, videotaping segments, and the accelerometer during the study. They will also allow the Contractor project staff to collect environmental samples from multiple media. The samples and data to be collected in the study are summarized above and in the study design document.

4. Completion of Survey Forms (Questionnaires) - Study participants will provide information via interviews with the Contractor’s technicians. The survey instruments to be completed by each respondent are included as attachments. The Eligibility Screening Questionnaire will be administered at clinics, hospitals, and other community sites to determine potential participants for the study. The Home Pesticide Inventory and Use Screening Questionnaire will be administered to verify potential participant use of pesticides in their homes prior to final enrollment into the study. The other questionnaires will be completed during each data collection monitoring event. They include the following:

- Participant and Housing Characteristics Questionnaire
- Monitoring Period Questionnaire
- Activity Time Line
- Food Diary
- Monthly Pesticide Purchase and Inventory Log
- Monthly Cleaning Products Purchase and Inventory Log

The Vineland Adaptive Behavior Scales will be completed during only two of the data collection events. The proposed activity schedule for each participant during each data collection

event is summarized in Table 4.

Table 2. List of chemicals to be analyzed in environmental media and duplicate diet.

<u>Organophosphate Pesticides (OPs)</u>	<u>Pyrethroid Pesticides</u>
Chlorpyrifos	cis, trans, total Allethrin
Diazinon	Resmethrin
<u>Phenyl-Pyrazole</u>	Bifenthrin
Fipronil	Sumithrin
<u>Synergist</u>	Tetramethrin I, II, total
Piperonyl butoxide	lamda-Cyhalothrin
<u>Phthalates</u>	cis, trans, total Permethrin
Butyl benzyl phthalate	Pyrethrin I, II
Dibutyl phthalate	Cyfluthrin I, II, III, IV, total
Diethyl phthalate	Cypermethrin I, II, III, IV, total
Di(2-ethylhexyl) phthalate	Esfenvalerate
Diisononyl phthalate	Delta/Tralomethrin
Diisodecyl phthalate	
<u>Brominated Flame Retardants</u>	<u>Perfluorinated Compounds</u>
PBDE congeners 47, 99, 100, 153, 154, 181, 183, 190, 197, 209	Perfluorooctanoic acid (PFOA)
Hexabromocyclododecane (HBCD)	Perfluorooctane sulfonate (PFOS)
Tetrabromobisphenol A (TBBPA)	

Table 3. List of chemicals to be analyzed in biological media.

Analyte	Analyte
3-phenoxybenzoic acid	Mono ethyl phthalate
4-fluoro-3-phenoxybenzoic acid	Mono butyl phthalates
<i>cis</i> -3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-1-carboxylic acid	Mono benzyl phthalate
<i>trans</i> -3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-1-carboxylic acid	Mono-2-ethylhexyl phthalate
<i>cis</i> -3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane-1-carboxylic acid	Mono isononyl phthalate
<i>cis</i> -3-(2,2-dimethylvinyl)-2,2-dimethylcyclopropane-1-carboxylic acid	Mono isodecyl phthalate
<i>trans</i> -3-(2,2-dimethylvinyl)-2,2-dimethylcyclopropane-1-carboxylic acid	PBDE Congeners 47, 99, 100, 153, 154, 181, 183, 190, 197, 209
3,5,6-trichloro-2-pyridinol	Hexabromocyclododecane (HBCD)
2-isopropyl-4-methyl-6-hydroxypyrimidine	Tetrabromobisphenol A (TBBPA)
	Perfluorooctanoic acid/Perfluorooctane sulfonate

Table 4. Schedule of Activities for Each Data Collection Monitoring Event.

Day	Activity
-2 (background sample collection)	<ol style="list-style-type: none"> 1. Contractor field technician collects background samples (surface wipes, air samples, etc.) prior to a pesticide application 2. Technician completes or updates Participant and Housing Characteristics survey 3. Technician provides training and instructions to participant for data collection 4. Participant collects urine samples, Activity Time Line, accelerometer, and videotape information
-1 (return after 24 hours)	<ol style="list-style-type: none"> 1. Contractor field technician retrieves air samples and wipe samples 2. Contractor field technician retrieves urine samples, Activity Time Line, and accelerometer information 3. Technician provides new urine collection devices, duplicate diet containers, and Activity Time Line form to participant 4. Technician provides instructions and training as required
1 (following a pesticide application)	<ol style="list-style-type: none"> 1. Technician sets up air samplers and collects other environmental samples (surface wipes, hand wipes, etc.) 2. Participant collects urine, duplicate diet samples, accelerometer, Food Diary, and Activity Time Line information 3. Technician collects Monthly Pesticide Purchase, Inventory, and Use Log and Monthly Cleaning Products Purchase, Inventory, and Use Log
2	<ol style="list-style-type: none"> 1. Technician retrieves air samples 2. Technician collects other environmental samples 3. Technician retrieves urine and diet samples from participant 4. Technician administers Monitoring Period Questionnaire
3	<ol style="list-style-type: none"> 1. Retrieve final urine sample

5. THE INFORMATION COLLECTED --Agency Activities, Collection Methodology, and Information Management

5(a). Agency Activities

The study is expected to span three years, beginning in FY 2004. Agency activities associated with the proposed study include the following:

- Develop and program questionnaires and prepare ICR package,
- Set up master database,
- Obtain Institution Review Board (IRB) approval,
- Screen and enroll participants,
- Train participants,
- Collect samples from respondents,
- Complete survey forms,
- Database entry and management, and
- Data review and validation.

5(b). Collection Methodology and Management

The design for the proposed study was developed by scientists at ORD. It was revised based on the comments and recommendations of the external peer-review panel. The questionnaires used for information collection are based on similar questionnaires used in other exposure measurement studies. Questionnaires were compiled from both large and small studies and evaluated. Questions were included in the CHEERS survey instruments only if the information was required to estimate aggregate exposures, assess temporal or spatial variability, or interpret the data. The survey instruments for the proposed study have in part, or full, been evaluated in pilot studies. The time required to complete each instrument has been determined by testing with fewer than nine individuals in pilot studies or with co-workers.

Survey Instruments

The following questionnaires will be administered electronically to ease burden and increase participation. They include:

- Eligibility Screening Questionnaire
- Home Pesticide Inventory and Use Screening Questionnaire
- Participant and Housing Characteristics Questionnaire
- Monitoring Period Questionnaire

The following questionnaires will be administered in paper copy to facilitate completion by the participant. Contractor field technicians will check data quality by reviewing the responses to questions at the time that the questionnaires are retrieved and will verify questionable responses with the study participants during the data collection event at the participant's residence.

- Activity Time Line
- Food Diary

- Monthly Pesticide Purchase and Inventory Log
- Monthly Cleaning Product Purchase and Inventory Log
- Monthly Cleaning Product Use Log
- Vineland Adaptive Behavioral Scales

Sampling Methodology/Targeted Chemicals/Data Management and Analysis/Accuracy and Reliability/Data Processing

Sampling methodology, selected targeted chemicals, data management and analysis, accuracy and reliability, and data processing are discussed in the attached study design. For data collected on hard copy, a specially designed data entry program will perform quality control checks as paper data are entered, such as range checks, consistency checks, and checks for properly followed skip patterns. All paper data will be keyed in twice and verified with a computer verification program.

Public Access to Collected Data

The data and study results will be made available to the general public via several different sources, including the internet (EPA's Home page: www.epa.gov) and libraries. Summaries of study results will be provided in newsletters sent periodically to all members of the proposed cohorts and other interested individuals and organizations.

5(c). Small Entity Flexibility

Since the proposed study involves voluntary participation on the part of the children and their primary caregivers and no regulatory efforts are involved, small entity flexibility is not applicable.

5(d). Collection Schedule

The schedule for data collection covers three years beginning in 2004 and ending in 2006. The study involves repeated visits to collect information for the study participants. Multiple data collections will be made each year, but will not be more frequently than quarterly. The schedule for information collection during the study differs for the two cohorts of study participants. For the 30 participants recruited at the age of less than 3 months, information collection will be performed at the participant ages of 3, 6, 9, 12, 18, and 24 months (+/- approximately 2 months). For children recruited into the study at 12 months of age, information collection will be performed at the participant ages of 12, 18, 24, 30, and 36 months (+/- approximately 2 months). The ages of the children were selected based on the EPA's Risk Assessment Forum proposed age bins for developmental stages. The Eligibility Screening Questionnaire will be administered at a health clinic, hospital, doctor's office or other community contact location. If the participant is eligible, a screening visit will be schedule to visit the potential participant's home. During the visit, the Contractor technician will collect information with the Home Pesticide Inventory and Use Screening Questionnaire. If the potential participant meets all eligibility criteria, s/he will be enrolled into the study. The schedule for information collection at each subsequent time period was described previously in Table 4.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a). Estimating Respondent Burden

Estimates for study activities were based on information on burden from similar EPA pilot and field measurement studies. The times necessary to complete the questionnaires were also based on pre-testing of the instruments by EPA personnel.

Estimates of the time each participant (respondent) must spend to complete each study activity during each of the data collection monitoring events are listed in Table 5. As described previously, this study involves repeated visits to collect data from each study participant. For children enrolled at 0 to 3 months of age, there will be six repeated visits; for children enrolled at one year of age, there will be five repeated data collection events. Therefore, the total number of data collection events are 11. Table 6 lists the total respondent burden for the study using the burden estimates for each activity listed in Table 5. As indicated in Table 6, the total respondent labor hours for the complete study are 1174 hours for all 60 respondents over three years, or an average of 6.52 hours per respondent annually.

6(b). Estimating Respondent Costs

Respondents are study participants who are individuals living in private residences. The wages of the respondents are unknown. The estimates for respondent's costs are based on the median per capita income of \$9.98 (rounded to \$10.00) per hour in Duval County, Florida, based on Census 2000 data. These estimates are used for each respondent activity and the basis for all subsequent calculations. The average annual respondent labor costs are \$65.22, as shown in Table 7. Participants are individuals living in private residences; there are no capital and operations and maintenance costs associated with information collection from the participants except for the direct costs associated with the collection of data for this survey that include approximately \$1 for electricity and approximately \$3 for each duplicate diet sample, for which participants will be reimbursed.

Table 5. Respondent burden estimates for completing each activity one time.

Data Item	Time (minutes)
SCREENING AND ENROLLMENT	
Complete Eligibility Screening Questionnaire	10
Complete Home Pesticide Inventory and use Screening Questionnaire	20
Describe study and obtain informed consent	20
Discuss scheduling	5
TRAINING	
Instructions to collect the duplicate diet	5
Instructions to collect the urine samples	5
Instructions to collect the cotton garment	5
Instructions to collect the videotaping segments	5
Instructions on the use of the accelerometer	5
COLLECT SAMPLES	
Pre-application urine samples	2
Post-application urine samples	4
Duplicate diet	7
Cotton garment	5
Videotaping segments	12
Accelerometer	5
COMPLETE SURVEY FORMS	
Participant and Housing Characteristics Questionnaire	30
Monitoring Period Questionnaire	30
Activity Time Line	15
Food Diary	10
Monthly Pesticide Purchase, Inventory, and Use Log	5
Monthly Cleaning Products Purchase, Inventory, and Use Log	5
Vineland Adaptive Behavioral Scales	20
TOTALS	230

Table 6. Total study burden estimates and costs for all respondents participating in all data collection monitoring events (total study burden for three years).

Data Item	Time per data item (hours)	No. of Participants in Each Monitoring Event ^a	Total Respondent Labor Hours per Monitoring Event	Total Respondent Labor Hours for the Complete Study ^b	Capital /Start Up Cost (\$)	O&M Cost (\$)	Total Cost for the Study (\$) ^c
SCREENING AND ENROLLMENT							
Complete Eligibility Screening Questionnaire ^d	0.17	60	10	10	0	0	100
Complete Home Pesticide Inventory and use Screening Questionnaire ^d	0.33	30	10	20 ^e	0	0	200
Describe study and obtain informed consent	0.33	30	10	20 ^e	0	0	200
Discuss scheduling	0.08	30	2.5	27.5	0	0	275
TRAINING							
Instructions to collect the duplicate diet	0.08	30	2.5	27.5	0	0	275
Instructions to collect the urine samples	0.08	30	2.5	27.5	0	0	275
Instructions to collect the cotton garment	0.08	30	2.5	27.5	0	0	275
Instructions to collect the videotaping segments	0.08	30	2.5	27.5	0	0	275
Instructions on the use of the accelerometer	0.08	30	2.5	27.5	0	0	275
COLLECT INFORMATION							
Pre-application urine samples	0.03	30	1	11	0	0	110
Post-application urine samples	0.07	30	2	22	0	0	220

Data Item	Time per data item (hours)	No. of Participants in Each Monitoring Event ^a	Total Respondent Labor Hours per Monitoring Event	Total Respondent Labor Hours for the Complete Study ^b	Capital /Start Up Cost (\$)	O&M Cost (\$)	Total Cost for the Study (\$) ^c
Duplicate diet	0.12	30	3.5	38.5	0	0	385
Cotton garment	0.08	30	2.5	27.5	0	0	275
Videotaping segments	0.20	30	5	55	0	0	550
Accelerometer	0.08	30	2.5	27.5	0	0	275
COMPLETE SURVEY FORMS							
Participant and Housing Characteristics Questionnaire	0.5	30	15	30 ^e	0	0	300
Monitoring Period Questionnaire	0.5	30	15	165	0	0	1650
Activity Time Line	0.25	30	7.5	247.5 ^g	0	0	248
Food Diary	0.17	30	5	55	0	0	550
Monthly Pesticide Purchase, Inventory, and Use Log	0.08	30	– ^h	120 ^h	0	0	1200
Monthly Cleaning Products Purchase, Inventory, and Use Log	0.08	30	– ^h	120 ^h	0	0	1200
Vineland Adaptive Behavioral Scales	0.33	30	10	40 ⁱ	0	0	400
TOTALS	3.8	--	--	1174	0	0	\$11,740

^aOne cohort of 30 respondents participates in each monitoring event (for eligibility screening, the number is assumed to be 60, but screening only occurs once during the study).

^bThere will be 11 data collection monitoring events during the three years of the study; burden estimates in this column are hours per monitoring event times 11. The total of 1174 is for all 60 participants. Total respondent hours per participant are 19.57 for the complete study.

^c Labor cost was estimated based on per capita income data for Duval County, Florida from Census 2000; median annual per capita income was \$20,753. Divided by 2080 = \$9.98/hour, which was rounded to \$10.00 per hour for the calculation.

^d Eligibility screening questionnaire administered one time to estimate of 120 respondents.

^e Home pesticide inventory and use screening questionnaire and consent form are only completed once by 30 respondents in each cohort for a total of 60 respondents in the study.

^f Participant and housing characteristics questionnaire is only completed once by each participant.

^g Activity time line is completed for three separate 24-hour periods during each monitoring event (30 respondents per cohort X 3 forms X 11 events)

^h Participant completes each month.

ⁱ Developmental assessment will be completed twice during the study.

^j Logs will be completed once each month by each of the 60 respondents for 24 months.

^k The Vineland will be completed only two times during the study by each of the 60 respondents.

Table 7. Annual respondent burden and cost estimates.

Data Item	Annual burden per respondent (hours) ^a	Annual labor cost per respondent (\$) ^b	Capital /Start Up Cost (\$)	O&M Cost (\$)	Annual cost per respondent (\$) ^c
SCREENING AND ENROLLMENT					
Complete Eligibility Screening Questionnaire ^d	0.06	0.56	0	0	0.56
Complete Home Pesticide Inventory and use Screening Questionnaire ^a	0.11	1.10	0	0	1.10
Describe study and obtain informed consent	0.11	1.10	0	0	1.10
Discuss scheduling	0.15	1.53	0	0	4.53
TRAINING					
Instructions to collect the duplicate diet	0.15	1.53	0	0	4.53
Instructions to collect the urine samples	0.15	1.53	0	0	4.53
Instructions to collect the cotton garment	0.15	1.53	0	0	4.53
Instructions to collect the videotaping segments	0.15	1.53	0	0	4.53
Instructions on the use of the accelerometer	0.15	1.53	0	0	4.53
COLLECT INFORMATION					
Pre-application urine samples	0.06	0.61	0	0	0.61
Post-application urine samples	0.12	1.22	0	0	1.22

Data Item	Annual burden per respondent (hours) ^a	Annual labor cost per respondent (\$) ^b	Capital /Start Up Cost (\$)	O&M Cost (\$)	Annual cost per respondent (\$) ^c
Duplicate diet	0.21	2.14	0	0	2.14
Cotton garment	0.15	1.53	0	0	1.53
Videotaping segments	0.31	3.06	0	0	3.06
Accelerometer	0.15	1.53	0	0	1.53
COMPLETE SURVEY FORMS					
Participant and Housing Characteristics Questionnaire	0.17	1.67	0	0	1.67
Monitoring Period Questionnaire	0.92	9.17	0	0	9.17
Activity Time Line	1.38	13.75	0	0	13.75
Food Diary	0.31	3.06	0	0	3.06
Monthly Pesticide Purchase, Inventory, and Use Log	0.67	6.67	0	0	6.67
Monthly Cleaning Products Purchase, Inventory, and Use Log	0.67	6.67	0	0	6.67
Vineland Adaptive Behavioral Scales	0.22	2.22	0	0	2.22
TOTALS	6.52	\$65.22	0	0	\$65.22

^a Numbers rounded. Actual values used to calculate labor cost.

^b Labor cost was estimated based on per capita income data for Duval County, Florida from Census 2000; median annual per capita income was \$20,753. Divided by 2080 = \$9.98/hour, which was rounded to \$10.00 per hour for the calculation.

6(c). Estimating Agency Burden and Cost

The estimates for the Agency burden and cost are presented in Table 8. The table includes labor hours and costs for Agency staff and for the Contractor that are applicable to the activities described in Section 5. Costs are included for developing and programming the questionnaires and developing the ICR package, setting up the database, obtaining IRB approval, recruitment costs that include screening and enrollment and the collection of the data items described in Section 4. Labor hours and costs are not included for collection and analysis of environmental samples and tasks associated with the exposure measurements. Labor, capital startup, and operation & maintenance (O&M) values for the Contractor portion of this table have been estimated based upon confidential business information related to the Agency's Contractor quoted cost estimates for performing the field data collection. Labor costs/hr recorded in the table represent those from off-site contract employees currently expected to provide Agency support in the data collection and represent loaded costs (incorporating labor, overhead, G&A, fringe, fee) using an average rate for the primary categories of staff that will perform the work. There will be minimal capital start-up costs associated with the survey and the questionnaire-type information collection. O&M costs are included which cover items such as copying of forms and purchase of containers and supplies needed for samples to be collected by the participants.

The estimated labor cost of Agency staff is based on GS pay scales (Research Triangle Park, NC- locality). GS rates were used to provide the estimates using the 1.6 time rule for inclusion of fringe benefit costs. Agency labor associated with the direct collection of respondent data and the direct interaction of Agency staff with respondents in the collection of data is limited. Contract staff (whose labor has been estimated in the table) have the responsibility of performing nearly all of the data collection.

The annual Agency labor per respondent is estimated to be 89.5 hours. The Agency labor cost is estimated to be \$6,801 per respondent per year. The total annual Agency labor and capital costs are estimated to be \$6,954 per respondent per year.

6(d) Estimating the Respondent Universe and Total Burden and Costs

The respondent universe will be 60 study participants that voluntarily enroll in the study. The total respondent burden and costs were presented in Table 6. The estimated annual burden per respondent of 6.5 hours was multiplied by the number of respondents (60) multiplied by 3 years to determine the total respondent burden for the study of 1,174 hours. The total respondent cost for the 60 respondents for 3 years is \$11,740 (\$65.22 multiplied times 60 respondents times 3 years).

There are a total of 22 individual respondent activities under the four primary categories of activities, as shown in Table 5. The Eligibility Screening Questionnaire, Home Pesticide Inventory and Use Screening Questionnaire, Informed Consent, and Participant and Housing Characteristics Questionnaire are completed once during the study. The Vineland Adaptive Behavioral Scales is completed twice. Most other activities are performed eleven times. The pesticide and cleaning product use logs are completed monthly. The total number of activities is 14, 520 for the full study.

Table 8. Annual EPA (Agency and Contractor) burden hours and costs per respondent (Part I of table).

Information Collection Activity	Contractor Legal (\$165) - hours	Contractor Mgr. (P4) (\$159) - hours	Contractor Team Lead (P3) (\$106) - hours	Contractor Support Staff (P2) (\$90) - hours	Contractor Tech. (T1) (\$56) - hours	Contractor Clerical (\$64) - hours	EPA Legal (\$79) - hours	EPA Mgr. (GS-15) (\$79) - hours	EPA Scientist (GS-14) (\$67) - hours
Develop questionnaires and ICR	0	1.2	2.0	7.8	3.4	0.2	0	1.1	0.3
Set up master database	0	0.9	2.7	0.7	0.3	0.1	0	0	0
Obtain IRB approval	0	1.3	0	0.4	0	0	0	0.2	0.2
Screen and enroll participants	0	2.1	0.2	6.2	15.1	0.4	0	0.4	0
Train participants	0	0.1	0.2	0	1.5	0	0	0	0
Collect samples from participants	0	0.1	0.4	0	2.8	0	0	0	0
Complete survey forms	0	0.7	1.4	0	6.9	0	0	0	0
Database entry and management	0	0.2	0.7	0	6.4	0	0	0	0
Data review and validation	0	0.2	0.3	3.7	0.7	0	0	0	0

Table 8. Annual EPA (Agency and Contractor) burden hours and costs per respondent (Part II of table).

Information Collection Activity	EPA Scientist (GS-13) (\$57) - hours	EPA Clerical (\$48) - hours	Labor Hours per Respondent per Year	Agency Labor Cost (\$) per Respondent per Year	Capital Start Up Costs per Respondent per Year	O&M Costs per Respondent per Year	Total Cost per Respondent per Year	Number of Respondents	Total Costs for Study (all 3 years) ^a
Develop questionnaires and ICR	9.3	0	25.3	1945	0	0.83	1946	60	350,212
Set up master database	0.7	0	5.3	552	0	0.56	553	60	99,481
Obtain IRB approval	0	0	2.1	274	0	0.28	274	60	49,304
Screen and enroll participants	1.8	0.2	26.4	1930	0	51.07	1981	60	356,641
Train participants	0.4	0	2.2	138	0	6.11	144	60	25,963
Collect samples	0	0	3.3	220	55	19.38	294	60	52,906
Complete survey forms	0	0	9.0	649	0	20.23	669	60	120,388
Database entry and management	1.8	0	9.1	560	0	0	560	60	100,812
Data review and validation	1.8	0	6.7	534	0	0	534	60	96,060
Total	--	--	89.5	\$6,801	\$55	\$98	\$6,954	60	\$1,251,766

^a Note: Due to rounding of numbers values may differ slightly when calculated from values provided in the table.

6(e). Bottom Line Burden Hours and Cost Tables

(i) Respondent Tally

The bottom line burden hours and costs for respondents were shown in Table 6, labeled as the “Total study burden estimates.” As discussed in the previous sub-section, the total respondent burden and cost was presented in Table 6. The estimated annual burden per respondent of 6.5 hours was multiplied by the number of respondents (60) multiplied by 3 years to determine the total respondent burden for the study of 1,174 hours. The total respondent cost for the 60 respondents for 3 years is \$11,740 (\$65.22 multiplied times 60 respondents times 3 years). The burden and cost are summarized in Table 9.

Table 9. Total Estimated Respondent and Agency Burden and Cost Summary (Primary data in Table 6).

	Number of Respondents	Total Number of Activities for Study	Total Hours for the Study	Total Capital Start up (\$K)	Total O&M (\$K)	Total Cost for the Study (\$K)
Respondent	60	14,520	1,174	\$0	\$0	\$11.7
Agency	--	--	16,110	\$9.9	\$17.7	\$1.251
TOTAL	--	--	17,284	\$9.9	\$17.7	\$1.264

(ii) Agency Tally

The bottom line burden hours and costs for the Agency for the three years of the study were shown in Table 8. The total Agency labor burden (Table 8) is 16,110 hours (89.5 hours per respondent times 60 respondents times 3 years). The Total Agency Cost is \$1,251,766 (\$6,954 times 60 respondents times 3 years), as shown in Table 9.

iii. Variations in the Annual Bottom Line

Significant variations (>25%) are not anticipated in the annual respondent burden. The data collection events are expected to begin in the middle of 2004 and end in 2006, resulting in a similar number of data collections in each of the three years.

6(f). Reasons for Change in Burden

This section is inapplicable to this ICR.

6(g). Burden Statement

The annual public reporting and recordkeeping burden for this collection of information is estimated to average 6.52 hours per person per year. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions;

develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID No. ORD-2003-0011, which is available for public viewing at the Office of Environmental Information Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the Office of Environmental Information Docket is (202) 566-1752. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at <http://www.epa.gov/edocket>. Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search", then key in the docket ID number identified above. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Officer for EPA. Please include the EPA ICR No. 2126.01 in any correspondence.

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APPENDIX TO PART A: SUPPORTING STATEMENT FOR INFORMATION COLLECTION REQUEST
2126.01

LONGITUDINAL STUDY OF YOUNG CHILDREN'S EXPOSURES IN THEIR HOMES TO SELECTED
PESTICIDES, PHTHALATES, BROMINATED FLAME RETARDANTS, AND PERFLUORINATED
CHEMICALS

Short Title - A Children's Environmental Exposure Research Study (CHEERS)

INFORMATION COLLECTION REQUEST

Rationale for Data Collection Forms

Eligibility Screening Questionnaire (Version Final Draft 11/24/2003)

Qx #	Question	Rationale	Analytic Use
1	Do you live in Duval County?	Information to verify where potential participant may live.	Used to determine eligibility; analysis will be on the spot as the responses “no”, “don’t know”, or “refused to answer” are exclusion criteria.
2, 2A, 2B, 2C	Are you the parent or legal guardian of a child under the age of 14 months? If you are pregnant, what is your due date? How many children under the age of 14 months do you have? What is the child’s date of birth?	Information to verify whether the potential participant has a child in the appropriate age range.	Used to determine eligibility; analysis will be on the spot as the responses “no”, “don’t know” or “refused to answer” are exclusion criteria.
3, 3A	(Does your child/Do your children) under the age of 14 months stay home during the week (that is, not attend a day care or stay with a baby sitter at a place away from your home)? How many days per week and hours per day (does/do) your (child/children) go to a day care center or baby sitter away from home?	Information to verify whether the potential participant has a child who attends day care. Participants who answer positively to this question will be retained in the pool of eligible participants in the event that recruitment is low.	Used to determine eligibility.
4, 4A, 4B	Do you plan on sending your child under the age of 14 months to a day care or a baby sitter’s home in the near future? At what age (how many months old) do you plan on sending your child to a day care or a baby sitter’s home? About how many days per week and hours per day do you plan on sending your (child/children) to a day care center or a baby sitter’s home?	Information to determine whether the child will be away from home for extensive periods of time.	Used to determine eligibility.

Qx #	Question	Rationale	Analytic Use
5	Are pesticides or chemicals to kill bugs used inside your home?	Potential participants need to be regular pesticide users to participate in this study.	Used to determine eligibility; analysis will be on the spot as the responses “no”, “don’t know” or “refused to answer” are exclusion criteria.
6, 6A, 6B	How long have you lived in your current home? Do you plan on living in your current home for at least the next two years? Will you be moving to a different home within Duval County?	Potential participants need to be residents of Duval County for the entire study period.	Used to determine eligibility.
7	Children’s exposures may change as they grow older and engage in different activities. We would like to study children’s exposures to pesticides and chemicals in their homes for two years. If you were selected to participate in this study, would you be willing to participate in this study for up to two years?	This study is a longitudinal study and participants will have to interact with the field technicians for two full years.	Used to determine eligibility.
8	In this study, we want to evaluate your child’s potential exposure to pesticides that you use to kill bugs in your home. The timing of our data collection activities will depend on the time of your pesticide application. This is very important to the success of the study. If you were selected to participate in this study, would you be willing to contact us and let us know when you plan to apply pesticides inside your home?	This study is a longitudinal study and participants will have to interact with the field technicians for two full years. The potential participants have to be willing to inform the field staff of planned pesticide activities prior to them occurring.	Used to determine eligibility.

Qx #	Question	Rationale	Analytic Use
9	For us to understand how your child is potentially exposed to pesticides, we will ask you to collect some samples of the food your child eats, to collect some urine samples, and to videotape some of your child's activities during each data collection event. Our research staff will show you how to do this and provide you with the needed supplies and the camcorder. If you were selected to participate in this study, would you be willing to help us conduct these activities?	This study is a longitudinal study and participants will have to interact with the field technicians for two full years. The participants would have to be willing to help the field staff by collecting samples.	Used to determine eligibility.
10	Who usually applies pesticides or chemicals to kill bugs inside your home?	Pesticide usage is critical to evaluating exposure factors. The pesticide-related questions allow us to rank the potential participants as low, medium, or high pesticide users.	Used to determine eligibility.
11	What kind of bugs do you usually try to kill inside your home?	Pesticide usage is critical to evaluating exposure factors. The pesticide-related questions allow us to rank the potential participants as low, medium, or high pesticide users.	Used to determine eligibility.
12	Are pesticides or chemicals that kill bugs normally applied in your home by you or someone else using an aerosol can, sprayer or fogger?	Pesticide usage is critical to evaluating exposure factors. The pesticide-related questions allow us to rank the potential participants as low, medium, or high pesticide users.	Used to determine eligibility.
13	Do you use any other types of chemicals inside your home to kill bugs, such as...?	Pesticide usage is critical to evaluating exposure factors. The pesticide-related questions allow us to rank the potential participants as low, medium, or high pesticide users.	Used to determine eligibility.

Qx #	Question	Rationale	Analytic Use
14, 14A	During the hot months, from May through October, did you use any pesticides or chemicals to kill bugs inside your home? How often did you use pesticides or chemicals to kill bugs during the hot months?	Pesticide usage is critical to evaluating exposure factors. The pesticide-related questions allow us to rank the potential participants as low, medium, or high pesticide users.	Used to determine eligibility.
15, 15A	During the cold months, from November through April, did you use any pesticides or chemicals to kill bugs inside your home? How often did you use pesticides or chemicals to kill bugs during the cold months?	Pesticide usage is critical to evaluating exposure factors. The pesticide-related questions allow us to rank the potential participants as low, medium, or high pesticide users.	Used to determine eligibility.
16	Did anyone use pesticides or chemicals to kill bugs inside you home in the past...?	Pesticide usage is critical to evaluating exposure factors. The pesticide-related questions allow us to rank the potential participants as low, medium, or high pesticide users.	Used to determine eligibility.
17, 17A	In the past 30 days, how many times did someone use pesticides or chemicals to kill bugs inside your home? Where was it applied inside your home?	Pesticide usage is critical to evaluating exposure factors. The pesticide-related questions allow us to rank the potential participants as low, medium, or high pesticide users.	Used to determine eligibility.
18, 18A	What is the name of the child who is eligible to participate in the study? Confirm child's gender.	Used to identify the age eligible child for participation in the study.	Identification information.
19, 19A	What is your name? What is your relationship to the child?	Contact information for potential participants.	Contact information for study participants.
20	What is your spouse's (or partner's) name?	Contact information for potential participants.	Contact information for study participants.
21	What is your home address?	Contact information for potential participants.	Contact information for study participants.

Qx #	Question	Rationale	Analytic Use
22, 22A, 22B, 22C, 22D, 22E	<p>Can you suggest the best way to contact you? Do you have a phone number that we can reach you? What is the phone number? Do you have other phone numbers or pagers that we can reach you? What are the phone numbers? What will be the best times to call you? Do you have an email address that we can reach you? What is your email address?</p>	<p>Contact information for potential participants.</p>	<p>Contact information for study participants.</p>

Home Pesticide Inventory and Use Screening Questionnaire (Version Final Draft 11/24/2003)

Qx #	Question	Rationale	Analytic Use
1	Respondent's name	Confirm that the most appropriate person is answering the questions on pesticide use.	Allows for interpretation of the quality of the data collected.
2	Relationship to the child	Confirm that the most appropriate person is answering the questions on pesticide use.	Allows for interpretation of the quality of the data collected.
3	I will be asking you some questions about the specific products of pesticides or chemicals that have been used to kill bugs, rodents (rats), weeds or grass, inside or outside your home during the past year. These could have been used by you, a family member, a professional pest control worker, and/or the building (or apartment) maintenance staff. You may no longer use some of these products now, but we would still like to know what you have used during the past year. If the application was done by a professional pest control worker or the building (or apartment) maintenance staff, and you don't know what was used to treat your home, we will ask you to contact them to find out the product used to treat your home. Let's start with the pesticides and chemicals that you currently use in your home.	Field technician needs the pesticide products to complete the inventory.	Aids in the ranking of the type of pesticide user.
3A	Assign the product code for each product.	Label.	Differentiate between products.
3B	What is the name of the product?	Record information on product used.	Provides information on active ingredients, application information, and frequency of use. This information is used to rank the participant as a low, medium, or high pesticide user.

Qx #	Question	Rationale	Analytic Use
3C	What is the EPA registration number?	Record information on product used.	Provides information on active ingredients, application information, and frequency of use. This information is used to rank the participant as a low, medium, or high pesticide user.
3D	Who usually applied this product?	Record information on product used.	Provides information on active ingredients, application information, and frequency of use. This information is used to rank the participant as a low, medium, or high pesticide user.
3E	How was this product applied (What was the method of application?)	Record information on product used.	Provides information on active ingredients, application information, and frequency of use. This information is used to rank the participant as a low, medium, or high pesticide user.
3F	What kind of bugs did you usually try to kill with this product? Did the participant use it to kill weeds?	Record information on product used.	Provides information on active ingredients, application information, and frequency of use. This information is used to rank the participant as a low, medium, or high pesticide user.
3G1, 3G1A, 3G2, 3G2A	Was this product used during the hot months from May through October? How often was it used between May and October? Was this product used during the cold months from November through April? How often was it used between November and April?	Record information on product used.	Provides information on active ingredients, application information, and frequency of use. This information is used to rank the participant as a low, medium, or high pesticide user.

Qx #	Question	Rationale	Analytic Use
3H	When was this product last applied?	Record information on product used.	Provides information on active ingredients, application information, and frequency of use. This information is used to rank the participant as a low, medium, or high pesticide user.
3I	Where was it applied inside and outside your home?	Record information on product used.	Provides information on active ingredients, application information, and frequency of use. This information is used to rank the participant as a low, medium, or high pesticide user.
3J	Interviewer: If the product was applied by a commercial company or a building maintenance staff, ask the participant to contact the company to find out the product information. Also obtain the company information here.	Prompting for information on products used but not in stock, and commercial applications.	Provides a complete picture of the pesticide usage.

Participant and Housing Characteristics Questionnaire (Version Final Draft 11/24/2003)

Qx #	Question	Rationale	Analytic Use
1	Is this the same house as the previous sampled house?	Indicates whether the participant was living in the same home as the last sampling period.	Determines whether this questionnaire needs to be completed.
2	Since the last monitoring visit, have there been any changes to the following house or household information?	Prompts for specific changes in the house characteristics or participant demographics.	Prompts for updates to the questionnaire.
A1	Which of the following best describes your home? It's...	Classification of housing type.	Demographic characterization.
A2	About what year was this house/building first built?	Classification of housing type.	Demographic characterization.
A3	Is there an enclosed garage attached to this house/apartment?	Information needed to determine the potential movement of contaminants from outside to inside the house.	Used to track contaminant movement.
A4	Is air conditioning used to cool your home during hot weather?	Information needed to estimate air exchange rates and amount of mixing in the house.	Estimation of air exchange rates.
A5	Which kinds of air conditioning units do you use?	Information used to estimate mixing.	Helps to interpret the concentrations of chemicals measured in air.
A6	Do you use any heating device to provide heat in your home during cold weather?	Data used to estimate air exchange rates and amount of mixing.	Interpret concentrations in air in the residence.
A7	Which kinds of heating devices or systems do you use?	Data used to estimate amount of mixing in the residence.	Interpret concentrations in air in the residence.
A8	What is the source of tap water in your home?	Response helps to identify each unique water source that needs to be collected. Responses will be used to limit the number of water samples collected in the study.	Field technician uses this response to determine if a water sample needs to be collected.

Qx #	Question	Rationale	Analytic Use
A9-1	Let's start with the room where (participating child's name) spend most time doing activities during the day (child's primary play room).	Identification of primary play room by caregiver.	Information identification. Identification of child's primary play room for sample collection.
A9A	Is this also the room where (participating child's name) sleeps?	Information on sleeping locations of the young participant.	Identification of the child's sleeping location for sample collection.
A10, A10A	What type of floor does this room have? Interviewer: Check the room and estimate the % of each floor type.	Collection of flooring type.	Used in the dermal and indirect ingestion exposure algorithms.
A10B	How old is the carpet (area rug) in the room?	Age of carpet.	Estimates the amount of dust that could be collected for chemical loadings in the residence.
A11	Is there any ceiling fan in the room?	Response provides information on air exchange rates and mixing.	Used to estimate mixing for air concentrations.
A12	Is there a window air conditioning unit or portable AC in this room?	Room inventory.	Estimate of air exchange rate and mixing to explain the air concentrations.
A13, A13A	Are there any major electronic devices such as television, stereo, or computer in this room? How many major electronic devices in this room?	Inventory of the number of electronic devices.	Responses used to generate a brominated flame retardant loading.
A14, A14A	Are there any windows with draperies or curtains in the room? How many windows with draperies or curtains in the room?	Inventory of the number of draperies/textiles in the residence.	Responses used to generate a brominated flame retardant loading.
A15, A15A	Is there any upholstered furniture (that is, furniture made with fabric, padding) in the room? Please tell me the type and number of upholstered pieces of furniture in the room.	Inventory for the amount of textiles in the residence.	Responses used to generate a brominated flame retardant loading.

Qx #	Question	Rationale	Analytic Use
A9-2	Now what about this room?	Complete room inventory.	Aids field technician in completing room inventory.
A9-3	Now what about this room?	Complete room inventory.	Aids field technician in completing room inventory.
A16	What kind(s) of pets do you have? How many do you have?	Response aids in cataloging the number and type of pets.	Used to determine the potential for collecting pet wipe samples.
A17	Do you keep your pet(s) inside or outside the house?	Response aids in estimating track-in.	Used in assessing the potential movement of contaminants from outdoors to indoors by the pet. Aids in interpretation of the sample wipe.
A18	How often does (participating child's name) play with or touch the pets?	Response aids in evaluating the amount of interaction between the child participant and the pets.	Used in the indirect ingestion algorithm.
B1	How many people live in this household?	Response used for household demographics.	Household demographics.
B2, B2A	Would you please tell me the first name of the head of the household? This will help me finish the interview quickly and correctly. Interviewer: Is the head of the household the respondent?	Data will be collected on the two primary caregivers to the child.	Household demographics.
B3	What is ((name in B2)'s/your) relationship to (participating child's name)?	Contact information.	Household demographics.
B4	Is (name in B2) a male or female?	Response used to classify the participant.	Household demographics.
B5	What is (the date of birth of (name in B2)/your date of birth)?	Response used to classify the participant.	Household demographics.
B6	What is the highest grade or level of schooling that (name in B2/you) (has/have) completed?	Response used to classify the participant.	Household demographics.

Qx #	Question	Rationale	Analytic Use
B7, B7A	(Is(name in B2)/Are you) currently working outside the home? (Is(name in B2)/Are you) currently self-employed or working at home?	Response used to evaluate the potential for chemical exposures inside the home.	Used to evaluate the potential for contaminants to be found in the home.
B8	What kind of business or industry (does (name in B2)/do you) work at?	Response used to determine potential exposures to chemicals in the workplace.	Used to predict confounding levels of chemicals.
B9	What kind of work (does (name in B2)/do you) do?	Response used to determine potential exposures to chemicals in the workplace.	Used to predict confounding levels of chemicals.
B10	(Does (name in B2)/Do you) work with pesticides on this job?	Response used to determine potential exposures to pesticides in the workplace.	Used to predict confounding levels of pesticides.
B11A	(Does (name in B2)/Do you) work in a manufacturing job or industry where the following types of chemicals are used? Phthalates?	Response used to determine potential exposures to phthalates, brominated flame retardants, and perfluorinated compounds in the workplace.	Used to predict confounding levels of chemicals.
B11B	Brominated flame retardants?	Response used to determine potential exposures to phthalates, brominated flame retardants, and perfluorinated compounds in the workplace.	Used to predict confounding levels of chemicals.
B11C	Perfluorinated compounds?	Response used to determine potential exposures to phthalates, brominated flame retardants, and perfluorinated compounds in the workplace.	Used to predict confounding levels of chemicals.
B12	Is your child a...?	Data used to classify the child participant.	Participant demographics.
B13	What is your child's race? Is he/she...?	Data used to classify the child participant.	Participant demographics.
B14, B14A, B14B	What was your total household income last year? Was it... How many people, including you, were supported by that income? Does anyone in your household currently receive public assistance, such as food stamps, AFDC, WIC, or any other government support?	Responses used to classify the participants.	Household demographics.

Qx #	Question	Rationale	Analytic Use
C1	Condition of exterior structure	Classification of exterior of the house to estimate chemical usage.	Household characteristics.
C7	Is there standing water around the house/building?	Response used to predict the likelihood of exterior pesticide applications.	Used to predict pesticide usage.
C8	Surrounding area	Area characterization.	Area characterization.
C9	Sketch locations and surroundings of the house/building.	Sketch used to record items of interest, sampling locations, etc.	Sketch for field notes.
	Sketch interior of the house/building.	Sketch used to record items of interest, sampling locations, etc.	Sketch for field notes.

Monitoring Period Questionnaire (Version Final Draft 11/24/2003)

Qx #	Question	Rationale	Analytic Use
A1	Interviewer: Enter the dates and times of the 48-hour monitoring period.	Information entered by field technician for interview preparation.	Prepares field technician for interview with participant.
A2, A3	Interviewer: Measure the height and weight of child. CAPI calculates child's age.	Record height and weight of child.	Data needed in the aggregate exposure calculations.
A4	Interviewer: Record (with verification from caregiver, as required) child's movements are primarily...	Record mobility of child.	Data used to determine sampling locations.
A5	Interviewer: Is this the same house?	Response from participant triggers the field technician to update the other questionnaires.	Field technician will analyze the response and address the relevant questions.
A6	Interviewer: Record the date/time of pesticide application. Review monthly pesticide use log. Record application and EPA registration number.	Field technician records the information to document the specific pesticide application and confirm that an application did occur.	Confirm pesticide application.
A7	Since our last visit, have any of the following renovations or repairs been performed in your home?	Response provides information on household activities that may lead to introduction of chemicals inside the residence that could affect sampling.	Provides evidence of household alterations that may impact chemical loadings in the residence.
A8, A8A	Have there been any other changes to your home, household members or activities since our last visit? What sort of changes?	Responses may include anything that the field technician has not specifically asked about.	Open-ended question to collect information that may have not been recorded elsewhere.
B1	During the last 48-hours, were any doors or windows opened to allow for natural air ventilation?	Response used to estimate mixing in the home.	Estimate air exchange rate.
B2	During the last 48-hours, were any fans or heating/air conditioning units used?	Response used to estimate mixing in the home.	Estimate air exchange rate.

Qx #	Question	Rationale	Analytic Use
B3, B3A	During the last 48-hours, did anyone dust, sweep, wet mop, vacuum, or steam-clean your home (any rooms)? Please tell me which rooms were cleaned and how it was cleaned.	Responses used to record cleaning habits during the monitoring period.	Responses used to interpret any anomalies in the data.
B4	Have you used the following toiletries or medical products on (child's name) during the last 48 hours?	Response used to assess potential exposures to products that may contain phthalates.	Analyze data and validate relationship between questionnaire response and biomarker data.
B5	Does (participating child's name) frequently play in the yard that would involve contact with soil?	Response used to assess potential exposures to outdoor chemicals.	Response used in the dermal and indirect ingestion exposure algorithms.
B6	Have the following chemical products been used in your home during the last 48 hours (whether by you or others)?	Response used to assess potential exposures to products that may contain phthalates.	Analyze data and validate relationship between questionnaire response and biomarker data.
B7	Were any of the following cleaning products used in your home during the last 48 hours (whether by you or others)?	Response used to assess potential exposures to products that may contain phthalates.	Analyze data and validate relationship between questionnaire response and biomarker data.
B8	Have you used the following toiletries and cosmetics during the last 48 hours?	Response used to assess potential exposures to products that may contain phthalates.	Analyze data and validate relationship between questionnaire response and biomarker data.
B9	Are you (still) breastfeeding (child's name)?	Response used to assess potential exposures to products that may contain phthalates.	Analyze data and validate relationship between questionnaire response and biomarker data.
B9A	Did you visit a beauty salon during the last 48 hours?	Response used to assess potential exposures to products that may contain phthalates.	Analyze data and validate relationship between questionnaire response and biomarker data.
B9B	Was your hair permed, straightened, or relaxed during the last 48 hours?	Response used to assess potential exposures to products that may contain phthalates.	Analyze data and validate relationship between questionnaire response and biomarker data.

Qx #	Question	Rationale	Analytic Use
B9C	Did you apply hair perm, straightener, or relaxer to your own hair or someone else's hair during the last 48 hours?	Response used to assess potential exposures to products that may contain phthalates.	Analyze data and validate relationship between questionnaire response and biomarker data.
B9D, B9D1	Was your hair colored or highlighted during the last 48 hours? Please tell me what type of coloring was used. Was it...?	Response used to assess potential exposures to products that may contain phthalates.	Analyze data and validate relationship between questionnaire response and biomarker data.
B9E, B9E1	Did you apply a hair-coloring product to your own hair or someone else's hair during the last 48 hours? Please tell me what type of coloring was used. Was it...?	Response used to assess potential exposures to products that may contain phthalates.	Analyze data and validate relationship between questionnaire response and biomarker data.
B9F	Was nail polish removed or applied to your finger or toe nails during the last 48 hours?	Response used to assess potential exposures to products that may contain phthalates.	Analyze data and validate relationship between questionnaire response and biomarker data.
B9G	Did you apply or remove nail polish from your own or someone else's nails during the last 48 hours?	Response used to assess potential exposures to products that may contain phthalates.	Analyze data and validate relationship between questionnaire response and biomarker data.
B9H	Did you have someone apply, fill, or remove artificial nails for you during the last 48 hours?	Response used to assess potential exposures to products that may contain phthalates.	Analyze data and validate relationship between questionnaire response and biomarker data.
B9I	Did you apply, fill, or remove artificial nails for someone during the last 48 hours?	Response used to assess potential exposures to products that may contain phthalates.	Analyze data and validate relationship between questionnaire response and biomarker data.
B10, B10A, B10B, B10C	The next few questions are about your pets. If you have a dog or a cat, did (child's name) play with, and have contact with it during the last 48 hours? We would like to see if there are any pesticides on your pet's fur by wiping a dry cloth across your pet. May we collect the sample? What is your pet's name? Interviewer: Record whether the pet is a cat or a dog.	Response used to record information on interactions with pets. Also aids in proper sample collection.	Response aids in collecting the sample from the pet that the child interacts with in the event there is more than one pet in the household.

Qx #	Question	Rationale	Analytic Use
C1	On the day of the pesticide application, did you use a central forced air system for air conditioning or heating?	Response used to evaluate the amount of air mixing in the house.	Estimates mixing and air exchange rates.
D1	Interviewer: Verify with the participant about the item provided to the child.	Response used to verify standard object provided to the child during the study.	Data collected for inputs to the indirect ingestion exposure algorithm.
D2, D2A, D2B	Did your child use the item during the last 24 hours? Approximately, how many hours during the last 24-hour period? How long has it been since your child sucked on the (item in D1)?	Responses used to generate exposure factors for the indirect ingestion algorithm.	Data collected for inputs to the indirect ingestion exposure algorithm.
D3	Is (child's name) currently teething?	Response used to assess the likelihood of mouthing because of the developmental stage.	Data collected for inputs to the indirect ingestion exposure algorithm.
D4, D4A	Does (child's name) use a pacifier? How often does (child's name) use a pacifier?	Response used to assess the likelihood of mouthing because of the developmental stage.	Data collected for inputs to the indirect ingestion exposure algorithm.
D5, D5A	How often does (child's name) put his/her hands into his/her mouth when indoors? How much of his/her hand does he/she generally put into his/her mouth when indoors?	Responses used to assess mouthing of hands and objects of the child participant.	Data collected for inputs to the indirect ingestion exposure algorithm.
D6, D6A	How often does (child's name) put his/her hands into his/her mouth when outdoors? How much of his/her hand does he/she generally put into his/her mouth when outdoors?	Responses used to assess mouthing of hands and objects of the child participant.	Data collected for inputs to the indirect ingestion exposure algorithm.
D7	How often does (child's name) put objects into his/her mouth when indoors?	Responses used to assess mouthing of hands and objects of the child participant.	Data collected for inputs to the indirect ingestion exposure algorithm.
D8	How often does (child's name) put objects into his/her mouth when outdoors?	Responses used to assess mouthing of hands and objects of the child participant.	Data collected for inputs to the indirect ingestion exposure algorithm.
D9	Please tell me the 3 most favorite toys, objects, or surfaces that (child's name) likes to put his/her mouth on while indoors.	Field technician uses this data to collect the appropriate field samples while in the residence.	Data used to aid the field technician in applicable sample collection for the indirect ingestion exposure algorithm.

Qx #	Question	Rationale	Analytic Use
D10, D10A	Does (child's name) watch TV? Where does your child normally spend time when watching TV?	Responses used to assess the likelihood of dermal exposure.	Data collected for inputs to the dermal exposure algorithm.
D11	Where does your child normally spend time when playing with favorite toys?	Responses used to assess the likelihood of dermal exposure.	Data collected for inputs to the dermal exposure algorithm.
D12	Where does your child normally spend time when being read to?	Responses used to assess the likelihood of dermal exposure.	Data collected for inputs to the dermal exposure algorithm.
D13	If your child likes to be on the floor, how would you describe his/her typical contact with the floor?	Responses used to assess the likelihood of dermal exposure.	Data collected for inputs to the dermal exposure algorithm.
D14	If your child likes to be on the furniture, how would you describe his/her typical contact with the furniture?	Responses used to assess the likelihood of dermal exposure.	Data collected for inputs to the dermal exposure algorithm.
D15	Except when (child's name) is sleeping, typically when he/she is laying on his/her back, stomach, or side, would you describe (child's name) as...	Responses used to assess the likelihood of dermal exposure.	Data collected for inputs to the dermal exposure algorithm.
E1	Is this duplicate diet representative of what (child's name) normally eats in a 24-hour period?	Response confirms data collected in food diary.	Data to confirm food diary and foods typically eaten.
E1A, E1A1, E1A2	Was breakfast different? Why was breakfast not usual? Did (child's name) eat more than the sample collected, did he/she eat less, or did he/she simply eat different food? Why did this happen?	If the response to E1 was "no" or "don't know", then the field technician asks about each individual meal to determine which meal is different and why.	Data collected for inputs to the dietary exposure algorithm.
E1B, E1B1, E1B2	Was lunch different? Why was lunch not usual? Did (child's name) eat more than the sample collected, did he/she eat less, or did he/she simply eat different food? Why did this happen?	If the response to E1 was "no" or "don't know", then the field technician asks about each individual meal to determine which meal is different and why.	Data collected for inputs to the dietary exposure algorithm.

Qx #	Question	Rationale	Analytic Use
E1C, E1C1, E1C2	Was dinner different? Why was dinner not usual? Did (child's name) eat more than the sample collected, did he/she eat less, or did he/she simply eat different food? Why did this happen?	If the response to E1 was "no" or "don't know", then the field technician asks about each individual meal to determine which meal is different and why.	Data collected for inputs to the dietary exposure algorithm.
E1D, E1D1, E1D2	Were snacks different? Why were snacks not usual? Did (child's name) eat more than the sample collected, did he/she eat less, or did he/she simply eat different food? Why did this happen?	If the response to E1 was "no" or "don't know", then the field technician asks about each individual meal to determine which meal is different and why.	Data collected for inputs to the dietary exposure algorithm.
F1	In the next question, I will read a list of activities related to eating habits. Please tell me whether (child's name) did it during the last 24-hours...	Responses used to evaluate the potential added chemical contaminations in the diet from the habits of the child while eating.	Data collected for inputs to the dietary and indirect ingestion exposure algorithms.
F2	For (child's name)'s age, do you think his/her eating habits are...?	Response used to determine eating behavior based on observations.	Describes eating behavior.
F3	Interviewer: Was the child provided a standard food object?	Response used to record whether the standard food item was provided and then used by the child. Assess and generate exposure factors on indirect ingestion based on a standard food item.	Data collected for inputs to the dietary and indirect ingestion exposure algorithms based on a standard food item provided to the children.
F3A	The following questions are about the cheese cube we provided to (child's name). I will read a list of eating activities. Please tell me whether (child's name) did it all the time, frequently, occasionally, rarely, or never when he/she was eating the cheese cube.	Response used to record whether the standard food item was provided and then used by the child. Assess and generate exposure factors on indirect ingestion based on a standard food item.	Data collected for inputs to the dietary and indirect ingestion exposure algorithms based on a standard food item provided to the children.
F3B	For (child's name)'s age, do you think the way he/she ate the cheese cube was...?	Response used to record observations on eating a standard food.	Describes eating behavior.

Qx #	Question	Rationale	Analytic Use
G1, G1A	In the past three months, how many times has (child's name) visited a health care provider such as a doctor or nurse practitioner for health conditions? What was the reason or reasons that (child's name) went to the health care provider for the (first) visit?	Response used to record types of illnesses experienced by the child.	Analyzed to evaluate the general health and well-being of the study participants.

Activity Time Line (Version Final Draft 11/24/2003)

Diary used by caregiver to record microenvironment and macroactivity information needed in the models to estimate aggregate exposure. Also needed in the evaluation of the interrelationship between environmental measurements, activity, and biological markers in estimating aggregate exposure.

Food Diary (Version Final Draft 11/24/2003)

Data needed in the models to estimate dietary ingestion exposure algorithms.

Monthly Pesticide Purchase, Inventory, and Use Log (Version Final Draft 11/24/2003)

The data collected in this log is used in the models to estimate aggregate exposure. This data is also needed to define the interrelationship between a pesticide application and the environmental measurements.

Monthly Cleaning Products Purchase, Inventory, and Use Log (Version Final Draft 11/24/2003)

Diaries used to collect information on cleaning products that may contain pesticides that may be used in the home. This information is important to the Office of Pollution, Prevention, and Toxics (OPPT). OPPT will use this data to monitor the various types of antimicrobial cleaning products on which they should focus their risk assessments.

Vineland Adaptive Behavioral Scale

The Vineland Adaptive Behavioral Scale is a semi-structured interview administered to a parent or other primary caregiver. It is published in four versions: interview edition, survey form, expanded form, and classroom edition. This study will employ the survey form which contains 297 items spanning adaptive behavior components from birth to age 18. Only a small fraction of the available items will be used in the present study; the exact number will be determined by the individual child's age and developmental status. Each interview will take approximately 20 minutes to complete. Raw scores and chronological age information will be converted to derived scores. The derived scores provide norm-referenced information based on the performance of representative national standardization samples of 4,800 handicapped and non-handicapped subjects. Interview and scoring materials are available in both Spanish and English.