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Sulfuryl Fluoride
Summary Document
Registration Review: Initial Docket
June 2009

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Case # 0176

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Date

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Please Note

This Preliminary Work Plan and Fact Sheet summarize the Environmental Protection Agency's current position based on the following documents:

1. *Sulfuryl Fluoride: Human Health Assessment Scoping Document in Support of Registration Review.* May 28, 2009.
2. *Sulfuryl Fluoride – Addendum to the Human Health Assessment Scoping Document in Support of Registration Review.* June 17, 2009.
3. *Registration Review: Preliminary Problem Formulation for Ecological Risk, Environmental Fate, Endangered Species, and Drinking Water Assessments for Sulfuryl Fluoride.* June 15, 2009.
4. *Usage/Label Use Report for Sulfuryl Fluoride.* November 11, 2008.

Additional supporting documents for sulfuryl fluoride may be found in docket EPA-HQ-OPP-2009-0136, located on the internet at www.regulations.gov.

I. PRELIMINARY WORK PLAN

Introduction

The Food Quality Protection Act (FQPA) of 1996 mandated a registration review program. All pesticides distributed or sold in the United States generally must be registered by the U.S. Environmental Protection Agency (EPA or the Agency), based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at www.epa.gov/oppsrrd1/registration_review/.

The Agency is implementing the registration review program, and will review each registered pesticide every 15 years to determine whether it continues to meet the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) standard for registration. Where assessments indicate risks above the Agency's level of concern, the Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop and commit to a final work plan and schedule for the registration review of sulfuryl fluoride.

Sulfuryl fluoride was first registered in 1959 as a structural fumigant, and has been used as a post-harvest fumigant for commodities since tolerances were established on a number of commodities in 2004 and 2005. Sulfuryl fluoride has been deemed a methyl bromide alternative by the Agency and is an insecticide used to fumigate closed structures and their contents such as domestic dwellings, garages, barns, storage buildings, commercial warehouses, ships in port, and railroad cars. It controls numerous insect pests including termites, powder post beetles, old house borers, bedbugs, carpet beetles, clothes moths and cockroaches as well as rats and mice. There are four section 3 registrations, all of which are end-use products. It has a restricted-use classification due to acute inhalation and eye irritation.

Anticipated Risk Assessment and Data Needs:

The Agency anticipates conducting an ecological risk assessment of sulfuryl fluoride, including an endangered species assessment. The Agency also anticipates conducting human health risk assessments for sulfuryl fluoride.

Ecological Risk:

- The most recent ecological risk assessment was completed in support of the 1993 RED and concluded that none of the Agency's levels of concern were exceeded due to sulfuryl fluoride's indoor use pattern. However, based on new information and technological advances, the Agency believes there is potential for ecological exposure to sulfuryl fluoride despite the fact it is applied indoors. Therefore, a new ecological risk assessment is anticipated.
- The Agency anticipates requiring the following environmental fate study:
 - Measurement of Henry's Law Constant (special study)
 - The measured Henry's Law Constant may be required to confirm the deposition resistance properties of airborne sulfuryl fluoride residues in order to assess potential exposure to terrestrial and aquatic environments.
- The Agency anticipates requiring the following ecological studies:
 - Avian Inhalation (special study)
 - Sulfuryl fluoride is highly volatile and gaseous at room temperature and standard pressure. Since inhalation of vapor following structural fumigation is the major potential exposure pathway for non-target birds, avian inhalation data may be required.
 - Terrestrial Plant (special study)
 - Sulfuryl fluoride has a general mechanism of action that indicates the chemical may be toxic to plant species. Since potential exposure exists during the aeration phase following structural fumigation, terrestrial plant data may be required.
- The Agency has not conducted a risk assessment that supports a complete endangered species determination. The ecological risk assessment planned during registration review will allow the Agency to determine whether sulfuryl fluoride's use has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitat. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Services (the Services), as appropriate.
- Please refer to *Registration Review: Preliminary Problem Formulation for Ecological Risk, Environmental Fate, Endangered Species, and Drinking Water Assessments for Sulfuryl Fluoride*, dated May 28, 2009, located in the sulfuryl fluoride docket, for a detailed discussion of the anticipated ecological risk assessment needs.

Human Health Risk:

- The most recent comprehensive human health risk assessment was conducted for the 1993 RED.
- An aggregate risk assessment for sulfuryl fluoride was completed as part of the Agency's review of a petition to establish tolerances on post-harvest commodities and in food processing facilities. An updated version of the risk assessment was completed in January 2006 after the tolerances were established to correct errors in the previous

assessment. The discrepancies between the assumptions made in the risk assessment and the uses being allowed on product labels were resolved in the revised assessment. This did not change the regulatory recommendations and conclusions presented in the previous assessment.

- The absence of an inhalation toxicity study with comprehensive evaluations of the respiratory tract may result in increased uncertainty around the hazard endpoints. A 3X uncertainty factor to address the use of a subchronic study to establish a chronic endpoint is currently in place for sulfuryl fluoride. This uncertainty factor may need to be reconsidered during registration review.
- The Agency anticipates evaluating the potential for bystander exposure and exposure from additional occupational scenarios, and incorporating this information into the human health risk assessment during registration review.
- The Agency anticipates requiring the following toxicology and occupational/residential exposure studies:
 - Developmental Neurotoxicity (870.6300)
 - This study had been waived and a 10X uncertainty factor had been applied. Recent advances in study technique have made inhalation DNTs appropriate for endpoint consideration; therefore, an inhalation DNT may be required.
 - Immunotoxicity (rats) (870.7800)
 - This study may be required as per the recently revised pesticide registration data requirements (40 CFR Part 158).
 - Inhalation Exposure for Applicators (875.1400)
 - These data may be required to assess exposures for applicators involved in fumigating commodities/materials and/or structural facilities.
 - Product Use Information (875.1700)
 - This information may be required to assess possible occupational and residential exposures. Product use information may include major use region, frequency, and application equipment.
 - Post-Application Inhalation Exposure (875.2500)
 - These studies may be required to assess post-application exposures for:
 - workers near fumigation facilities and those who work directly with previously treated commodities;
 - indoor air for residences in proximity to fumigation activities; and
 - communities-based ambient air concentrations
 - Monitoring Data on Fumigated Commodities (special study)
 - These data may be required to evaluate emission rates for sulfuryl fluoride from treated commodities/materials and the potential for occupational exposure due to those emissions in the channels of trade after fumigation activities are complete.
- The Agency will also reexamine aggregate fluoride exposure and risk as part of registration review for sulfuryl fluoride. However, fluoride will be evaluated in a separate risk assessment because sulfuryl fluoride and fluoride have different regulatory endpoints. EPA's Office of Water, working in conjunction with OPP, is taking the lead in developing a revised risk assessment for fluoride. The Agency does not anticipate the exposure from sulfuryl fluoride will significantly contribute to the dietary or aggregate risk assessments for fluoride.

- Please refer to *Sulfuryl Fluoride: Human Health Assessment Scoping Document in Support of Registration Review*, dated May 28, 2009, located in the sulfuryl fluoride docket, for a detailed discussion of the anticipated human health risk assessment needs.

Additional Considerations:

- Two studies published in early 2009, one from the University of California – Irvine and one from the Massachusetts Institution of Technology in collaboration with the Scripps Institution of Oceanography and other institutions, discuss new information on the persistence of sulfuryl fluoride as a greenhouse gas. OPP is coordinating with the Office of Air and Radiation (OAR) and other program offices on this issue during the registration review process.

Timeline:

EPA has created the following estimated timeline for the completion of the sulfuryl fluoride registration review.

Registration Review for Sulfuryl Fluoride Projected Registration Review Timeline	
Milestone	Date
Opening the Docket	
Open Docket & Public Comment for Preliminary Work Plan	June 2009
Close Public Comment	Aug. 2009
Case Development	
Final Work Plan	Oct. 2009
Issue DCI	July – Sept. 2010
Data Submission	July – Sept. 2012
Open Public Comment for Preliminary Risk Assessment	Jan. – March 2014
Close Public Comment Period	Apr. – June 2014
Registration Review Decision	
Open Public Comment for Proposed Registration Review Decision	July – Sept 2014
Close Public Comment	Oct. – Dec. 2014
Final Reg Review Decision and begin post-decision follow-up	2015
Total	6 years

Guidance for Commenters:

The public is invited to comment on EPA’s preliminary registration review work plan and rationale. The Agency will carefully consider all comments as well as any additional information or data provided in a timely manner prior to issuing a final work plan for the sulfuryl fluoride case.

- Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues

resulting from lack of Maximum Residue Levels (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern. U.S. permanent tolerances are established for the post-harvest use of sulfuranyl fluoride on a number of raw and dried agricultural plant and animal commodities [40 CFR § 180.575]. The difference between the tolerances in the U.S., Codex and Canada is a trade irritant/concern if there are reciprocal imports and may need to be further evaluated during this registration review action.

- Sulfuryl fluoride is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act, based on information provided at http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885. In addition, no Total Maximum Daily Loads (TMDL) have been developed for sulfuranyl fluoride, based on information provided at http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES. More information on impaired water bodies and TMDLs can be found at <http://www.epa.gov/owow/tmdl/>. The Agency invites submission of water quality data for this pesticide. To the extent possible, data should conform to the quality standards in Appendix A of the *OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process* (see: <http://www.epa.gov/oppfead1/cb/ppdc/2006/november06/session1-sop.pdf>), in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.
- EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to sulfuranyl fluoride, compared to the general population. Please comment if you are aware of any sub-populations that may have atypical or unusually high exposure compared to the general population.

Stakeholders are also specifically asked to provide information and data that will assist the Agency in refining the human health and ecological risk assessments, including any species-specific effects determinations. The Agency is interested in the following information:

1. Confirmation of the following label information.
 - a. sites of application
 - b. formulations
 - c. application methods and equipment
 - d. maximum application rates in units related to mass per unit area of treatment zone
 - e. frequency of application, application intervals, and maximum number of applications per season
 - f. geographic limitations on use.

2. Use or potential use distribution (*e.g.*, geographical distribution of relevant uses).
3. Use history.
4. Median and 90th percentile reported use rates from usage data – national, state, and county.
5. Application timing (date of first application and application intervals) by use – national, state, and county.
6. Sub-county use site data.
7. Usage/use information for non-agricultural uses (*e.g.*, warehouses, railroad cars, domestic dwellings).
8. Directly acquired county-level usage data (not derived from state level data).
 - a. maximum reported use rate from usage data – county
 - b. median and 90th percentile number of applications – county
 - c. total pounds per year – county
 - d. the year the pesticide was last used in the county/sub-county area
 - e. the years in which the pesticide was applied in the county/sub-county area
9. Typical application interval (days).
10. State or local use restrictions.
11. Ecological incidents (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency.
12. Monitoring data.

Next Steps:

After the 60-day public comment period closes, the Agency will review and respond to any comments received in a timely manner and then issue a Final Work Plan for sulfuryl fluoride.

II. FACT SHEET

Background Information:

- Sulfuryl Fluoride Registration Review Case Number: 0175
- Sulfuryl Fluoride PC Code: 078003; CAS#: 2699-79-8
- Registrants: Dow Agrosiences LLC, Drexel Chemical Company, and Ensystex II, Inc.
- Sulfuryl fluoride was first registered in 1959 as a structural fumigant.
- The Reregistration Eligibility Decision document (RED) for sulfuryl fluoride was signed in February 1993. The RED assessed human exposure to and risk from the structural use of sulfuryl fluoride, and concluded that registered pesticide products containing sulfuryl fluoride did not pose unreasonable risks to humans or the environment when used according to the label.
- Tolerances associated with the food uses of sulfuryl fluoride range from 0.01 ppm to 15 ppm for sulfuryl fluoride [40 CFR 180.575], and from 3 ppm to 900 ppm for fluoride [40 CFR 180.145].
- Special Review and Reregistration Division (SRRD), Chemical Review Manager (CRM) Dana L. Friedman (friedman.dana@epa.gov)
- Registration Division (RD) Contacts: Venus Eagle (eagle.venus@epa.gov)

Use & Usage Information:

- Sulfuryl fluoride is registered as an insecticide for the fumigation of closed structures and their contents. It is also used as a post-harvest fumigant for commodities.
- Sulfuryl fluoride end use products are classified as restricted use due to acute toxicity to humans and are formulated as a liquid gas in pressurized steel containers. Chloropicrin, which produces a strong odor and eye irritation, must be used as a warning agent for structural uses of sulfuryl fluoride.
- In 2006, approximately 2.9 million pounds of sulfuryl fluoride were applied in California according to California Department of Pesticide Regulation (CDPR) data available to the public through <http://www.cdpr.ca.gov/docs/pur/purmain.htm>. Additional usage data is not currently available.
- Sulfuryl fluoride has been deemed as a methyl bromide replacement by the Agency for certain structural and post-harvest commodity uses.

Recent Actions:

- In 2004, tolerances were established for post-harvest use for a number of commodities including grains, nuts, some fresh fruit, and dried fruit. Additional post-harvest uses were added in 2005, and these include coffee beans, cocoa beans, powdered milk, dried meat, and rice flour. Objections to these tolerance actions were filed by the Fluoride Action Network (FAN) and other groups.
- In 2006, the National Academy of Sciences (NAS) completed a review of the current drinking water standards for fluoride as requested by EPA's Office of Water (OW). The NAS recommended that the existing fluoride water standards be lowered (i.e., made more stringent). Following the findings of the NAS review, Fluoride Action Network (FAN)

and other objectors requested a stay of the sulfuryl fluoride and fluoride tolerances, while their objections are resolved. The FAN request for a stay is still pending with EPA and the tolerances are still in effect. OW, with the support of OPP, is revising the risk assessment for fluoride.

- The Agency is currently reviewing an application received in April 2009 for an Experimental Use Permit (EUP) for the use of sulfuryl fluoride as a soil fumigant.

Ecological Risk Assessment Status:

Please refer to *Registration Review: Preliminary Problem Formulation for Ecological Risk, Environmental Fate, Endangered Species, and Drinking Water Assessments for Sulfuryl Fluoride*, located in the sulfuryl fluoride docket at regulations.gov (EPA-HQ-OPP-2009-0136), for a discussion of the key findings of the most recent ecological risk assessment for sulfuryl fluoride:

- Toxicological information for sulfuryl fluoride was only available for mammals in the risk assessment for the 1993 RED. Despite high toxicity to mammals, none of the Agency's levels of concern were exceeded because of the assumption of no exposure due to the indoor use pattern.

Human Health Risk Assessment Status:

Please refer to the document *Sulfuryl Fluoride: Human Health Assessment Scoping Document in Support of Registration Review*, located in the sulfuryl fluoride docket at regulations.gov (EPA-HQ-OPP-2009-0136), for a discussion of the key findings of the most recent human health risk assessment for sulfuryl fluoride:

Hazard Characterization:

- The available toxicology data for sulfuryl fluoride shows that the primary effect is vacuolation of the white matter of the brain (a neurotoxic effect).
- In acute toxicity studies, sulfuryl fluoride is Toxicity Category I via the inhalation and eye irritation exposure routes. Sulfuryl fluoride is Toxicity Category II via the oral route and Toxicity Category IV via the dermal and skin irritation route. It is not a dermal sensitizer.
- Sulfuryl fluoride is classified as "Not likely to be carcinogenic to humans".
- Applied uncertainty factors included 10X for intraspecies variation, 10X for interspecies extrapolation, 10X for database uncertainty for the lack of a DNT study, and 3X for using a subchronic study for chronic assessment. Chronic dog and rat studies were available but were not selected because the effects from the rabbit study are considered to be more severe and the study would be protective of the effects seen following chronic exposure.

Dietary (Food and Water):

- In the 2006 risk assessment for the registration of sulfuryl fluoride as a fumigant for foods and food processing facilities, both the risks from sulfuryl fluoride and fluoride were assessed. Dietary risk estimates for both sulfuryl fluoride and fluoride were below EPA's level of concern for the general population and all population subgroups.

Residential:

- The 1993 sulfuryl fluoride RED did not assess residential scenarios because historically, the Agency had assumed negligible exposure to residents provided adequate aeration of dwellings was completed prior to re-entry.

Aggregate:

- As residential exposure was assumed to be negligible, the aggregate exposure and risk estimates for sulfuryl fluoride were equivalent to the dietary exposure and aggregate risk estimates in the 2006 risk assessment, which were below EPA's level of concern.

Occupational:

- Because sulfuryl fluoride is a Restricted Use Pesticide, it may only be applied by or under the direct supervision of a trained, certified applicator. Sulfuryl fluoride is dispensed as a gas from a steel cylinder through a hose into the interior of an enclosed, sealed structure. People must be evacuated from the structure before it is treated. After treatment, the structure remains closed for a period of time after which aeration begins. People not wearing a NIOSH-approved self contained breathing apparatus (SCBA) are prohibited from entering the treated areas until air levels of sulfuryl fluoride have declined to 1 part per million (ppm) or less. At this level, the risks are below the Agency's level of concern.
- Past sulfuryl fluoride risk assessments have relied in part on a human study which may have involved intentional exposure to sulfuryl fluoride. EPA will reconsider this study in the course of registration review, and will consider as well any other research involving intentional exposure or human subjects to sulfuryl fluoride brought to its attention. If EPA decides to rely on any of these studies, EPA will ensure that all applicable regulatory requirements are met, including, but not limited to, the requirements for EPA ethics review and Human Studies Review Board review of certain research involving intentional exposure of human subjects.

Cumulative:

- Sulfuryl fluoride has not been identified as a member of a common mechanism group.

Incidents:

Ecological:

- There were no incident reports for sulfuryl fluoride in the Agency's Ecological Incident Information System (EIIS). A lack of reported incidents does not necessarily mean that such incidents have not occurred.

Human:

- The OPP Incident Database System (IDS) was searched for human incidents involving sulfuryl fluoride in the United States from 2002 to the present. IDS includes reports of incidents from various sources, including mandatory FIFRA Section 6 (a) (2) reports

from registrants, other federal and state health and environmental agencies and individual consumers. There were 71 incidents reported for sulfuryl fluoride, and there is no clear pattern of toxicity or consistency of exposure scenarios. For details, please refer to *Updated Review of Sulfuryl Fluoride Incident Reports* in the sulfuryl fluoride docket.

- A comprehensive review of human incident reports will be conducted during the registration review process.

Data Status:

- The most recent human health risk assessment for the registration decision on establishing sulfuryl fluoride and fluoride tolerances on commodities requested data pertaining to use of a total fluoride analytical method as well as information on the transfer of fluoride to livestock commodities. Those data have been submitted and will be reviewed by EPA during registration review
- A number of air monitoring studies have been provided to the Agency since the 1993 RED. These studies will be evaluated during registration review, and data will be used to refine the occupational risk assessment as appropriate.

Tolerances:

A table listing the differences between U.S. tolerances, Canadian, and CODEX MRLs for sulfuryl fluoride is included in the *Sulfuryl Fluoride: Human Health Assessment Scoping Document in Support of Registration Review*. Tolerances and MRLs are not harmonized for a number of commodities, thus the Agency will determine the feasibility of harmonization during registration review.

Labels:

A list of registration numbers is included below and the labels can be obtained from the Pesticide Product Label System (PPLS) website: <http://oaspub.epa.gov/pestlabl/ppls.home>.

Registration Numbers:

REGISTRATION #	PRODUCT NAME	COMPANY NAME	% ACTIVE INGREDIENT
19713-596	MASTER FUME	DREXEL CHEMICAL COMPANY	99.8
62719-4	VIKANE	DOW AGROSCIENCES LLC	99.8
62719-376	PROFUME	DOW AGROSCIENCES LLC	99.8
81824-1	ZYTHOR	ENSYSTEX II, INC.	99.3