ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0174; FRL–8857–9]

Sulfuryl Fluoride; Proposed Order Granting Objections to Tolerances and Denying Request for a Stay

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Order.

SUMMARY: In this document, EPA is making available its proposed resolution of objections and a stay request with regard to sulfuryl fluoride and fluoride tolerances promulgated in 2004 and 2005 under section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA). The objections and stay request were filed by the Fluoride Action Network, the Environmental Working Group, and Beyond Pesticides. Notwithstanding the fact that this document is a proposed resolution, and regulatory assessment requirements do not apply, EPA is inviting public comment on all aspects of the proposed resolution of objections, including the underlying scientific evaluations.

DATES: Comments must be received on or before April 19, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2005–0174, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2005–0174. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Meredith Laws, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–308–7038; e-mail address: *laws.meredith@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, pesticide manufacturer, or consumer. Potentially affected entities may include, but are not limited to:

- Food manufacturing (NAICS code 311), *e.g.,* grain and oilseed milling; animal food manufacturing; flour milling; bread and bakery product manufacturing; cookie, cracker, and pasta manufacturing; snack food manufacturing.
- Pesticide manufacturing (NAICS code 32532), *e.g.,* pesticide manufacturers; commercial applicators.
- Community Food Services (NAICS code 624210), *e.g.,* food banks.
- Farm Product Warehousing and Storage (NAICS code 493130), *e.g.,* grain elevators, private and public food warehousing and storage.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

C. What are the acronyms used in this order?

The following is a list of acronyms used in this order:

CAA—Clean Air Act
CAAA—Clean Air Act Amendments of 1990
CSFII—Continuing Survey of Food Intakes by Individuals
CUE—Critical Use Exemption
EPA—Environmental Protection Agency
FACA—Federal Advisory Committee Act
FAN—Fluoride Action Network
FDA—Food and Drug Administration
FIFRA—Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA—Federal Food, Drug, and Cosmetic Act
FQPA—Food Quality Protection Act of 1996
IOM—Institute of Medicine
L—liter
LOAEL—Lowest Observed Adverse Effect Level
MCL—Maximum contaminant level
MCLG—Maximum contaminant level goal
mg—milligram
MOE—Margin of Exposure
MRID—Master Record Identification
NAS—National Academy of Sciences
NOAEL—No Observed Adverse Effect Level
NPDWR—National Public Drinking Water Regulations
NRC—National Research Council
NRDC—Natural Resources Defense Council
OPP—EPA's Office of Pesticide Programs
OW—EPA's Office of Water
PAD—Population Adjusted Dose
ppm—parts per million
RED—Reregistration Eligibility Decision
RfD—Reference Dose
SDWA—Safe Drinking Water Act
SMCL—Secondary maximum contaminant level
SOP—Standard Operating Procedure
USDA—United States Department of Agriculture

II. Introduction

A. What action is the agency taking?

In this document, EPA is making available for comment a proposed order granting objections and denying a stay request with regard to tolerances established for sulfuryl fluoride and fluoride in 2004 (69 FR 3240, January 23, 2004) (FRL–7342–1) and 2005 (70 FR 40899, July 15, 2005) (FRL–7723–7) under FFDCA section 408 (21 U.S.C. 346a). (*See* 40 CFR 180.145(c); 180.575). These objections were first filed by the Fluoride Action Network (FAN) and Beyond Pesticides/National Coalition Against the Misuse of Pesticides. (Ref. 1). FAN and Beyond Pesticides also requested a hearing on their objections. At a later date, FAN and Beyond Pesticides were joined by the Environmental Working Group (hereinafter the three parties are referred to as "the Objectors") (Refs. 2 and 3). The Objectors argue that the sulfuryl fluoride and fluoride tolerances should not have been established by EPA because aggregate exposure to fluoride is unsafe under FFDCA section 408. The stay request as to the tolerances was filed by the Objectors in June, 2006, following release of a report by the National Research Council (NRC) of the National Academy of Sciences (NAS) concerning the risk of fluoride. (71 FR 38125, July 5, 2006) (FRL–8075–6).

After reviewing the objections and the NRC Report, EPA is proposing to grant the objections because it agrees that aggregate exposure to fluoride for certain major identifiable population subgroups does not meet the safety standard in FFDCA section 408. Because EPA is proposing to grant the Objectors' objections a hearing is not warranted. Finally, EPA is proposing to deny the Objectors' request for a stay because the risks from continued sulfuryl fluoride use in the short term is insignificant while the environmental and economic consequences from a sudden withdrawal of sulfuryl fluoride, a methyl bromide replacement, are considerable.

B. What is the agency's authority for taking this action?

The procedure for filing objections to tolerance actions and EPA's authority for acting on such objections is contained in section 408(g) of FFDCA (21 U.S.C. 346a(g)) and regulations at 40 CFR part 178. That same authority governs hearing and stay requests.

III. Statutory and Regulatory Background

In this Unit, EPA provides background on the relevant statutes and regulations governing the Objectors' objections, requests for hearing, and request for a stay as well as on pertinent Agency policies and practices.

Unit III.A. summarizes the requirements and procedures in section 408 of FFDCA and applicable regulations pertaining to pesticide tolerances, including the procedures for objecting to EPA tolerance actions and the substantive standards for evaluating the safety of pesticide tolerances. This unit also discusses the closely-related statute under which EPA regulates the sale, distribution, and use of pesticides, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*).

Unit III.B. provides an overview of the risk assessment process followed by EPA's Office of Pesticide Programs (OPP). It contains an explanation of how EPA identifies the hazards posed by pesticides, how EPA determines the level of exposure to pesticides that pose a concern (level of concern), how EPA measures human exposure to pesticides, and how hazard, level of concern conclusions, and human exposure estimates are combined to evaluate risk. Further, this unit presents background information on two Agency policies with particular relevance to this action.

Unit III.C. provides a brief overview of the Safe Drinking Water Act (SDWA) and the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol) and Title VI of the Clean Air Act (CAA) addressing Stratospheric Ozone Protection. These statutory schemes and international treaty are relevant to this proceeding because EPA regulates fluoride, a sulfuryl fluoride degradate, under SDWA, and because sulfuryl fluoride has played an important role in the United States fulfilling its obligations under the Montreal Protocol and CAA. Specifically, sulfuryl fluoride is a substitute for the ozone-depleting pesticide, methyl bromide.

A. FFDCA/FIFRA and Applicable Regulations

1. *In general.* EPA establishes maximum residue limits, or "tolerances," for pesticide residues in food under section 408 of FFDCA. (21 U.S.C. 346a). Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is "adulterated" under section 402 of FFDCA and may not be legally moved in interstate commerce. (21 U.S.C. 331, 342). Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). Section 408 was substantially rewritten by the Food Quality Protection Act of 1996 (FQPA), which added the provisions establishing a detailed safety standard for pesticides, additional protections for infants and children, and the estrogenic substances screening

program. (Pub. L. 104–170, 110 Stat. 1489 (1996)).

EPA also regulates pesticides under FIFRA (7 U.S.C. 136 *et seq.*). While FFDCA authorizes the establishment of legal limits for pesticide residues in food, FIFRA requires the approval of pesticides prior to their sale and distribution, (7 U.S.C. 136a(a)), and establishes a registration regime for regulating the use of pesticides. FIFRA regulates pesticide use in conjunction with its registration scheme by requiring EPA review and approval of pesticide labeling and specifying that use of a pesticide inconsistent with its labeling is a violation of Federal law. (7 U.S.C. 136j(a)(2)(G)). In the FQPA, Congress integrated action under the two statutes by requiring that the safety standard under FFDCA be used as a criterion in FIFRA registration actions as to pesticide uses which result in dietary risk from residues in or on food, (7 U.S.C. 136(bb)), and directing that EPA coordinate, to the extent practicable, revocations of tolerances with pesticide cancellations under FIFRA. (21 U.S.C. 346a(l)(1)).

2. *Safety standard for pesticide tolerances.* A pesticide tolerance may only be promulgated by EPA if the tolerance is "safe." (21 U.S.C. 346a(b)(2)(A)(i)). "Safe" is defined by the statute to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." (21 U.S.C. 346a(b)(2)(A)(ii)). Section 408(b)(2)(D) directs EPA, in making a safety determination, to:

> Consider, among other relevant factors—
> * * *
> * * *available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources.* * *

(21 U.S.C. 346a(b)(2)(D)(v), (vi) and (viii)). EPA must also consider, in evaluating the safety of tolerances, "safety factors which * * * are generally recognized as appropriate for the use of animal experimentation data." (21 U.S.C. 346a(b)(2)(D)(ix).

Risks to infants and children are given special consideration. Specifically, section 408(b)(2)(C)(i)(II) requires that EPA assess the risk to pesticides based on "available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of *in utero* exposure to pesticide chemicals.* * * " (21 U.S.C. 346a(b)(2)(C)(i)(II)). This provision also creates a presumption that EPA will use an additional safety factor for the protection of infants and children. Specifically, it directs that "[i]n the case of threshold effects, * * * an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." (21 U.S.C. 346a(b)(2)(C)). EPA is permitted to "use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children." (*Id.*). The additional safety margin for infants and children is referred to throughout this Order as the "children's safety factor."

3. *Procedures for establishing, amending, or revoking tolerances.* Tolerances are established, amended, or revoked by rulemaking under the unique procedural framework set forth in FFDCA. Generally, a tolerance rulemaking is initiated by the party seeking to establish, amend, or revoke a tolerance by means of filing a petition with EPA. (*See* 21 U.S.C. 346a(d)(1)). EPA publishes in the **Federal Register** a notice of the petition filing and requests public comment. (21 U.S.C. 346a(d)(3)). After reviewing the petition, and any comments received on it, EPA may issue a final rule establishing, amending, or revoking the tolerance, issue a proposed rule to do the same, or deny the petition. (21 U.S.C. 346a(d)(4)).

Once EPA takes final action on the petition by either establishing, amending, or revoking the tolerance or denying the petition, any person may file objections with EPA and seek an evidentiary hearing on those objections. (21 U.S.C. 346a(g)(2)). Objections and hearing requests must be filed within 60 days. (*Id.*). The statute provides that EPA shall "hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections." (21 U.S.C. 346a(g)(2)(B)). EPA regulations make clear that hearings will only be granted where it is shown that there is "a genuine and substantial issue of fact," the requestor has identified evidence "which, if established, resolve one or more of such issues in favor of the requestor," and the issue is "determinative" with regard to the relief requested. (40 CFR 178.32(b)). EPA's final order on the objections and requests for hearing is subject to judicial review. (21 U.S.C. 346a(h)(1)). The statute directs that tolerance regulations shall take effect upon publication unless EPA specifies otherwise. (40 U.S.C. 346a(g)(1)). EPA is authorized to stay the effectiveness of the tolerance if objections are filed. (*Id.*).

B. EPA Risk Assessment for Tolerances—Policy and Practice

1. *The safety determination—risk assessment.* To assess risk of a pesticide tolerance, EPA combines information on pesticide toxicity with information regarding the route, magnitude, and duration of exposure to the pesticide. The risk assessment process involves four distinct steps:

(1) Identification of the toxicological hazards posed by a pesticide;

(2) Determination of the "level of concern" with respect to human exposure to the pesticide;

(3) Estimation of human exposure to the pesticide; and

(4) Characterization of risk posed to humans by the pesticide based on comparison of human exposure to the level of concern.

a. *Hazard identification.* In evaluating toxicity or hazard, EPA reviews toxicity data, typically from studies with laboratory animals, to identify any adverse effects on the test subjects. Where available and appropriate, EPA will also take into account studies involving humans, including human epidemiological studies. For most pesticides, the animal toxicity database usually consists of studies investigating a broad range of endpoints including gross and microscopic effects on organs and tissues, functional effects on bodily organs and systems, effects on blood parameters (such as red blood cell count, hemoglobin concentration, hematocrit, and a measure of clotting potential), effects on the concentrations of normal blood chemicals (including glucose, total cholesterol, urea nitrogen, creatinine, total protein, total bilirubin, albumin, hormones, and enzymes such as alkaline phosphatase, alanine aminotransfersase and cholinesterases), and behavioral or other gross effects identified through clinical observation and measurement. EPA examines whether adverse effects are caused by different durations of exposure ranging from short-term (acute) to long-term (chronic) pesticide exposure and different routes of exposure (oral, dermal, inhalation). Further, EPA evaluates potential adverse effects in

different age groups (adults as well as fetuses and juveniles). (Ref. 4 at 8–10).

EPA also considers whether the adverse effect has a threshold—a level below which exposure has no appreciable chance of causing the adverse effect. For effects that have no threshold, EPA assumes that any exposure to the substance increases the risk that the adverse effect may occur.

b. *Level of concern/dose-response analysis.* Once a pesticide's potential hazards are identified, EPA determines a toxicological level of concern for evaluating the risk posed by human exposure to the pesticide. In this step of the risk assessment process, EPA essentially evaluates the levels of exposure to the pesticide at which effects might occur. An important aspect of this determination is assessing the relationship between exposure (dose) and response (often referred to as the dose-response analysis). EPA follows differing approaches to identifying a level of concern for threshold and non-threshold hazards.

i. *Threshold effects.* In examining the dose-response relationship for a pesticide's threshold effects, EPA evaluates an array of toxicity studies on the pesticide. In each of these studies, EPA attempts to identify the lowest observed adverse effect level (LOAEL) and the no observed adverse effect level (NOAEL), which by definition is the next lower tested dose level below the LOAEL. Generally, EPA will use the lowest NOAEL from the available studies as a starting point (called "the Point of Departure") in estimating the level of concern for humans. (Ref. 4 at 9 (The Point of Departure "is simply the toxic dose that serves as the 'starting point' in extrapolating a risk to the human population.")). At times, however, EPA will use a LOAEL from a study as the Point of Departure when no NOAEL is identified in that study and the LOAEL is close to, or lower than, other relevant NOAELs. The Point of Departure is in turn used in choosing a level of concern. EPA will make separate determinations as to the Points of Departure, and correspondingly levels of concern, for both short and long exposure periods as well as for the different routes of exposure (oral, dermal, and inhalation).

In recent years, EPA has increasingly used a more scientifically sophisticated approach to choosing the Point of Departure. This approach, called a benchmark dose, or BMD, estimates a point along a dose-response curve that corresponds to a specific response level. (Ref. 5). For example, a BMD_{10} represents a 10% change from the background or typical value for the response of concern. In contrast to the NOAEL/LOAEL approach, a BMD is calculated using a range of dose response data and thus better accounts for the variability and uncertainty in the experimental results due to characteristics of the study design, such as dose selection, dose spacing, and sample size. In addition to a BMD, EPA generally also calculates a "confidence limit" in the BMD. Confidence limits express the uncertainty in a BMD that may be due to sampling and/or experimental error. The lower confidence limit on the dose used as the BMD is termed the BMDL, which the Agency often uses as the Point of Departure. Use of the BMDL for deriving the Point of Departure rewards better experimental design and procedures that provide more precise estimates of the BMD, resulting in tighter confidence intervals. It also provides a health protective conservative estimate of the safe dose. Numerous scientific peer review panels over the last decade have supported the Agency's application of the BMD approach as a scientifically supportable method for deriving Points of Departure in human health risk assessment, and as an improvement over the historically applied approach of using NOAELs or LOAELs. (Refs. 6 and 7).

In estimating and describing the level of concern, the Point of Departure is at times used differently depending on whether the risk assessment addresses dietary or non-dietary exposures. For dietary risks, EPA uses the Point of Departure to calculate an acceptable level of exposure or reference dose (RfD). The RfD is calculated by dividing the Point of Departure by all applicable safety or uncertainty factors. Typically, EPA uses a baseline safety/uncertainty factor of 100X in assessing pesticide risk. That value includes a factor of 10 (10X) where EPA is using data from laboratory animals to account for the possibility that humans potentially have greater sensitivity to the pesticide than animals and another factor of 10X to account for potential variations in sensitivity among members of the human population. Additional safety factors may be added to address data deficiencies or concerns raised by the existing data. Under the FQPA, an additional safety factor of 10X is presumptively applied to protect infants and children, unless reliable data support selection of a different factor. This FQPA additional safety factor largely replaces pre-FQPA EPA practice regarding additional safety factors. (Ref. 8 at 4–11).

In implementing FFDCA section 408, EPA's Office of Pesticide Programs, also calculates a variant of the RfD referred to as a Population Adjusted Dose (PAD). APAD is the RfD divided by any portion of the FQPA safety factor that does not correspond to one of the traditional additional safety factors used in general Agency risk assessments. (*Id.* at 13–16). The reason for calculating PADs is so that other parts of the Agency, which are not governed by FFDCA section 408, can, when evaluating the same or similar substances, easily identify which aspects of a pesticide risk assessment are a function of the particular statutory commands in FFDCA section 408. Today, RfDs and PADs are generally calculated for both acute and chronic dietary risks although traditionally RfDs and PADs were only calculated for chronic risks. Throughout this document general references to OPP's calculated safe dose are denoted as an RfD/PAD.

For non-dietary, and combined dietary and non-dietary, risk assessments of threshold effects, the toxicological level of concern is not expressed as an RfD/PAD but rather in terms of an acceptable (or target) margin of exposure (MOE) between human exposure and the Point of Departure. The "margin" of interest is the ratio between human exposure and the Point of Departure which is calculated by dividing human exposure into the Point of Departure. An acceptable MOE is generally considered to be a margin at least as high as the product of all applicable safety factors for a pesticide. For example, if a pesticide needs a 10X factor to account for potential inter-species differences, 10X factor for potential intra-species differences, and 10X factor for the FQPA children's safety provision, the safe or target MOE would be a MOE of at least 1,000. What that means is that for the pesticide in the example to meet the safety standard, human exposure to the pesticide would generally have to be at least 1,000 times smaller than the Point of Departure. Like RfD/PADs, specific target MOEs are selected for exposures of different durations. For non-dietary exposures, EPA typically examines short-term, intermediate-term, and long-term exposures. Additionally, target MOEs may be selected based on both the duration of exposure and the various routes of non-dietary exposure—dermal, inhalation, and oral.

ii. *Non-threshold effects.* For risk assessments for non-threshold effects, EPA does not use the RfD/PAD or MOE approach to choose a level of concern if quantification of the risk is deemed appropriate. Rather, EPA calculates the slope of the dose-response curve for the non-threshold effects from relevant

studies frequently using a linear, low-dose extrapolation model that assumes that any amount of exposure will lead to some degree of risk. This dose-response analysis will be used in the risk characterization stage to estimate the risk to humans of the non-threshold effect.

c. *Estimating human exposure.* Risk is a function of both hazard and exposure. Thus, equally important to the risk assessment process as determining the hazards posed by a pesticide and the toxicological level of concern for those hazards is estimating human exposure. Under FFDCA section 408, EPA is concerned not only with exposure to pesticide residues in food but also exposure resulting from pesticide contamination of drinking water supplies and from use of pesticides in the home or other non-occupational settings. (*See* 21 U.S.C. 346a(b)(2)(D)(vi)). Additionally, EPA must take into account non-occupational exposure from "other related substances." (*Id.*).

i. *Exposure from food.* There are two critical variables in estimating exposure in food:

- The types and amount of food that is consumed; and
- The residue level in that food.

Consumption is estimated by EPA based on scientific surveys of individuals' food consumption in the United States conducted by the USDA. (Ref. 4 at 12). Information on residue values comes from a range of sources including crop field trials, data on pesticide reduction (or concentration) due to processing, cooking, and other practices, information on the extent of usage of the pesticide, and monitoring of the food supply. (*Id.* at 17).

In assessing exposure from pesticide residues in food, EPA, for efficiency's sake, follows a tiered approach in which it, in the first instance, assesses exposure using the worst case assumptions that 100% of the crop or commodity in question is treated with, or exposed to, the pesticide and 100% of the food from that crop or commodity contains pesticide residues at the tolerance level. (*Id.* at 11). When such an assessment shows no risks of concern, a more complex risk assessment is unnecessary. By avoiding a more complex risk assessment, EPA's resources are conserved and regulated parties are spared the cost of any additional studies that may be needed. If, however, a first tier assessment suggests there could be a risk of concern, EPA then attempts to refine its exposure assumptions to yield a more realistic picture of residue values through use of data on the percent of the crop or commodity actually treated with, or exposed to, the pesticide and data on the level of residues that may be present on the treated crop or commodity. These latter data are used to estimate what has been traditionally referred to by EPA as "anticipated residues."

Use of percent crop/commodity treated data and anticipated residue information is appropriate because EPA's worst-case assumptions of 100% treatment and residues at tolerance value significantly overstate residue values. There are several reasons why this is true. First, all growers of a particular crop would rarely choose to apply the same pesticide to that crop (some may apply no pesticide; some may apply an alternative pesticide); generally, the proportion of the crop treated with a particular pesticide is significantly below 100%. (70 FR 46706, 46731, August 10, 2005) (FRL–7727–4). This is true with food and structural fumigants such as sulfuryl fluoride as well, especially with regard to the structural fumigant use in food processing facilities because such use incurs infrequently and only potentially affects a small portion of the food processed in the facility. Second, the tolerance value represents a high end or worst case value. Tolerance values are chosen only after EPA has evaluated data from experimental trials in which the pesticide has been used in a manner, consistent with the draft FIFRA label, that is likely to produce the highest residue in the crop or food in question (*e.g.,* maximum application rate, maximum number of applications, minimum pre-harvest interval between last pesticide application and harvest). (Refs. 4 and 9). These experimental trials are generally conducted in several locations and involve multiple samples. (*Id.* at 5, 7 and Tables 1 and 5). The results from such experimental trials invariably show that the residue levels for a given pesticide use will vary from as low as non-detectable to measurable values in the parts per million (ppm) range with the majority of the values falling at the lower part of the range. (70 FR 46731) (FRL–7727–4). EPA uses a statistical procedure to analyze the experimental trial results and identify the upper bound of expected residue values. This upper bound value is typically used as the tolerance value. (Ref. 10). There may be some commodities from a treated crop or commodity that approach the tolerance value where the maximum label rates are followed, but most generally fall significantly below the tolerance value. If less than the maximum legal rate is applied, residues will be even lower. Third, residue values measured at the time of treatment do not take into account the lowering of residue values that frequently occurs as a result of degradation over time and through food processing and cooking.

EPA uses several techniques to refine residue value estimates. (Ref. 4 at 17–28). First, where appropriate, EPA will take into account all the residue values reported in the experimental trials, either through use of an average or individually. Second, EPA will consider data showing what portion of the crop or commodity is not treated with, or exposed to, the pesticide. Third, data can be produced showing pesticide degradation and decline over time, and the effect of commercial and consumer food handling and processing practices. Finally, EPA can consult monitoring data gathered by the FDA, the USDA, or pesticide registrants, on pesticide levels in food at points in the food distribution chain distant from the farm, including retail food establishments.

Another critical component of the exposure assessment is how data on consumption patterns are combined with data on pesticide residue levels in food. Traditionally, EPA has calculated exposure by simply multiplying average consumption by average residue values for estimating chronic risks and high-end consumption by maximum residue values for estimating acute risks. Using average residues is a realistic approach for chronic risk assessment due to the fact that variations in residue levels and consumption amounts average out over time especially given the nationwide market for food in the United States. Using average values is inappropriate for acute risk assessments, however, because in assessing acute exposure situations it matters how much of each treated food a given consumer eats in the short-term and what the residue levels are in the particular foods consumed. Yet, using maximum residue values for acute risk assessment tends to greatly overstate exposure because it is unlikely that a person would consume at a single meal multiple food components bearing high-end residues. To take into account the variations in short-term consumption patterns and food residue values for acute risk assessments, EPA uses probabilistic modeling techniques for estimating exposure when more simplistic models appear to show risks of concerns.

All of these refinements to the exposure assessment process, from use of food monitoring data through probabilistic modeling, can have dramatic effects on the level of exposure

predicted, typically reducing worst case estimates by at least 1 or 2 orders of magnitude. (Ref. 11 at 16–17; 70 FR 46706, 46732, August 10, 2005) (FRL–7727–4).

ii. *Exposure from water.* EPA may use either or both field monitoring data and mathematical water exposure models to generate pesticide exposure estimates in drinking water. Monitoring and modeling are both important tools for estimating pesticide concentrations in water and can provide different types of information. Monitoring data can provide estimates of pesticide concentrations in water that are representative of specific agricultural or residential pesticide practices and under environmental conditions associated with a sampling design. Although monitoring data can provide a direct measure of the concentration of a pesticide in water, it does not always provide a reliable estimate of exposure because sampling may not occur in areas with the highest pesticide use, and/or the sampling may not occur when the pesticides are being used.

In estimating pesticide exposure levels in drinking water, EPA most frequently uses mathematical water exposure models. EPA's models are based on extensive monitoring data and detailed information on soil properties, crop characteristics, and weather patterns. (69 FR 30042, 30058–30065, May 26, 2004) (FRL–7355–7). These models calculate estimated environmental concentrations of pesticides using laboratory data that describe how fast the pesticide breaks down to other chemicals and how it moves in the environment. These concentrations can be estimated continuously over long periods of time, and for places that are of most interest for any particular pesticide. Modeling is a useful tool for characterizing vulnerable sites, and can be used to estimate peak concentrations from infrequent, large storms.

Unlike assessments of exposure to pesticides in food, assessments of exposure to pesticides in drinking water conducted under FIFRA and FFDCA section 408 do not assume there is a nationwide market for drinking water. A person's source of drinking water is primarily local and often the pesticide use is quite localized as well. Thus, generally EPA assesses drinking water exposure to pesticides under FIFRA and FFDCA section 408 based on the most vulnerable watersheds and not on a national or even regional average. (*See* 74 FR 59608, 59618–59619, 59658, November 18, 2009) (FRL–8797–6). Further, these assessments commonly use high-end residue estimates from models and assume average consumption levels.

In the case of fluoride, however, the primary source of exposure is not from pesticide use. Additionally, as described in Unit V.A.2., EPA has an extensive monitoring database from across the United States on fluoride levels in drinking water. These factors have been taken into account in how EPA has conducted its FFDCA section 408 risk assessment for fluoride.

d. *Risk characterization.* The final step in the risk assessment is risk characterization. In this step, EPA combines information from the first three steps (hazard identification, level of concern/dose-response analysis, and human exposure assessment) to quantitatively estimate the risks posed by a pesticide. Separate characterizations of risk are conducted for different durations of exposure. Additionally, separate and, where appropriate, aggregate characterizations of risk are conducted for the different routes of exposure (dietary and non-dietary).

For threshold risks, EPA estimates risk in one of two ways. Where EPA has calculated a RfD/PAD, risk is estimated by expressing human exposure as a percentage of the RfD/PAD. Exposures lower than 100% of the RfD/PAD are generally not of concern. Alternatively, EPA may express risk by comparing the MOE between estimated human exposure and the Point of Departure with the acceptable or target MOE. As described previously, the acceptable or target MOE is the product of all applicable safety factors. To calculate the actual MOE for a pesticide, estimated human exposure to the pesticide is divided into the Point of Departure. In contrast to the RfD/PAD approach, higher MOEs denote lower risk. Accordingly, if the target MOE for a pesticide is 100, MOEs equal to or exceeding 100 would generally not be of concern.

As a conceptual matter, the RfD/PAD and MOE approaches are fundamentally equivalent. For a given risk and given exposure of a pesticide, if exposure to a pesticide were found to be acceptable under an RfD/PAD analysis it would also pass under the MOE approach, and vice-versa. However, for any specific pesticide, risk assessments for different exposure durations or routes may yield different results. This is a function not of the choice of the RfD/PAD or MOE approach but of the fact that the levels of concern and the levels of exposure may differ depending on the duration and route of exposure.

For non-threshold risks (generally, cancer risks), EPA uses the slope of the dose-response curve for a pesticide in conjunction with an estimation of human exposure to that pesticide to estimate the probability of occurrence of additional adverse effects. Under FFDCA section 408, for non-threshold cancer risks, EPA generally considers cancer risk to be negligible if the probability of increased cancer cases falls within the range of 1 in 1 million. EPA describes this quantitative standard as a "range" because it does not want to impart a false precision to numerical cancer risk estimates. EPA seeks to identify risks differing significantly from a 1 in 1 million risk and that involves both a quantitative as well as qualitative assessment of what a risk estimate represents.

2. *EPA policy on the children's safety factor.* As the previous brief summary of EPA's risk assessment practice indicates, the use of safety factors plays a critical role in the process. This is true for traditional 10X safety factors to account for potential differences between animals and humans when relying on studies in animals (inter-species safety factor) and potential differences among humans (intra-species safety factor) as well as the FQPA's additional 10X children's safety factor.

In applying the children's safety factor provision, EPA has interpreted it as imposing a presumption in favor of applying an additional 10X safety factor. (Ref. 8 at 4, 11). Thus, EPA generally refers to the additional 10X factor as a presumptive or default 10X factor. EPA has also made clear, however, that this presumption or default in favor of the additional 10X is only a presumption. The presumption can be overcome if reliable data demonstrate that a different factor is safe for children. (*Id.*). In determining whether a different factor is safe for children, EPA focuses on the three factors listed in section 408(b)(2)(C)—the completeness of the toxicity database, the completeness of the exposure database, and potential pre- and post-natal toxicity. In examining these factors, EPA strives to make sure that its choice of a safety factor, based on a weight-of-the-evidence evaluation, does not understate the risk to children. (*Id.* at 24–25, 35).

C. SDWA and the Montreal Protocol/CAA

1. *SDWA.* SDWA (42 U.S.C. 300f *et seq.*) was enacted to assure that water supply systems serving the public meet minimum national standards for the protection of public health and to protect the underground sources of drinking water upon which the public

relies. (*See* generally A Legislative History of the Safe Drinking Water Act, Committee Print, 97th Cong., 2d Sess. (1982) at 533–541). Under SDWA, EPA is authorized to set "National primary drinking water regulations" (NPDWRs) governing contaminants which the Administrator determines may have an adverse effect on the health of persons. NPDWRs apply to "public water systems" nationwide and include monitoring and reporting requirements. (42 U.S.C. 300g–1).

"Public water systems" are defined as systems that provide water to the public through pipes or other constructed conveyances for human consumption and that have at least 15 service connections or regularly serve at least 25 individuals. (42 U.S.C. 300f(4)(A)). By regulation, EPA has interpreted "regularly serve at least 25 individuals" to mean providing water to an average of at least 25 individuals daily at least 60 days of the year. (40 CFR 141.2). There are over 160,000 public water systems in the United States. The vast majority of these systems (95%) are small (*i.e.* serve populations of 3,300 persons or less) and these systems only serve about 10% of the population. Many of these small systems rely on groundwater as a water source. The largest 2% of the public water systems serve 80% of the population and include the large metropolitan water systems such as in New York City, Washington, DC, Boston and Chicago. Most of these systems rely on surface waters as their primary water source. Public drinking water systems provide water to roughly 85 to 90% of the U.S. population.

In promulgating a NPDWR for a contaminant, EPA must establish both a maximum contaminant level goal (MCLG) for that contaminant as well as either a maximum contaminant level (MCL) or a treatment technology requirement. (42 U.S.C. 300g–1(a)(3) and 300g–1(b)(4)(7)). MCLGs are not regulatory requirements and do not impose any obligations on public water systems. Rather, MCLGs are health goals that are to be set at a level at which, in the Administrator's judgment, "no known or anticipated adverse effects on the health of persons occur and which allows for an adequate margin of safety." (42 U.S.C. 300g–1(b)(4)(A)).

A MCL sets a level of the contaminant not to be exceeded by public water systems and, with some exceptions is to be set as close to the MCLG as is "feasible." (42 U.S.C. 300g–1(b)(4)(B)). The Act defines feasible to mean "feasible with the use of the best technology, treatment techniques or other means which the Administrator finds * * * are available (taking costs into consideration)." (42 U.S.C. 300g–(b)(4)(D)). The legislative history for this provision makes it clear that "feasibility" is to be defined relative to "what may reasonably be afforded by large metropolitan or regional public water systems." (A Legislative History of the Safe Drinking Water Act, Committee Print, 97th Cong., 2d Sess. (1982) at 550. MCLs appear at 40 CFR part 141, subparts B and G).

A treatment technique requirement imposes an obligation on public water systems to use an identified treatment technology and it must "prevent known or anticipated adverse effects on the health of persons to the extent feasible." (42 U.S.C. 300g–1(b)(7)(A). EPA may establish treatment technique requirements in lieu of an MCL only if it is not economically or technologically feasible to ascertain the level of the contaminant. (*Id.*).

SDWA also authorizes EPA to set "secondary" drinking water standards or "SMCLs." Such standards specify levels which are necessary to protect "the public welfare," (42 U.S.C. 300f(2)), but are not Federally enforceable (*see* A Legislative History of the Safe Drinking Water Act, Committee Print, 97th Cong., 2d Sess. (1982) at 557). For example, such a contaminant level might be one which adversely affects the odor or appearance of water so that a large number of people discontinue using that source. SMCLs may vary by geography or other circumstances. EPA has established SMCLs for 15 contaminants, which are intended to be guidelines for the States. (40 CFR part 143).

Every 6 years, EPA is required to review and revise "as appropriate" its existing drinking water standards. (42 U.S.C. 300g–1(b)(9)).

There is a long history of regulation of fluoride under SDWA. In 1975, EPA established a MCL for fluoride at a level varying between 1.4 milligrams (mg)/liter (L) and 2.4 mg/L depending on annual ambient air temperature. (40 FR 59566, December 24, 1975). These levels were set to prevent objectionable dental fluorosis. In 1981, South Carolina petitioned EPA to revoke the fluoride MCL arguing that dental fluorosis is merely a cosmetic effect not an adverse health effect. (*See* 50 FR 20164, May 14, 1985). In response to that petition, EPA took a series of actions. First, in 1985, EPA established a MCLG for fluoride at 4 mg/L. (50 FR 47142, November 14, 1985) (At that time MCLGs were termed "recommended maximum contaminant levels" (RMCLs) under SDWA.). The MCLG was set to protect against crippling skeletal fluorosis, an adverse health effect associated with high levels of fluoride exposure. EPA concluded that dental fluorosis, which had formed the basis for the earlier MCL, was not an adverse health effect under SDWA but only a cosmetic effect. Second, in 1986, EPA established a MCL for fluoride at 4 mg/L, again based on the crippling skeletal fluorosis endpoint. (51 FR 11396, April 2, 1986). Finally, also in 1986, EPA established a SMCL for fluoride at 2 mg/L to protect against objectionable dental fluorosis. (*Id.*). Judicial review of the MCLG was sought by both the Natural Resources Defense Council (NRDC) and by South Carolina. (*NRDC* v. *EPA,* 812 F.2d 721 (DC Cir. 1987)). NRDC argued that the level was too high because, among other reasons, the MCLG should have been set on dental fluorosis. Taking the opposite position, South Carolina claimed that no MCLG at all was appropriate because the evidence did not support that fluoride caused any adverse health effects. The DC Circuit upheld EPA's regulation ruling that EPA had reasonably interpreted SDWA term adverse health effect to be limited to functional impairments and that EPA had reasonably concluded that effects of dental fluorosis were cosmetic in nature and did not result in functional impairment. South Carolina's challenge was dismissed based on the court's conclusion that EPA had made a "permissible administrative judgment" based on the evidence before it. (*Id.* at 725).

Subsequent to these rulemakings, EPA has on two occasions asked NAS to reevaluate the potential risks of fluoride exposure in regard to the MCLG/MCL. The NRC Report on the second request is discussed extensively in Unit IV.D.

2. *The Montreal Protocol/CAA and methyl bromide.* The Montreal Protocol is the international agreement aimed at reducing and eliminating the production and consumption of stratospheric ozone-depleting substances. The stratospheric ozone layer protects humans from overexposure to harmful ultraviolet radiation. The United States was one of the original signatories to the 1987 Montreal Protocol and the United States ratified the Protocol in April, 1988. Congress then enacted the Clean Air Act Amendments (CAAA) of 1990 which included Title VI on Stratospheric Ozone Protection, codified as 42 U.S.C. Chapter 85, Subchapter VI, to ensure that the United States could satisfy its obligations under the Montreal Protocol. EPA issued regulations in 40 CFR part 82 to implement this legislation and has since modified and updated the regulations as needed. In 2009, the Montreal Protocol became the first

universally ratified international environmental treaty.

Methyl bromide was added to the Montreal Protocol as an ozone-depleting substance in 1992 through the Copenhagen Amendment to the Protocol. The Parties to the Montreal Protocol (Parties) agreed that each developed country's level of methyl bromide production and consumption in 1991 should be the baseline for establishing a freeze. Under the Montreal Protocol and Title VI of the CAAA the term "consumption" is a calculated amount equal to production plus imports minus exports. EPA published a final rule in the **Federal Register** on December 10, 1993 (58 FR 65018), listing methyl bromide as a Class I, Group VI controlled substance, freezing U.S. production and consumption at this 1991 baseline level of 25,528,270 kilograms, and setting forth the percentage of baseline allowances for methyl bromide granted to companies in each control period (each calendar year) until 2001, when the complete phase-out would occur. This phase-out date was established in response to a petition filed in 1991 under sections 602(c)(3) and 606(b) of CAAA of 1990, requesting that EPA list methyl bromide as a Class I substance and phase out its production and consumption. This date was consistent with section 602(d) of CAAA of 1990, which, for newly listed Class I ozone-depleting substances, provides that "no extension [of the phase-out schedule in section 604] under this subsection may extend the date for termination of production of any class I substance to a date more than 7 years after January 1 of the year after the year in which the substance is added to the list of class I substances."

At the Seventh Meeting of the Parties (MOP) in 1995, the Parties made adjustments to the methyl bromide control measures and agreed to reduction steps and a 2010 phase-out date for industrialized countries with exemptions permitted for critical uses. At that time, the United States continued to have a 2001 phase-out date in accordance with section 602(d) of CAAA of 1990. At the Ninth MOP in 1997, the Parties agreed to further adjustments to the phase-out schedule for methyl bromide in industrialized countries, with reduction steps leading to a 2005 phase-out.

In October 1998, the U.S. Congress amended CAA to conform the U.S. schedule to the schedule specified under the Protocol for developed countries by requiring EPA to move the date for ending production to January 1, 2005 and authorizing EPA to provide certain exemptions. These amendments were contained in section 764 of the 1999 Omnibus Consolidated and Emergency Supplemental Appropriations Act (Pub. L. 105–277, October 21, 1998) and were codified in section 604 of CAA. (42 U.S.C. 7671c). The amendment that specifically addresses the critical use exemption (CUE) appears at section 604(d)(6), 42 U.S.C. 7671c(d)(6). EPA revised the phase-out schedule for methyl bromide production and consumption in a direct final rulemaking on November 28, 2000 (65 FR 70795) (FRL–6906–4), which allowed for the phased reduction in methyl bromide consumption specified under the Protocol and extended the phase-out to 2005. EPA again amended the regulations to allow for an exemption for quarantine and preshipment purposes with an interim final rule on July 19, 2001 (66 FR 37752)(FRL–7014–5) and with a final rule on January 2, 2003 (68 FR 238)(FRL–7434–1).

On December 23, 2004 (69 FR 76982)(FRL–7850–8), EPA published a final rule that established the framework for the CUE; set forth a list of approved critical uses for 2005; and specified the amount of methyl bromide that could be supplied in 2005 from stocks and new production or import to meet the needs of approved critical uses. EPA subsequently published rules applying the CUE framework to the 2006, 2007, 2008, 2009, and 2010 control periods.

Since its introduction in 2004, sulfuryl fluoride has served as an alternative to methyl bromide with regard to methyl bromide's use as a post-harvest commodity fumigant and fumigant for food processing warehouses and facilities. Introduction of sulfuryl fluoride has played a significant role in the United States' reduction of the postharvest methyl bromide CUEs by almost 80% over the last 6 years.

IV. Regulatory History of Sulfuryl Fluoride

A. In General

Sulfuryl fluoride is a fumigant that is used to kill insect pests, rodents, birds, and snakes. It is used both for the treatment of structures as well as stored food. Sulfuryl fluoride was initially registered under FIFRA as Vikane®, a fumigant to treat drywood termites and other wood boring insects in 1959. More recently, sulfuryl fluoride was identified as a potential alternative for uses of methyl bromide as a food fumigant and as a fumigant of food processing facilities. It was registered under the name of ProFume® by Dow AgroSciences for these uses in 2004 and 2005. Sulfuryl fluoride has achieved significant penetration of several methyl bromide markets. EPA and Dow AgroSciences have concluded that sulfuryl fluoride is used in approximately 40% of mills and food processing facilities and is used on 100% of cocoa beans. More recently, sulfuryl fluoride has been used extensively in fumigating walnuts and dried fruit other than raisins.

Sulfuryl fluoride rapidly breaks down to form sulfate and the fluoride anion.

B. 2004 Registration and Tolerances

In 2004, EPA registered sulfuryl fluoride for use as a direct fumigant of various grains and dried fruits under FIFRA and established corresponding tolerances under FFDCA section 408. (69 FR 3240, January 23, 2004)(FRL–7342–1). Tolerances were established for both the parent chemical, sulfuryl fluoride, and the breakdown product, fluoride. (For convenience, both the sulfuryl fluoride and fluoride tolerances established in association with the use of sulfuryl fluoride are, hereinafter, referred to in this document as sulfuryl fluoride tolerances.) Separate risk assessments were conducted for sulfuryl fluoride and fluoride.

In assessing the risk of fluoride, EPA relied on the MCLG that had been established under SDWA to establish a RfD-like value for fluoride. Established in 1986, the fluoride MCLG is 4 mg/L and is based on the adverse effect of crippling skeletal fluorosis. (40 CFR 141.41). As was the case with the MCLG, EPA determined that dental fluorosis was not an adverse effect and thus was not an appropriate benchmark for evaluating the safety of fluoride under FFDCA. EPA also determined that, "given the wealth of reliable human data on fluoride," the presumptive additional 10X children's safety factor could be removed. (69 FR 3253) (FRL–7342–1). Using the MCLG in combination with high-end water consumption information and body weights for age subgroups from infants through adults, EPA calculated safe fluoride levels on a milligram of fluoride per kilogram of body weight per day (mg/kg/day) basis. (69 FR 3248) (FRL–7342–1). These RfD-like values were compared to estimated aggregate exposure levels to fluoride from numerous sources: From use of the pesticides sulfuryl fluoride and cryolite on food; from natural and artificial levels of fluoride in drinking water; from background levels of fluoride in beverages, food, and ambient air; and from fluoride in dental products. Because aggregate exposure for each of

the age-based population subgroups fell below the calculated RfD-like values, EPA concluded that the tolerances were safe.

Although FAN did not submit comments on the notice announcing Dow AgroSciences' petition for tolerances, FAN had submitted objections to an earlier sulfuryl fluoride tolerance action. That earlier tolerance action was the establishment of temporary tolerances for sulfuryl fluoride on various grains and dried fruits in conjunction with an experimental use permit for sulfuryl fluoride under FIFRA section 5. (7 U.S.C. 136c). Sulfuryl fluoride was never used under that experimental permit and the temporary tolerances were revoked with the establishment of the 2004 tolerances. However, EPA treated the FAN objections as comments on the petition for tolerances and responded to them in detail in promulgating the 2004 tolerances. (Refs. 13, 14 and 15). Because EPA recognized that the NAS was undertaking a comprehensive evaluation of the latest data on fluoride, EPA noted that its review of the data submitted by FAN was preliminary and subject to reevaluation once the NRC Report was complete. (Ref. 14).

On March 23, 2004, FAN, joined by Beyond Pesticides, filed objections to the 2004 tolerances and requested a hearing on those objections. (*See* Unit IV.D.).

C. 2005 Registration and Tolerances

In 2005, EPA registered sulfuryl fluoride for use as a direct fumigant on additional commodities and also as a structural fumigant for food processing facilities under FIFRA and established corresponding tolerances under FFDCA section 408. (70 FR 40899, July 15, 2005) (FRL–7723–7). Again, EPA relied on the MCLG in assessing the aggregate risk to fluoride, taking into account the additional fluoride exposure from the new uses. (*Id.* at 40905). EPA also assessed fluoride risk using the Point of Departure suggested by NAS' Institute of Medicine for evaluating the risk of crippling skeletal fluorosis. (*Id.* at 40906). Under both approaches, EPA concluded that the tolerances were safe.

FAN submitted comments on the notice announcing Dow AgroSciences' petition for tolerances. EPA prepared a detailed response to these comments. (Ref. 16).

On September 13, 2005, FAN, joined by Beyond Pesticides and the Environmental Working Group, filed objections to the 2005 tolerances and requested a hearing on those objections. (*See* Unit IV.D.).

D. The 2006 NRC Report

In 2003, EPA's Office of Water (OW) asked the NRC to review new research on fluoride to determine whether the MCLG and SMCL for fluoride established under SDWA adequately protect the public health. (Ref. 17 at xii). Specifically, EPA asked NRC "to review toxicologic, epidemiologic, and clinical data on fluoride—particularly data published since NRC's previous (1993) report—and exposure data on orally ingested fluoride from drinking water and other sources * * *," and "to evaluate independently the scientific basis of EPA's MCLG of 4 mg/L and SMCL of 2 mg/L in drinking water and the adequacy of those guidelines to protect children and others from adverse health effects." (*Id.* at 2). NRC was also asked to identify data gaps and to make recommendations for future research relevant to setting the MCLG and SMCL for fluoride." (*Id.*).

NRC completed its report in March 2006. Its overall conclusions were that: (1) "EPA's MCLG of 4 mg/L should be lowered;" (2) further study was needed to assess the protectiveness of the SMCL of 2 mg/L; and (3) "EPA should update the risk assessment of fluoride to include new data on health risks and better estimates of total exposure (relative source contribution) in individuals and to use current approaches to quantifying risk, considering susceptible subpopulations, and characterizing uncertainties and variability." (*Id.* at 352).

NRC's decision as to the MCLG was driven by its concern regarding the fluoride exposure levels that produce the following effects: Severe enamel fluorosis (referred to in this document generally as severe dental fluorosis); clinical stage II skeletal fluorosis; and bone fractures. (*Id.*). Previously, all forms of dental fluorosis had been regarded merely as cosmetic effects and thus not properly considered in setting a MCLG. In the 2006 Report, NRC stated that: "The damage to teeth caused by severe enamel fluorosis is a toxic effect that the majority of the committee judged to be consistent with prevailing risk assessment definitions of adverse health effects." (*Id.* at 127). NRC reasoned as follows:

> Severe enamel fluorosis is characterized by enamel loss and pitting. This damage compromises enamel's protective barrier and can make the teeth more susceptible to environmental stresses and to caries formation because it allows bacteria, plaque, and food particles to become entrapped in the enamel. Caries is dental decay caused by bacterial infection. When the infection goes unchecked, cavities may form that can cause toothache and tooth sensitivity to temperature and sweets. If cavities are untreated, the infection can lead to abscess, destruction of bone, and spread of the infection to other parts of the body. While increased risk of caries has not been firmly established, the majority of the committee found that destruction of the enamel and the clinical practice of treating the condition even in the absence of caries provide additional lines of evidence for concluding that severe enamel fluorosis is an adverse health effect.

(*Id.* at 346) (citation omitted).

Two of the 12 members of the NRC committee "did not agree that severe enamel fluorosis should now be considered an adverse health effect" and would have characterized it as an "adverse dental effect." (*Id.*). Nonetheless, these two committee members concurred in the overall NRC conclusion that the MCLG should protect against this effect. Specifically, the Report stated: "Despite their disagreement on characterization of the condition, these two members concurred with the committee's conclusion that the MCLG should prevent the occurrence of this unwanted condition." (*Id.*). Turning to the level of exposure that can cause severe dental fluorosis, NRC concluded that such fluorosis occurs at an "appreciable frequency" in communities with water supplies containing at or near 4 mg/L but that "the prevalence of severe enamel fluorosis would be reduced to nearly zero by bringing the water fluoride levels in these communities down to below 2 mg/L." (*Id.* at 127–128).

As to skeletal fluorosis, NRC concluded that the MCLG should not be based solely on stage III (crippling) skeletal fluorosis but also take into account stage II skeletal fluorosis (the stage before mobility is significantly affected). Although the data on what level of fluoride exposure was need to cause stage II skeletal fluorosis was inconclusive, NRC ventured that the data "suggest[] that the MCLG might not protect all individuals from the adverse stages of the condition." (*Id.* at 347). NRC advised that "more research is needed to clarify the relationship between fluoride ingestion, fluoride concentrations in bone, and stage of skeletal fluorosis." (*Id.*).

NRC found the evidence on the level of fluoride exposure which could lead to an increased risk of bone fracture to be somewhat more compelling. There was general agreement by NRC with the proposition "that there is scientific evidence that under certain conditions fluoride can weaken bone and increase the risk of fractures." (*Id.* at 348). Further, "the majority of the committee

concluded that lifetime exposure to fluoride at drinking water concentrations of 4 mg/L or higher is likely to increase fracture rates in the population, compared with exposure to 1 mg/L, particularly in some demographic subgroups that are prone to accumulate fluoride into their bones (*e.g.,* people with renal disease)." (*Id.*). Three members of the NRC committee reached a more tempered conclusion suggesting that "the evidence only supported a conclusion that the MCLG *might not* be protective against bone fracture." (*Id.*) (emphasis in original).

Turning to the SMCL, NRC noted that, even if this standard now only addresses, at worst, moderate dental fluorosis, the 2 mg/L "SMCL does not completely prevent the occurrence of moderate enamel fluorosis." (*Id.* at 352). Specifically, NRC found that "[p]ast evidence indicated an incidence range of 4% to 15% (50 FR 20164 [1985])." (Ref. 17 at 130). NRC indicated that "[t]he prevalence of moderate cases that would be classified as being of aesthetic concern (discoloration of the front teeth) is not known but would be lower than 15%." (*Id.*). In the end, NRC recommended further study of U.S. communities with drinking water fluoride levels of greater than 1 mg/L to better characterize the degree and consequences of moderate dental fluorosis and the levels at which these effects occur. (*Id.* at 352–353).

NRC also examined in detail whether fluoride caused reproductive, developmental, neurotoxic, neurobehavioral, or cancer effects or had adverse effects on the endocrine, gastrointestinal, renal, hepatic, and immune systems. Although NRC recommended further study with regard to many of these effects, it did not conclude that any of these potential effects warranted a lowering of the MCLG.

A substantial portion of the NRC Report is devoted to examining fluoride exposure in the United States. NRC considered exposures from drinking water; background levels in food, beverages, soil, and air; residues in food from pesticide usage; and dental products. Drinking water was generally the most significant source but certain age groups' exposures from background levels in food and water and from dental products were not insubstantial. (*Id.* at 60, Fig.2–1). NRC summarized the information on fluoride levels in water from public systems as follows:

> Of the 144 million people with fluoridated public water supplies in 1992, approximately 10 million (7%) received naturally fluoridated water, the rest had artificially fluoridated water. Of the population with artificially fluoridated water in 1992, more than two-thirds had a water fluoride concentration of 1.0 mg/L, with almost one-quarter having lower concentrations and about 5% having concentrations up to 1.2 mg/L.
>
> Of the approximately 10 million people with naturally fluoridated public water supplies in 1992, approximately 67% had fluoride concentrations ≤ 1.2 mg/L. Approximately 14% had fluoride concentrations between 1.3 and 1.9 mg/L and another 14% had between 2.0 and 3.9 mg/L; 2% (just over 200,000 persons) had natural fluoride concentrations equal to or exceeding 4.0 mg/L.

(*Id.* at 25) (citations omitted).

As to persons who rely on private water sources, NRC noted:

> Little information is available on the fluoride content of private water sources, but the variability can reasonably be expected to be high and to depend on the region of the country. Fluoride measured in well water in one study in Iowa ranged from 0.06 to 7.22 mg/L (mean, 0.45 mg/L); home-filtered well water contained 0.02–1.00 mg/L (mean, 0.32 mg/L). Hudak (1999) determined median fluoride concentrations for 237 of 254 Texas counties (values were not determined for counties with fewer than five observations). Of the 237 counties, 84 have median groundwater fluoride concentrations exceeding 1 mg/L; of these, 25 counties exceed 2 mg/L and five exceed 4 mg/L. Residents in these areas (or similar areas in other States) who use groundwater from private wells are likely to exceed current guidelines for fluoride intake.

(*Id.* at 25–26).

E. The Objectors' Objections and Hearing Requests

1. *Procedural history.* The Objectors have filed several sets of objections and hearing requests on the 2004 and 2005 tolerance actions as a result of various preliminary responses by EPA to FAN's requests for hearing. As noted, the Objectors filed objections and hearing requests on March 23, 2004, as to the 2004 tolerance action. On June 4, 2005, EPA responded by letter to the Objectors' hearing request noting numerous potential flaws in the request and giving the Objectors 90 days to respond to the issues raised. On July 15, 2005, EPA issued additional tolerances for sulfuryl fluoride/fluoride and on September 13, 2005, the Objectors submitted objections and hearing requests as to these tolerances. Then, on December 16, 2005, Objectors submitted a revised set of objections and hearing requests in response to EPA's earlier letter. EPA responded to the December 16, 2005 filing on February 13, 2006, seeking further clarification on several issues and giving the Objectors 90 days to respond. On November 6, 2006, the Objectors filed a second set of revised objections and hearing requests that consolidated their objections to both the 2004 and 2005 tolerance actions. (Ref. 3).

The Objectors have made two additional filings with EPA. First, on June 1, 2006, the Objectors filed with EPA a motion for a stay of 2004 and 2005 tolerance actions. (Ref. 2). This stay request was largely in response to the NRC Report on fluoride. Second, in February 2009, the Objectors filed a collection of 18 studies addressing potential effects of fluoride exposure on IQ levels in children. (Ref. 18).

2. *Consolidated objections and hearing requests.* The Objectors' consolidated objections and hearing requests filed in November, 2006, raise six main arguments:

- The fluoride MCLG is not protective of the effects of fluoride on teeth and bones;
- The fluoride MCLG is not protective of other neurotoxic, endocrine, and renal effects of fluoride;
- EPA has not adequately protected children;
- EPA cannot determine the safety of sulfuryl fluoride and fluoride in the absence of a developmental neurotoxicity study;
- EPA has underestimated exposure to fluoride; and
- EPA has committed procedural errors in violation of the Administrative Procedures Act (APA) (5 U.S.C. 551 *et seq.*).

The Objectors argue that the 4 mg/L MCLG for fluoride does not provide adequate protection against severe dental fluorosis, pre-crippling skeletal fluorosis, and increased risk of bone fractures. The Objectors cite to government and literature studies documenting the significant consequences from severe dental fluorosis: "The enamel of the teeth become so porous that the teeth are 'prone to fracture and wear' (ATSDR 2003), 'subject to extensive mechanical breakdown of the surface' (Aoba & Fejerskov 2002), with a 'friable enamel that can result in loss of dental function' (Burt & Eklund 1999)." (Ref. 3 at 16). On pre-crippling skeletal fluorosis, the Objectors assert that pre-crippling skeletal fluorosis can be a painful condition for some people. (*Id.* at 19). Finally, the Objectors cite to many studies on the risk of increased bone fractures from fluoride exposure that allegedly show that these increased risks occur at fluoride exposure levels lower than those in communities with drinking water levels of 4 mg/L. (*Id.* at 22–24).

The Objectors also argue that the 4 mg/L MCLG for fluoride does not

protect against fluoride's effects on the brain, the endocrine system, and the kidneys. The Objectors cited a study in rats allegedly showing brain damage at a fluoride exposure level in water of 1 ppm [1 mg/L] and epidemiological studies showing reductions in IQ levels in children at a fluoride exposure level of 0.9 ppm [0.9 mg/L] in iodine-deficient areas and 1.8 ppm [1.8 mg/L] in areas with sufficient iodine in the diet. (*Id.* at 25–26). As to the endocrine system, the Objectors reference the NRC Report's conclusion that fluoride is an "endocrine disruptor" and argue that fluoride can have adverse effects on insulin secretion and on the thyroid. (*Id.* at 31–35). The Objectors argue that fluoride can affect insulin secretion where drinking water contains 4 mg/L or less of fluoride, (*Id.* at 33), and that NRC has concluded that thyroid effects can occur at exposure levels as low as 0.01–0.03 mg/kg/day for iodine-deficient humans, (*Id.* at 35). As to the kidneys, the Objectors claim that data show that adverse effects can occur when exposure levels in water are at the 1 and 2 mg/L level. (*Id.* at 38–39).

With regard to the safety of children, the Objectors assert that EPA, without basis or explanation, has applied a significantly less protective RfD to infants and children than the RfD applicable to adults. The Objectors note that prior to the promulgation of the 2004 fluoride tolerances EPA had utilized a RfD of 0.114 mg/kg/day for all population age groups. (*Id.* at 59). The Objectors point out, however, that, in both the 2004 and 2005 tolerance actions, EPA increased the RfD for several of the infant and children age groups to levels that are allegedly as much as 10 times higher than the RfD for adults. This higher RfD for infants and children, the Objectors argue, is inconsistent with the statutory requirement for providing an additional margin of safety for infants and children, the basic toxicological principle that bodyweight affects the impact of a chemical, data showing adverse effects at levels below the RfD levels, and data showing that children's bones are more sensitive to fluoride than adult's bones. (*Id.* at 58–67). Further, the Objectors assert that EPA failed to take into account, in its decision on the safety of fluoride to infants and children, the uncertainty in the database concerning fluoride's neurotoxic effects, and fluoride's effects on the endocrine system. (*Id.* at 68–70).

A developmental neurotoxicity study on sulfuryl fluoride, the Objectors claim, is critical to understanding the potential harmful effects of sulfuryl fluoride and fluoride. They argue that EPA's reasons for waiving the study lack merit and that a developmental neurotoxicity study is mandated given NRC's conclusion that fluoride is neurotoxic and that effects on the brain, including rare and severe effects, were seen in animal studies with sulfuryl fluoride. (*Id.* at 72–79).

Turning to human exposure to fluoride, the Objectors argue that EPA has underestimated fluoride exposure and corrected fluoride values show that some people are exposed to unsafe levels of fluoride. The Objectors claim EPA made numerous errors in estimating fluoride exposure: (1) EPA underestimated average fluoride levels in water, (*Id.* at 81–82); (2) EPA considered only average water and food consumption levels instead of taking into account the full range of consumption amounts, (*Id.* at 82–84, 105–106); (3) EPA underestimated fluoride exposures from toothpaste, (*Id.* at 88–91); and (4) EPA had insufficient data to estimate residues of fluoride on food from fumigation with sulfuryl fluoride (*Id.* at 106). The Objectors contend that a risk assessment using corrected exposure values will show that hundreds of thousands of people exceed the 0.114 mg/kg/day RfD and that millions of people would exceed a RfD set based on an endpoint of severe dental fluorosis. (*Id.* at 86, 94–95).

Finally, the Objectors claim that EPA has made several procedural errors that violate the dictates of the APA. First, the Objectors argue that EPA has unreasonably delayed responding to their objections and hearing requests filed in March 2004. Second, the Objectors argue that EPA erred by not making its risk assessment available at the time of issuance of the 2005 tolerance action. Third, EPA's failure to place all requested documents in the record, according to the Objectors, has thwarted full public participation. Fourth, the Objectors assert it was a procedural error for EPA to issue sulfuryl fluoride tolerances without first obtaining the advice of NRC.

The Objectors have also sought an adjudicatory hearing on each of these objections. In support of their hearing request, the Objectors have submitted all the data referenced in their consolidated objections.

F. The Objectors' Stay Request

On June 1, 2006, the Objectors filed a motion with EPA seeking a stay of the effectiveness of the 2004 and 2005 final rules establishing sulfuryl fluoride tolerances. A stay of the effectiveness of these rules would essentially ban use of sulfuryl fluoride because if the tolerances are not effective then any sulfuryl fluoride or fluoride residue remaining in treated foods would render the food adulterated under FFDCA and subject to seizure. This stay request appears to have been triggered by the March 2006 release of the NRC Report on fluoride. (Ref. 2 at 4). The Objectors argued they were entitled to a stay because they had demonstrated (1) that they were likely to prevail on the merits of their objections; (2) the tolerances posed an imminent, substantial and irreparable harm; (3) no other parties would be substantially harmed by a stay; and (4) the public interest supported a stay. (*Id.* at 2). EPA held a 30-day comment period on the stay request. (71 FR 38125, July 5, 2006) (FRL–8075–6).

To support their likelihood of success on the merits argument, the Objectors make similar arguments to those contained in their consolidated objections. As to irreparable harm, the Objectors cite to the NRC Report claiming it linked fluoride not just to adverse effects on bones and teeth but also to interactive and synergistic toxic effects with other chemicals, cancer, and diabetes, as well as adverse effects on the brain, thyroid, pineal gland, kidney, liver, and the endocrine, immune, gastrointestinal, and reproduction systems. (Ref. 2 at 11, 13–15). Further, the Objectors cite to the "high levels of fluoride from pesticides" arguing that "[a]s a result of these broad-reaching, staggeringly high fluoride tolerances, EPA's own data show that sulfuryl fluoride will become the second largest daily source of fluoride in the US." (*Id.* at 3, 35). The Objectors assert that other parties, including Dow AgroSciences, will not be substantially harmed "in view of the overwhelming concern for public health at the heart of the statute." (*Id.* at 36). Finally, the Objectors argue the public interest favors a stay because a stay would protect the public health. (*Id.* at 37).

G. Comments of Dow AgroSciences

Dow AgroSciences has filed two sets of comments on these matters. First, Dow AgroSciences filed comments on the Objectors' request for a stay of the effectiveness of the sulfuryl fluoride tolerances during the public comment period during mid-2006. (Ref. 19). Second, in October 2006, Dow AgroSciences submitted a memorandum to EPA arguing that the Objectors' were not entitled to a hearing on their objections. (Ref. 20).

1. *Comments on stay request.* In its comments, Dow AgroSciences offered a series of reasons as to why a stay was not warranted. First, Dow AgroSciences argues that EPA should follow the

already-established process for how the sulfuryl fluoride/fluoride tolerances would be reviewed in light of the NRC Report. This process, according to Dow AgroSciences, involves an analysis of the NRC Report by EPA's OW followed by a re-evaluation of the tolerances by EPA's OPP. (Ref. 19 at 6–7). Dow AgroSciences asserts that "[a]bandoning now a process established by the Agency and relied upon by SF registrants and the scientific community would be arbitrary, unfair and unwarranted." (*Id.* at 7).

Second, Dow AgroSciences argues that the stay request is delinquent because it was not filed within 60 days of issuance of the final tolerance actions. (*Id.* at 8). Dow AgroSciences bases this claim on the statutory requirement that objections to a tolerance must be filed within 60 days of issuance.

Third, Dow AgroSciences claims that a stay of the tolerance action is inappropriate because the stay request does not address "the underlying ProFume registration under FIFRA * * *." (*Id.* at 10). According to Dow AgroSciences, "[b]ypassing the hearing rights and other procedural requirements provided by FIFRA would deny Dow AgroSciences and other adversely affected parties their due process rights under the U.S. Constitution." (*Id.* at 9).

Fourth, Dow AgroSciences argues that the NRC Report only indicates a concern for "that small, localized segment of the population exposed to high *natural* fluoride levels." (*Id.* at 12). Such "an exceedingly small, isolated number of individuals," Dow AgroSciences contends, would not constitute a "major identifiable" subgroup which is the regulatory focus under FFDCA section 408. (*Id.*).

Fifth, Dow AgroSciences challenged the Objectors' claims that the NRC Report showed that there is a safety concern with fluoride. Dow AgroSciences noted that as to many potential health effects the NAS had either concluded that no risks were present from exposure in drinking water at 4 mg/L or there was insufficient data showing effects and more study was necessary. (*Id.* at 14). With regard to fluoride's effects on the risk of bone fractures, Dow AgroSciences argues that EPA had previously dismissed the value of two studies on which NRC relied and implies that NRC did not give proper weight to a recent study from the University of Michigan. (*Id.* at 15–16). Further, Dow AgroSciences claims that NRC actually had little concern for a potential link between fluoride and stage II skeletal fluorosis. According to Dow AgroSciences, NRC emphasized insufficiency of data on this effect and merely called for more research. (*Id.* at 18). Finally, Dow AgroSciences contends that NRC stepped beyond its competence in offering advice on the legal conclusion of whether severe dental fluorosis is an adverse health effect. (*Id.* at 19). Dow AgroSciences notes that a prior NRC panel had declined to make this ultimate conclusion and that a prior court ruling had indicated this was a question of statutory interpretation under SDWA. (*Id.* at 19–20). Switching tacks, Dow AgroSciences then argues there is a dispute within the scientific community as to whether severe dental fluorosis is an adverse effect. (*Id.* at 20).

Sixth, Dow AgroSciences argues that EPA is not authorized to consider exposure to fluoride from artificial fluoridation of public water supplies in evaluating the safety of the sulfuryl fluoride/fluoride tolerances. (*Id.* at 21). Although acknowledging that FFDCA section 408 directs EPA to consider "aggregate exposure" to both pesticides and other related substances, Dow AgroSciences contends that "[i]t is unnecessarily strained and counterintuitive to set tolerances for pesticides in or on food by looking at the therapeutic use of chemically related substances in humans." (*Id.*). As support for this proposition, Dow AgroSciences asserts that the definition of "pesticide chemical residue" limits EPA to considering pesticide chemicals and their degradates and metabolites. Further, Dow AgroSciences claims that the most plausible reading of the term "other related substances" is that this term covers other related "pesticidal" substances. (*Id.*at 22).

Finally, Dow AgroSciences claims that EPA overestimated exposure to fluoride from use of sulfuryl fluoride. Specifically, Dow AgroSciences states that its records show that sulfuryl fluoride has been utilized less extensively than EPA projected and at lower rates than EPA expected. (*Id.* at 34–35). When more realistic values are used in the exposure assessment, Dow AgroSciences contends that fluoride exposure from use of sulfuryl fluoride declines by over 80%. (*Id.* at 35).

2. *Comments on the hearing requests.* In a memorandum submitted to EPA in October 2006, Dow AgroSciences offered several reasons as to why the Objectors were not entitled to a hearing on their claims. First, Dow AgroSciences argues that many of the issues raised by the Objectors fail to state a material issue of fact because they are contingent in nature or otherwise fail to raise a disputed matter. (Ref. 20 at 9). Second, Dow AgroSciences claims that a number of the Objectors' issues dispute science policy determinations by EPA and thus do not constitute a matter of fact to be resolved at a hearing. (*Id.* at 11). For example, Dow AgroSciences identifies EPA conclusions regarding issues such as what constitutes a "conservative assumption," a "significant subpopulation," or an "adverse health effect" as decisions based on policy, as opposed to factual, reasons. Third, Dow AgroSciences asserts that the Objectors' claim of procedural errors by EPA is a legal issue not appropriate for a hearing. Fourth, Dow AgroSciences argues that many of the Objectors' claims are "no more than mere disagreements with Agency determinations made in earlier stages of the rulemaking process." (*Id.* at 12–13). According to Dow AgroSciences:

> In many instances, Objectors support their issues by citing to studies that have already been reviewed by EPA and have, either expressly or effectively, been found scientifically inadequate, procedurally flawed, or lacking in the requisite amount of empirical support. Objectors cite to these studies in spite of the clear edict that "[m]ere differences in the weight or credence given to particular scientific studies * * * are insufficient" to prompt EPA to hold a hearing. [citation omitted]. Clearly, Objectors disagree with EPA's interpretations of these studies, but such disagreement is irrelevant in the Agency's decision to grant a hearing on the objections submitted.

(*Id.* at 13).

Fifth, Dow AgroSciences contends that the Objectors have not submitted sufficient evidence in support of their claims based on Dow AgroSciences' conclusion that the NRC Report, upon which the Objectors rely, does not in fact substantiate the Objectors' position. (*Id.*) Finally, even where the NRC Report does support the Objectors' claims, Dow AgroSciences asserts that a hearing is not appropriate because the NRC Report was performed under the aegis of SDWA to review the fluoride MCLG and SMCL and not the sulfuryl fluoride/fluoride tolerances and because the NRC Report did not generate new data but simply reviewed studies already examined by EPA. (*Id.* at 17–18). Dow AgroSciences concludes that the "NRC's differences in opinion on the three issues detailed below [bone fracture, skeletal fluorosis, severe dental fluorosis] are just that—mere differences of opinion—and should be evaluated as such." (*Id.* at 18).

V. EPA's Proposed Response to the Objections

EPA is proposing to grant the objections to the establishment of the

sulfuryl fluoride/fluoride tolerances based on EPA's agreement with the Objectors that (1) fluoride risks should be assessed based upon a more sensitive endpoint than crippling skeletal fluorosis; and (2) assessing fluoride risks on a more sensitive endpoint shows that aggregate exposure to fluoride for major identifiable subgroups does not meet the safety standard in FFDCA section 408. In reaching this conclusion, EPA has taken into account, in addition to the arguments and data submitted by the Objectors, the 2006 NRC Report on fluoride, the detailed analysis of that Report and followup peer-reviewed assessment of fluoride by EPA's OW, and a revised risk assessment of fluoride performed by EPA's OPP in light of the NRC Report, and usage information submitted by Dow AgroSciences. (All of these materials have been included in the docket for this action.). The conclusions of the NRC Report are described in Unit IV.D. In Units V.A. and V.B., EPA summarizes OW's reassessment of fluoride risk undertaken on the recommendation of NRC, OPP's revised fluoride risk assessment, and sets forth EPA's proposed findings on the safety of the sulfuryl fluoride tolerances. Unit V.C. addresses comments from Dow AgroSciences pertaining to the safety of fluoride, and in particular, the conclusions of the NRC Report on fluoride safety. EPA is inviting public comment on all aspects of this proposal, including the underlying scientific documents discussed in Units V.A and V.B.

A. OW's Reassessment of Fluoride Risk

One of the principal conclusions of the NRC Report was that EPA "should update the risk assessment of fluoride to include new data on health risks and better estimates of total exposure (relative source contribution) in individuals and to use current approaches to quantifying risk, considering susceptible subpopulations, and characterizing uncertainties and variability." (Ref. 17 at 352). As the NRC Report was prepared in the context of evaluating the fluoride MCLG and SMCL for drinking water, EPA's OW took the lead in preparing this revised fluoride risk assessment. OW's risk assessment was broken into two parts: (1) A dose-response analysis directed at establishing a RfD for fluoride; and (2) an exposure and relative source contribution analysis that catalogued and estimated the various sources of fluoride exposure and characterized the risk of that exposure. EPA's OPP contributed information on exposure to fluoride from use of the pesticides sulfuryl fluoride and cryolite (which also breaks down to fluoride). Both parts of the OW risk assessment were subjected to an external peer review by scientific experts.

1. *Dose-response analysis.* OW's dose-response analysis focused on "examining available dose-response data for the critical noncancer effects of fluoride on teeth and bone identified by NRC (2006) as adverse health effects." (Ref. 21 at 1). For the most part, OW relied on the extensive database of epidemiological studies evaluating the relationship between the level of fluoride in drinking water and severe dental fluorosis, dental caries, and stage II skeletal fluorosis. OW noted a preference for older studies because determination of fluoride exposure levels in more recent studies is made more difficult by "the widespread use of fluoride-containing dentifrices and mouth rinses, the use of fluoride supplements in early childhood, and the potential presence of fluoride in processed foods and beverages (a result of the use of fluoridated water in the preparation of these products)." (*Id.* at 9).

a. *Dental fluorosis.* OW reviewed dozens of epidemiological studies bearing on the relationship of fluoride exposure to severe dental fluorosis. OW concluded that these studies supported the NRC Report conclusion that "the weight of evidence indicates that the threshold for severe dental fluorosis occurs at a water fluoride level of about 2 mg/L." (*Id.* at 35). OW also concluded that one study in particular, Dean (1942), provided the best data set for conducting a dose-response analysis. (*Id.*). In reaching this conclusion, OW undertook a detailed examination of the strengths and weaknesses of the study. OW summarized the strengths as follows:

> [The study was selected] due to its large size and geographic scale (22 U.S. communities in 10 States; 5824 children), range of fluoride concentrations evaluated (from 0.0 to 14.1 mg/L), and selection of an appropriate age class (school children primarily between the ages of 9 and 14; an age class in which a very high percentage of permanent teeth have erupted). In addition, every tooth per subject was examined using the same scoring protocol, and the community water supplies were tested for fluoride content by the same chemist. This dataset is sufficiently large and robust to support statistical analysis, the protocol is sound, and there were few alternate sources of commercially available fluoride (*e.g.,* mouthwash, detrifrice, *etc.*) or fluoridated community water supplies to confound the dental fluorosis data collected by Dean (1942) at the time this study was conducted (late 1930's and early 1940's).

(*Id.* at 92) (citations and internal cross-references omitted). Study weaknesses, identified by OW, included the lack of data on water intake amounts and fluoride exposure from food and the fact that the analytical method used for measuring fluoride was not as sensitive to fluoride and free from sensitivity to interfering substances as current fluoride methods. (*Id.* at 12–13). Additionally, although the time period of the study (late 1930's through early 1940's) makes assessing fluoride exposure levels relatively easier than it is today, the time period also raises uncertainties due to differences between the late 1930's/early 1940's and today with regard to "dental hygiene, dietary intakes, body weights and puberty/hormonal condition (*e.g.,* age of menarche)." (*Id.* at 13). OW concluded that the lack of information relating to exposure from food and water could be overcome, to a large extent, by other data. (*Id.* at 103–105; Appendix C). As to the analytical method, OW found that it was "sensitive to small increments of fluoride over a range of 0.0 ppm to 3.0 ppm, the critical range for assessing the threshold for severe [dental] fluorosis. * * *" (*Id.* at 13). A full discussion of the study can be found in the OW's dose-response report. (*Id.* at 10–13, 87–94, 103–107).

OW also reviewed a smaller set of studies examining the relationship between dental fluorosis and dental caries and the relationship between fluoride levels in drinking water and dental caries. These data were examined to assess whether "[t]he relationship between caries and fluoride exposure displays the U-shaped dose-response that characterizes many nutrients where there are adverse effects with intakes that are below those that confer a benefit and adverse effects with intakes that are greater than those with benefit." (*Id.* at 37). After closely examining all of the data, OW concluded:

> Although the data are supportive of NRC (2006) conclusions regarding enamel pitting they are moderately rather than strongly consistent with the hypothesis that the pitting of the enamel leads to an increased risk for caries. Socioeconomic status, availability of dental care, and personal dental hygiene habits are likely to confound the results from individual studies of the caries relationship. For this reason, OW has selected the pitting of the dental enamel as the critical effect for the dose-response analysis. EPA finding on the caries association is consistent with NRC (2006) that the "available evidence is mixed but generally supportive".

(*Id.* at 64).

b. *Skeletal fluorosis.* After reviewing the limited data available on the

relationship between fluoride exposure and stage II skeletal fluorosis, OW concluded that "the currently available data are not sufficiently robust to support a dose-response analysis of the effects of fluoride in drinking water on the skeletal fluorosis." (*Id.* at 84). Specifically, OW found that the limited data "suggested that a daily fluoride dose in excess of 10 mg may be required to produce signs of stage II skeletal fluorosis (except possibly in the case of individuals with renal disease)." (*Id.* at 83). OW also noted that the NRC Report called attention to the fact that a drinking water fluoride level of 4 mg/L can result in bone fluoride levels similar to those associated with stage II or III skeletal fluorosis; however, OW concluded that "because of inconsistencies in the entire data set, it is unlikely that bone fluoride concentration can be used in a dose-response analysis of skeletal fluorosis." (*Id.* at 65).

c. *Bone fractures.* OW found that more data were available on fluoride's potential effect on bone fractures than skeletal fluorosis. OW concluded that these data (1) "in general, support the conclusions of NRC that relative risk of fracture increases with increasing fluoride concentration * * *." (*Id.* at 84); and (2) "indicate[ ] that exposure to concentrations of fluoride in drinking water of 4 mg/L and above is suggestive of and appears to be positively associated with increased relative risk of bone fractures in susceptible populations when compared to populations exposed to 1 mg F/L." (*Id.* at 86). Nonetheless, OW also determined that "there is no clear evidence that fluoride will cause * * * bone fractures at levels as low as those associated with severe dental fluorosis." (*Id.* at 86). In a parallel to fluoride's effect on the frequency of dental caries, OW noted that there are some data suggesting that there is a U-shaped dose-response curve for fluoride's effect on the risk of bone fracture. Agreeing with the NRC Report, OW stated that fluoride in drinking water at 1 mg/L may result in a reduction of bone fractures compared to either higher or lower fluoride exposures. (*Id.* at 84).

d. *Quantification of dose response.* OW's examination of the data on severe dental fluorosis, stage II skeletal fluorosis, and bone fractures led it to conclude that severe dental fluorosis was the adverse effect due to fluoride exposure likely to occur at the lowest exposure level. (*Id.* at 87). As indicated previously, OW also identified the 1942 Dean study as presenting the most useful data for conducting a dose-response assessment. (*Id.*). To confirm the appropriateness of using the data from the Dean study for a dose-response analysis, OW analyzed the data under a statistical procedure known as categorical analysis. That analysis showed that "fluoride concentration in this dataset is significantly and positively associated with severity of effect ($\chi 2 = 1101.86$, $p < 0.0001$)." (*Id.* at 89). OW then used the Benchmark Dose approach to compute a benchmark dose (BMD) and a benchmark dose confidence limit (BMDL) for severe dental fluorosis at various severe dental fluorosis response rates. The lowest response rate of severe dental fluorosis within the range of probability that the dataset could support was severe dental fluorosis affecting at least 0.5% of the population exposed to fluoride at a particular level in drinking water. (*Id.* at 90–91). At a severe dental fluorosis response rate of 0.5%, the BMD for the concentration of fluoride in drinking water was 2.14 mg/L and the BMDL was 1.87 mg/L. OW ran various sensitivity analyses to confirm these results including comparing them to the NOAEL/LOAEL approach. These analyses supported the use of the BMDL from the Dean study data.

To establish a RfD, it was necessary to convert the 1.87 mg/L fluoride concentration in drinking water into an exposure value in terms of milligram of exposure per kilogram of body weight per day (mg/kg/day) and to take into account any other sources of fluoride exposure (also in terms of mg/kg/day). Because the Dean study did not record drinking water intakes or body weight, OW converted the 1.87 mg/L level using more recent data on drinking water intake and body weight. OW calculated exposure values from consumption of drinking water containing 1.87 mg/L for different age groups of children and at different levels of water intake within those age groups. After examining the range of values produced by this exercise, OW chose the value of 0.07 mg/kg/day as the contribution of drinking water to the fluoride RfD at the time of the Dean (1942) study (values ranged from 0.04 mg/kg/day to 0.19 mg/kg/day). That value was chosen because it was the most protective value assuming average water intake that provided some margin of safety above the IOM's minimum adequate intake level for fluoride of 0.05 mg/kg/day. (*Id.* at 101–102). OW concluded that the only other meaningful fluoride exposure at the time of the Dean study was from fluoride in food and OW estimated that exposure level to be 0.01 mg/kg/day based on data collected in the same time period of the Dean study. (*Id.* at 104). Combining these two values yields 0.08 mg/kg/day. Because the 0.08 mg/kg/day value only marginally exceeds the adequate intake value of fluoride and the value was primarily derived from a human study with a large sample size, OW determined that no safety or uncertainty factors were needed in computing the RfD for fluoride. (*Id.* at 105–106) Thus, 0.08 mg/kg/day was chosen as the fluoride RfD. Although the RfD is based on the endpoint of severe dental fluorosis in children, OW concluded that "the RfD is applicable to the entire population since it is protective for the endpoints of severe fluorosis of primary teeth, skeletal fluorosis and increased risk of bone fractures in adults." (*Id.* at 107).

OW described its confidence in the RfD as "medium." (*Id.*). OW's degree of confidence turned on its analysis of the data in the Dean study. On one hand, OW noted that the Dean study was:

- Internally consistent as evidenced by the BMD stability when end points at the high and low end of the curve were removed,
- Supported by later studies on some of the same water sources showing similar concentrations,
- Used average concentration values from 12 consecutive months for all but the three systems with the highest prevalence of severe dental fluorosis, thereby compensating for potential individual and seasonal variation,
- Based on water quality data from the same time period, and not likely to have been compromised by high levels of interfering substances.

(*Id.* at 106–107) On the other hand, OW found that some uncertainty flowed from its reliance on the Dean study because of the difficulties encountered in converting the concentration-response data to dose estimates for the RfD derivation. (*Id.* at 107).

2. *Exposure assessment.* In evaluating exposure to fluoride, OW focused on the following potentially significant sources:

- Drinking water from public drinking water systems;
- Solid foods and beverages such as milk and juices not from concentrate;
- Residues from the use of sulfuryl fluoride;
- Beverages prepared with commercial water which in some cases may have been fluoridated;
- Infant formula made from powdered concentrate;
- Toothpaste; and
- Incidentally ingested soil.

OW determined fluoride exposure from ambient air, dietary supplements, dental treatments, and pharmaceuticals was

minimal or too episodic to be of consideration for assessing long-term exposure. (Ref. 22).

OW evaluated fluoride levels in drinking water based on the largest and most comprehensive set of drinking water compliance monitoring data ever compiled and analyzed by the Agency. The data include records from approximately 136,000 public drinking water systems, many of which include reports of fluoride concentrations. The data span 8 years (1998–2005), with up to quarterly sample analysis for fluoride, depending on the system and reporting requirements. This amounts to approximately 7,000 to 12,000 quarterly samples depicting fluoride residues. There was an increase in the number of States reporting for the subset of data from 2002–2005; therefore, OW focused on those data when estimating exposure to fluoride from drinking water. For that time period, the average of the quarterly means is 0.87 ppm and the average for the quarterly 90th percentile values is 1.43 ppm. OW has also sub-sampled the monitoring data to focus on systems that had at least one detection equal to or greater than 2 ppm fluoride. Those systems represent 4.6 to 8.3% of the reporting systems, annually, during the 2002–2005 time frame and, over the 4-year reporting period, served approximately 10 million people. For water consumption information, OW relied on data from the CSFII for those consumers reporting consumption of drinking water. OW estimated fluoride exposure amounts for mean and 90th percentile consumers of drinking water from public systems considering both mean and 90th percentile fluoride levels. These values ranged from 0.26 mg/day for infants (mean consumption (all consumers), mean fluoride value) to 1.99 mg/day for adults (90th percentile consumption (consumers-only and mean fluoride level . (Ref. at 68–69, Tables 3–5 and 3–6). For 90th percentile consumers consuming mean fluoride levels, the values ranged from 0.63 mg/day for children 1 to 3 years old to 1.74 mg/day for adults. (*Id.* at 94, Table 6–3).

For exposure to fluoride from food, milk, and non-concentrated juices, OW relied on market basket data, dietary surveys, and national food consumption data, for various age groups. OW estimated that fluoride exposure from these sources ranged from 0.25 mg/day for infants to 0.47 mg/day for teenagers. (*Id.* at 90, Table 6–1).

Fluoride exposure from residues of sulfuryl fluoride in food was estimated by OPP based on usage data and residue data relevant to both sulfuryl fluoride's use as a direct commodity fumigant and as a structural fumigant. Estimated exposure values ranged from 0.03 mg/day for infants to 0.09 mg/day for children 7 to 10 years old. (*Id.* at 96, Table 6–5).

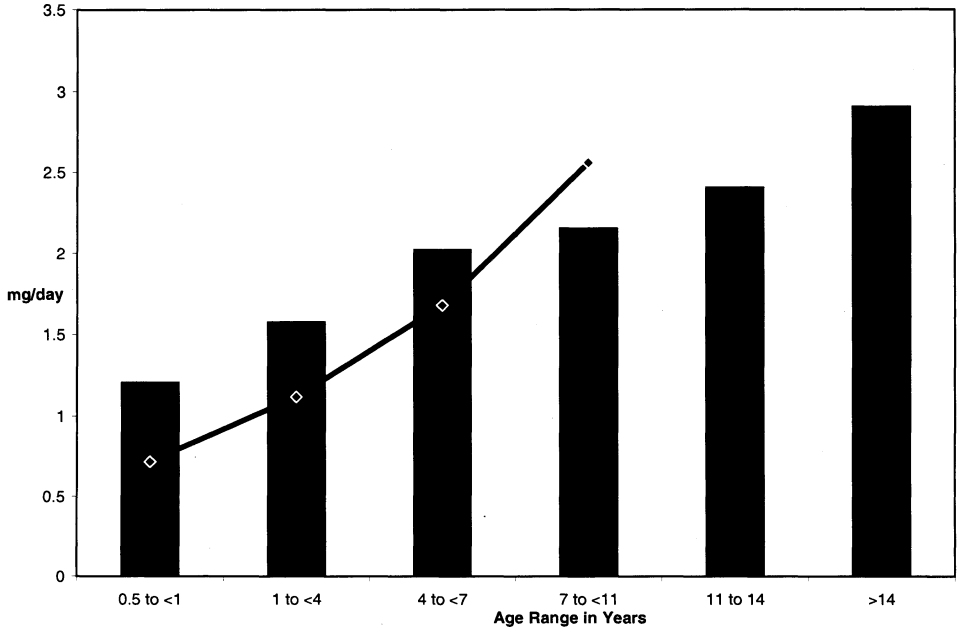
OW estimated fluoride exposure from beverages other than milk and non-concentrated juices from various studies and national consumption data, where appropriate. Fluoride exposure levels from beverages ranged from 0.36 mg/day for 1–<4 year olds to 0.60 mg/day for 7 to 11 year olds. (*Id.* at 92, Table 6–2).

Fluoride exposure from toothpaste was estimated by OW using studies that measure fluoride intake by subtracting the amount of toothpaste left on the toothbrush after brushing and the amount expectorated from the amount initially placed on the toothbrush. OW found a high level of uncertainty with these data because "the confidence bounds around the mean values are indicative of high inter-individual variability," and because the studies were conducted not long after release of FDA recommendations "for children to use only a pea-sized amount of toothpaste when brushing." (*Id.* at 94). OW also relied on data showing that generally young children only brushed their teeth once per day. Toothpaste label directions send different signals on this point, both recommending for children 2 years of age and older that teeth should be brushed "preferably after each meal or at least twice a day" and stating that for younger children a dentist or doctor should be consulted. 21 CFR 355.50(d)(1). Estimated fluoride exposure values ranged from 0.07 mg/day for 0.5 to 1 year olds to 0.34 mg/day for 1 to 4 year olds. (*Id.* at 94, Table 6–4).

OW concluded that other sources of fluoride exposure (*e.g.,* air, dental treatments) were insignificant with the exception of exposure to children through consumption of soil. Fluoride concentrations in the soil in the United States range from less than 10 ppm to 70,000 ppm, with mean or typical levels in the 300–430 ppm range. (*Id.* at 86). Assuming mean levels of fluoride in the soil, OW estimated fluoride exposure for children less than 1 year old to be 0.02 mg/day and for children in the 0–14 age group to be 0.04 mg/day. (*Id.* at 95).

3. *Risk characterization.* In characterizing the risk from fluoride for the purpose of evaluating the fluoride MCLG, OW compared the revised fluoride RfD (0.08 mg/kg/day) to the significant sources of fluoride exposure described previously. OW used average exposure values as to all sources of exposure other than drinking water. For drinking water, OW, examined several different variations of concentration level and consumption level, but principally relied on the approach in long-held OW policy in establishing national drinking water standards that recommends use of average fluoride concentrations in water and 90th percentile consumption levels. (*Id.* at 107–110). OW's characterization of risk using these assumptions is shown in Figure 1.

Figure 1. Total Daily Fluoride Intake Estimates Relative to the Proposed RfD (in mg/day) Using 90th Percentile Drinking Water Intake Data for Consumers Only and the Mean Drinking Water Fluoride Concentration (0.87 mg/L)



(*Id.* at 105, Figure 8–1).

OW explained the meaning of Figure 1 in the following manner:

When examining Figure [1] it is important to remember that the RfD represents an exposure that is estimated to provide the anticaries benefits from fluoride without causing severe dental fluorosis in 99.5% of the children who drink water with 0.87 mg/L F at a 90th percentile intake level and have average intakes from other media during the period of secondary tooth formation. Based on the dose-response for severe dental fluorosis in EPA (2010a) only 0.5% or fewer of children consistently ingesting fluoride at a level equivalent to the RfD for a several month period would be at risk of experiencing severe dental fluorosis in two or more teeth.

(*Id.* at 104–105).

OW noted that the data show both that fluoride exposure has increased over time and that the incidence of all types of dental fluorosis has also increased. According to OW, "The prevalence of dental fluorosis has increased from 10–12% in the areas with about 1 mg/L in drinking water at the time of Dean to 23% in 1986/87 and to 32% in the 1999–2002 NHANES survey."

(*Id.* at 108) (citations omitted).

OW summarized its overall conclusions as follows:

- Some young children are being exposed to fluoride up to about age 7 at levels that increase the risk for severe dental fluorosis.
- The contribution of residential tap water to total ingested fluoride is lower that it was in the past.
- Use of fluoridated water for commercial beverage production has likely resulted in increased dietary fluoride in purchased beverages, adding to the risk for over-exposure.
- The increase of fluoride in solid foods because of fluoridated commercial process water is more variable than that for beverages.
- Incidental toothpaste ingestion is an important source of fluoride exposure in children up to about 4-years of age. However, use of fluoridated toothpaste is not recommended for children under age 2 according to FDA guidance and package labeling suggesting the need for greater parental awareness of the FDA (2009) recommendations.
- Ambient air, soils, and sulfuryl fluoride residues in foods are minor contributions to total fluoride exposure.

(*Id.* at 108–109).

B. OPP's Revised Fluoride Risk Assessment

In light of the revised fluoride risk assessment by EPA's OW, EPA's OPP has conducted a revised aggregate assessment of fluoride exposure and risk under FFDCA section 408. (Ref. 23). EPA is inviting public comment on all aspects of the revised aggregate assessment.

1. *Hazard/dose-response assessment.* OPP agrees with OW's choice of severe dental fluorosis as the endpoint for assessing chronic risk from fluoride exposure. As noted, both OW and OPP had treated several dental fluorosis as a cosmetic effect and not an adverse health effect. Following the NRC Report and the re-examination of this issue by both OW and OPP, EPA has concluded that severe dental fluorosis is an adverse effect due to the fact that the pitting it causes in the permanent teeth is a structural defect to the teeth. As OW's analysis explains:

Pitting of the enamel is a structural defect that weakens the barrier between the oral environment and the dentin of the teeth. It is progressive in that the enamel can flake off from the sides of the pits allowing them to become progressively larger. Furthermore, the dentin of teeth with severe dental

fluorosis is hypomineralized and structurally variant increasing the importance of the enamel's protective function.

(Ref. 21 at 64) (citations omitted).

OPP also agrees with OW's choice of 0.08 mg/kg/day as a NOAEL for severe dental fluorosis relying on the Dean study, and the use of that value as a Point of Departure for calculating the RfD. Further, OPP concurs that neither an inter- or intra-species safety factor should be used in the RfD calculation. An inter-species factor is unnecessary because the endpoint is from a human epidemiological study; an intra-species factor is not needed given the extensiveness of the data and the fact that it studied the subpopulations of concern, children of different ages.

Given these findings, OPP concludes that the Objectors were correct in contesting the reliance on the endpoint of crippling skeletal fluorosis to set a RfD for fluoride. OPP agrees that the RfD should be based on a more sensitive endpoint—severe dental fluorosis. It follows that the Objectors were also correct to object to use of children-specific RfD values based on the endpoint of crippling skeletal fluorosis. A RfD based on the Dean study is appropriate for children, however, because such a RfD is derived from data on the effects of fluoride on children.

2. *Exposure assessment.* OPP's revised exposure analysis depends heavily on OW's Relative Source Contribution Analysis. A brief description of how that data and analysis have been incorporated into a FFDCA section 408 risk assessment is provided in the following sections.

a. *Fluoride from sulfuryl fluoride.* In the exposure assessments for the 2004 and 2005 tolerance actions, EPA conducted a somewhat refined exposure assessment of fluoride exposure in food from use of sulfuryl fluoride as both a commodity fumigant and as a structural fumigant for food handling facilities. Taking into account comments OPP has received from Dow AgroSciences, OPP has further refined this aspect of the exposure assessment. (Ref. 24). The three main refinements are:

(1) OPP used a regression analysis to estimate residue values of fluoride in food that occur from actual use rates rather than assuming residue values as measured under maximum application rates;

(2) OPP used a probabilistic analysis to estimate residues resulting from possible sequential treatment of food (*e.g.,* fumigation of raw commodity, incidental treatment during fumigation of structure, fumigation of the processed commodity) rather than conservatively assuming that 100% of food was sequentially treated; and

(3) OPP used more extensive data on the percent of food treated with sulfuryl fluoride. EPA used methyl bromide usage as the basis for estimating the percent usage of sulfuryl fluoride because sulfuryl fluoride was introduced as a replacement for methyl bromide. The refinements to this aspect of the exposure assessment result in a reduction of estimated exposure values to fluoride from sulfuryl fluoride use of roughly an order of magnitude.

Consistent with its well-established practice for chronic exposure assessments, OPP assessed exposure to fluoride residues in food based on average residue values and average food consumption values. Given the national food distribution patterns in the United States, exposure to foods with different residue levels average out over time. Further, because different people eat different foods in different amounts, it would dramatically overstate exposure to assume that a single person consumed all foods at a high end consumption value. The revised exposure values for fluoride from sulfuryl fluoride are presented in Table 1.

TABLE 1—SUMMARY OF SULFURYL FLUORIDE CONTRIBUTIONS TO DIETARY FLUORIDE EXPOSURE

Age range, years	Average estimated exposure (mg/day)			Average estimated exposure mg/kg/day		
	SF structural [a]	SF food [b]	Total	SF structural [a]	SF food [b]	Total
0.5–<1	0.0087	0.021	0.030	0.0008	0.0019	0.0027
1–<4	0.012	0.033	0.045	0.0008	0.0022	0.0030
4–<7	0.015	0.047	0.062	0.0007	0.0022	0.0029
7–<11	0.017	0.054	0.071	0.0005	0.0017	0.0022
11–<14	0.018	0.068	0.086	0.0004	0.0014	0.0018
14+	0.019	0.058	0.076	0.0003	0.0008	0.0011

[a] Reflecting residues resulting from fumigation of structures that may contain human food products.
[b] Reflecting residues resulting from intentional fumigation of human foods.

(Ref. 23 at 10, Table 1).

b. *Fluoride from cryolite.* Previously, OPP estimated fluoride exposure from use of the pesticide cryolite using residue data from cyrolite field trials and data on the percent of food treated with cryolite. Since cryolite has been in use for years, cryolite residues in food are captured by the monitoring data OW collected on fluoride data in food generally. As discussed in the next section, OPP is using this monitoring data in its exposure assessment and thus a separate assessment of fluoride from cryolite would result in double-counting.

c. *Fluoride in food and beverages.* OPP is relying on the comprehensive OW analysis of the extensive fluoride monitoring data in published literature in estimating fluoride exposure from foods and beverages. The food monitoring data predates sulfuryl fluoride use and thus does not capture those residue levels. Consistent with how it conducts chronic exposure assessments for pesticide residues in food, OPP has used central-tendency values in estimating exposure. Exposure estimates for fluoride from background levels in food (including cryolite residues) and in prepared beverages are presented in Table 2.

TABLE 2—SUMMARY OF ESTIMATED FLUORIDE EXPOSURES ATTRIBUTABLE TO BACKGROUND LEVELS IN FOOD AND BEVERAGES

Age range, years	Body weight, kg	Estimated fluoride exposure (mg/day)			Estimated fluoride exposure (mg/kg/day)		
		Solid food *	Beverages	Total	Solid food *	Beverages	Total
0.5–<1	9	0.26	*	0.26	0.029	*	0.029
1–<4	14	0.16	0.36	0.52	0.011	0.026	0.037
4–<7	21	0.35	0.54	0.89	0.017	0.026	0.042
7–<11	32	0.41	0.60	1.01	0.013	0.019	0.032
11–<14	51	0.47	0.38	0.85	0.0092	0.0075	0.017
14+	70	0.38	0.59	0.97	0.0054	0.0084	0.014

* Solid food includes milk as well as fruit and vegetable juices not made from concentrate. These are not categorized as beverages in the FDA Total Diet Study (Egan *et al.,* 2007). For the age range 0.5–<1 year, all fluoride was considered to be from powdered formula and falls into the food category.

(Ref. 23 at 15, Table 6).

d. *Fluoride from public drinking water systems.* People are exposed to fluoride from public drinking water both by direct consumption of the water and from indirect consumption of the water after its use in the preparation of foods and beverages in the home. References in this section to drinking water exposure are intended to capture both of these types of exposure. Exposure to fluoride from water containing fluoride residues that is used in the commercial preparation of food and beverages is accounted for in the estimates of fluoride in food and beverages. (*See* Unit V.B.2.c). To estimate exposure, OPP has coupled average, per-capita consumption from the CSFII with the fluoride concentrations for the water systems described previously. The CSFII consumption estimates include drinking water (direct water) and water used for in-home preparation of foods and beverages (indirect water).

In the earlier exposure assessments, OPP assumed that fluoride in drinking water was present at 2 mg/L. Extensive monitoring data on fluoride levels in drinking water, however, have now been collected and analyzed by OW in conducting its Relative Source Analysis in response to the NRC Report. OPP has relied on these data in estimating exposure. (Ref. 23 at 10–15).

Generally, OPP estimates pesticide exposure from drinking water by focusing on watersheds that are likely to have high end residue levels. This approach is based on several factors. First, pesticide residues in watersheds can have widely different values based on their regional relationship with agricultural areas and environmental factors (*e.g.,* soil type, rainfall amount). Second, consumption of drinking water, unlike food, is mainly a local phenomenon—*i.e.,* tap water is not an amalgam from drinking water systems around the country. Thus, focusing on watersheds with high-end residue levels is critical to fulfilling EPA's statutory obligation to consider aggregate exposure to "major identifiable subgroups of consumers * * *." (21 U.S.C. 346a(b)(2)(D)(vi)). Accordingly, in the first instance, OPP has used OW's drinking water monitoring data to identify drinking water systems with high-end fluoride levels. OPP has focused on water systems that have had at least one measured fluoride value of greater than 2 mg/L, at least one measured value of greater than 3 mg/L, and at least one measured value of greater than 4 mg/L. These groupings of water systems were used because of the significant population groups served by these systems—from well over 1 million to roughly 10 million. OPP believes it is reasonable to use average monitoring values from these groups of water systems because of the relative stability of fluoride levels in water. Importantly, these average values bracket OPP's prior assumption of 2 mg/L with the average values ranging from 1.76 mg/L to 2.58 mg/L.

Given the unusual circumstances of fluoride—not only are there multiple sources in addition to pesticidal sources but several sources are the result of intentional actions designed to result in wide-spread national exposure—OPP believes that OW's approach to assessing fluoride exposure in its Relative Source Analysis under SDWA has relevance to its aggregate exposure analysis under FFDCA section 408. OW's Relative Source Analysis focuses on high-end water consumers who are exposed to average exposures calculated on a national basis. Because the population concerned here is so large, roughly 300 million people, even looking at high-end consumers (OW's traditional approach is to use the 90th percentile) represents consideration of a large population subgroup.

Table 3 provides exposure estimates for fluoride in drinking water from both OPP and OW approaches.

TABLE 3—FLUORIDE EXPOSURE ESTIMATES (MG/KG/DAY) FROM MUNICIPAL WATER [1]

Age range, years	Fluoride concentration in drinking water (mg/L); consumption percentile			
	0.87 90th	1.76 Average	2.28 Average	2.59 Average
0.5–<1	0.093	0.077	0.10	0.11
1–<4	0.045	0.040	0.052	0.059
4–<7	0.039	0.033	0.043	0.049
7–<11	0.027	0.024	0.031	0.035
11–<14	0.024	0.018	0.024	0.027
14+	0.025	0.026	0.033	0.038

[1] Includes drinking water as well as water for in-home preparation of foods and beverages. Estimates are based on 90th percentile consumer only or average *per capita* consumption, as indicated, and do not include fluoride from toothpaste, from soil, or from sulfuryl fluoride.

(Ref. 23 at 11, Table 3; 14, Table 5).

e. *Fluoride from toothpaste.* OW has comprehensively reanalyzed the data on fluoride exposure from toothpaste taking into consideration all available studies. The results of that analysis are presented in Table 4.

TABLE 4—SUMMARY OF ESTIMATED FLUORIDE EXPOSURES FROM INCIDENTAL INGESTION OF FLUORIDATED TOOTHPASTE

Age range, years	Estimated fluoride exposure (mg/day)		Estimated fluoride exposure (mg/kg/day*)	
	1 brushing per day	2 brushings per day	1 brushing per day	2 brushings per day
0.5 – <1	0.07	0.14	0.0078	0.016
1 – <4	0.34	0.68	0.024	0.049
4 – <7	0.22	0.44	0.010	0.021
7 – <11	0.18	0.36	0.0056	0.011
11 – <14	0.2	0.4	0.0039	0.0078
14+*	0.1	0.2	0.0014	0.0029

* No data were available for this age group. The exposure estimate is one half that of the 11 to 14 year group.

(Ref. 23 at 16, Table 7).

OW was also able to identify limited data on the frequency of teeth brushing by children. Those data are presented in Table 5.

TABLE 5—NUMBER OF TOOTHBRUSHINGS PER DAY REPORTED FOR CHILDREN (SIX MONTHS TO FIVE YEARS OLD)

Study	N =	Age (years)	Percentages*		
			1 time/day	2 times/day	3 times/day
Simard *et al.,* 1989	23	2 to 5	4.8	71.4	23.8
Simard *et al.,* 1991	15	1 to 2	60	32	8
Levy *et al.,* 1997	899	0.5	41.2	16.9	6.3
	665	0.75	33.2	17	3.1
	508	1	37	14.7	3.5
Franzman *et al.,* 2006	90	1.3	48	14	4
	100	2	51	23	2
	100	3	51	24	1

* Some studies also reported those brushing their teeth less than once per day and more than three times per day. In these cases the percentages do not add up to 100%.

(Ref. 22 at 81, Table 4–10). Based on the fact that a substantial portion of children brush two or more times per day and that brushing twice per day is consistent with health care recommendations, OPP is assuming two brushings per day in its assessment.

f. *Fluoride from soil.* Young children are exposed to fluoride from inadvertent consumption of soil. OPP estimated fluoride exposure from soil using standard EPA estimates on soil consumption and assuming average fluoride residues in soil. These estimates are presented in Table 6.

TABLE 6—SUMMARY OF ESTIMATED FLUORIDE EXPOSURES FROM INCIDENTAL INGESTION OF SOIL AND OUTDOOR DUST

Age range, years	Estimated fluoride exposure* (mg/day)	Estimated fluoride exposure* (mg/kg/day)
0.5–<1	0.02	0.0022
1–<4	0.04	0.0029
4–<7	0.04	0.0019
7–<11	0.04	0.0013
11–<14	0.04	0.00078
14+	0.02	0.00029

* Assumes soil and dust contains 400 ppm fluoride.

(Ref. 23 at 17, Table 8).

g. *Other sources of fluoride exposure.* Although people are also potentially exposed to fluoride from fluoride in ambient air, fluoride dental treatments, and pharmaceuticals, among other things, OW concluded that these sources of exposure are insignificant compared to other sources of fluoride exposure. Accordingly, OPP is not including such exposures in its aggregate assessment. (Ref. 23 at 16).

3. *Children's safety factor.* In choosing a revised RfD for fluoride, OW did not apply any uncertainty or safety factors to the BMDL for severe dental fluorosis. OW reasoned that uncertainty factors were not warranted due to the extensive human epidemiological data on the effects of fluoride, including extensive data on children, the population of greatest concern. Decisions on pesticide tolerances, however, require OPP to apply special provisions for protection of children. Specifically, section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. In making determinations on this children's safety factor, OPP has focused on the statutory factors of data completeness with regard to toxicity and exposure and evidence bearing on pre- and post-natal toxicity.

As with so many other aspects of the fluoride risk assessment, application of

the children's safety factor provision to fluoride presents unique issues. OPP considered the following factors in determining whether reliable data show that an additional safety factor other than the default 10X value would be safe:

a. *Toxicity data.* As a result of the decades-long water fluoridation program in the United States as well as the substantial areas with high natural levels of fluoride in drinking water, OPP has an epidemiological dataset for fluoride that is far more extensive than for any other pesticide. EPA also has an extensive set of animal data on sulfuryl fluoride and to the extent that sulfuryl fluoride breaks down to the fluoride anion during testing, these studies capture the effects of fluoride (dental fluorosis was observed in a number of studies). On the other hand, OPP has recently requested additional studies on sulfuryl fluoride, a developmental neurotoxicity study and an immunotoxicity study, and the NRC Report identified several areas, notably brain and endocrine effects, where further study would be useful. On the whole, however, OPP concludes that the completeness of the database with regard to fluoride exceeds what is generally available even on the most well-studied pesticides.

b. *Exposure data.* OPP has an extremely extensive database on fluoride levels in drinking water due to the water monitoring data OW has collected. OPP also has reliable data on fluoride exposure from sulfuryl fluoride and on background levels of fluoride in food. To the extent sulfuryl fluoride has not replaced methyl bromide as a fumigant the fluoride estimate from sulfuryl fluoride overstates exposure. There is some uncertainty as to the amount of fluoride exposure from toothpaste. There are several factors here: Data on fluoride exposure from toothpaste are less extensive and are highly variable; the data may not reflect the latest recommendations on the amount of toothpaste children should use; label directions for adults and children 2 years old and above state that teeth should be brushed "thoroughly, preferably after each meal or at least twice a day;" and label directions for children below 2 years of age state that a dentist or doctor should be consulted. However, by assuming two brushings per day and relying on studies that may have used greater amounts of toothpaste than is used today as well as focusing on high-end exposure groups for drinking water, OPP believes it has addressed any uncertainties regarding fluoride exposure from toothpaste.

c. *Pre- and post-natal toxicity.* Not only does OPP have extensive data identifying fluoride's effects in humans and the dose at which those effects occur, but fluoride, unlike most pesticides or their metabolites, is considered a human nutrient. Fluoride's classification as a nutrient—especially its role at certain doses in protecting teeth—cannot be ignored in the safety factor calculation. OPP is averse to choosing a safety factor that would result in the choice of a PAD that indicates that fluoride is harmful at levels below the adequate intake level for beneficial effects. The Objectors have raised concerns about potential other effects of fluoride—for example, brain, endocrine, kidney, and reproductive effects. Nonetheless, data on these effects generally either shows effects only at considerably higher levels than the levels causing severe dental fluorosis or are very equivocal.

On balance, the extensiveness of the data on toxicity of fluoride and human exposure to it, the clear data defining the safe level for the effect of concern on children, and fluoride's status as a human nutrient at levels only slightly below the level that is protective against severe dental fluorosis lead OPP to conclude that reliable data show that an additional safety factor for the protection of children is not necessary. Accordingly, OPP has not used an additional safety factor in its fluoride risk assessment. Hence, the PAD for fluoride is equivalent to the RfD (0.08 mg/kg/day). (Ref. 23 at 9).

4. *Risk characterization.* To characterize the risk of fluoride, OPP has aggregated exposure to fluoride from sulfuryl fluoride, background levels in food (including from cryolite), beverages, drinking water, toothpaste, and soil, and compared that aggregated exposure to the PAD. In evaluating exposure to major identifiable subgroups of consumers, OPP believes that for fluoride it is appropriate to consider the aggregate exposure of at least four different subgroups:

a. Communities served by a water system with at least one sample showing fluoride levels greater than 2 mg/L (2 mg/L communities);

b. Communities served by a water system with at least one sample showing fluoride levels greater than 3 mg/L (3 mg/L communities);

c. Communities served by a water system with at least one sample showing fluoride levels greater than 4 mg/L (4 mg/L communities); and

d. High-end water consumers generally.

The aggregate exposure of these subgroups relative to the RfD/PAD is shown in Table 7:

TABLE 7—AGGREGATE EXPOSURE COMPARED TO RFD BY AGE GROUPS (MG/KG/DAY)

Age groups	RfD/PAD	High-end water consumers	2 mg/L community	3 mg/L community	4 mg/L community
0.5–<1	0.08	0.13	0.13	0.15	0.16
1–<4	0.08	0.11	0.13	0.14	0.15
4–<7	0.08	0.097	0.10	0.11	0.12
7–<11	0.08	0.068	0.070	0.077	0.081
11–<14	0.08	0.047	0.045	0.051	0.054
14+	0.08	0.042	0.044	0.051	0.056

(Ref. 23 at 21, Table 9).

This risk assessment shows that aggregate fluoride exposure to young children exceeds the RfD/PAD under various different methods of identifying major population subgroups. In evaluating this assessment at least two other factors are relevant. First, the assessment of the 2–4 mg/L communities deviates from OPP's traditional approach to assessing exposure in drinking water in that it averages exposures from systems that are surface water-based and systems that are groundwater-based. EPA generally assesses drinking water exposure on the higher value from surface water or groundwater because people get the majority of their drinking water exposure from one location. For fluoride, focusing only on groundwater-based systems would modestly increase the exposure estimate. Second, this assessment does not take into account those people that depend on private drinking water wells and not public drinking water systems. Drinking water

wells in certain portions of the United States can have fluoride levels exceeding those used in the assessments discussed previously.

Based on these assessments, EPA cannot conclude that there is a reasonable certainty of no harm for certain major identifiable groups of consumers from aggregate exposure to fluoride. Therefore, EPA cannot make the required finding that the sulfuryl fluoride and fluoride tolerances are "safe" and is proposing to grant the Objectors' objections to the establishment of the sulfuryl fluoride and fluoride tolerances promulgated on January 23, 2004, and July 15, 2005.

C. Comments From Dow AgroSciences

As noted previously, Dow AgroSciences has filed comments contesting the Objectors' claims regarding the safety of fluoride. First, Dow AgroSciences argues that the Objectors have only potentially shown that small, localized groups of people are exposed to unsafe levels of fluoride and such small groups do not constitute a "major identifiable" subgroup under FFDCA. EPA disagrees with Dow AgroSciences that the groups of people exposed at levels that exceed the RfD are not major identifiable subgroups of consumers. As noted previously, the subgroups OPP relies upon include at least 1 million, and in some cases, many millions of people. Although the individuals within these subgroups facing unacceptable risks from aggregate fluoride exposure are limited to infants and children up to the age of 7, the persons at risk remain substantial.

Second, Dow AgroSciences challenges whether the NRC Report showed that there is a more sensitive endpoint than crippling skeletal fluorosis. Dow AgroSciences' comments on this issue focused on the endpoints of bone fracture, stage II skeletal fluorosis, and severe dental fluorosis.

1. *Bone fracture.* Dow AgroSciences argued that the NRC Report did not place sufficient weight on a 2005 observational study from the University of Michigan (Sowers) and placed too much weight on two other studies (Alarcon and Li) that were judged unreliable by OPP. OW undertook a comprehensive review of all of the available data. Like NRC, it found certain weaknesses in the 2005 Sowers study but overall considered it along with the Li study and several other studies to be one of the key studies for assessing the risk of bone fractures. The Alarcon study was given less weight. Also similar to the NRC Report, OW concluded that "the available data indicate that exposure to concentrations of fluoride in drinking water of 4 mg/L and above is suggestive of and appears to be positively associated with increased relative risk of bone fractures in susceptible populations when compared to populations exposed to 1 mg mg/L." (Ref. 21 at 86). OW also noted, however, that "there are insufficient data to conclude that this increase in relative risk would also apply if comparisons were made to groups exposed to negligible fluoride concentrations or if comparisons were made based on total fluoride intake rather than on the basis of drinking water concentrations." (*Id.*). Ultimately, OW concluded that the fluoride RfD should be based on severe dental fluorosis and that this endpoint was protective of any risk of bone fractures and thus a more definite resolution of this issue is unnecessary.

2. *Stage II skeletal fluorosis.* Dow AgroSciences emphasized that the NRC Report's finding on fluoride's link to stage II skeletal fluorosis were equivocal. OW's conclusions on stage II skeletal fluorosis were similar to those of NRC. OW found that "[t]he results of the limited epidemiological studies and case histories suggest that a daily fluoride dose in excess of 10 mg may be required to produce signs of stage II skeletal fluorosis (except possibly in the case of individuals with renal disease)." (Ref. 21 at 83). But OW concluded that "the currently available data are not sufficiently robust to support a dose-response analysis of the effects of fluoride in drinking water on skeletal fluorosis." (*Id.*). As with risk of bone fractures, because OW determined that the fluoride RfD should be based on severe dental fluorosis and that this endpoint was protective of any risk of stage II skeletal fluorosis, a more definite resolution of this issue is unnecessary.

3. *Severe dental flurosis.* Dow AgroSciences challenged the competency of NRC to make the legal conclusion that severe dental fluorosis is an adverse health effect and also argued that there is dispute within the scientific community regarding the adversity of severe dental fluorosis. Without question, it is EPA that is charged with interpreting SDWA and making legal findings in implementation of that Act. Nonetheless, EPA does not view NRC as stepping beyond its scientific advisory role in its report. OW has previously defined adverse health effects as involving functional impairment and NRC focused on whether the data showed functional impairment in reaching a conclusion on whether severe dental fluorosis is an adverse health effect. For example, the NRC Report states:

> One of the *functions* of tooth enamel is to protect the dentin and, ultimately, the pulp from decay and infection. Severe enamel fluorosis compromises this health-protective *function* by causing structural damage to the tooth. The damage to teeth caused by severe enamel fluorosis is a toxic effect that the majority of the committee judged to be consistent with prevailing risk assessment definitions of adverse health effects.

(Ref. 17 at 127) (emphasis added).

Finally, while there may be a dispute within the scientific community about how to characterize the adversity of severe dental fluorosis, there does not appear to be any significant dispute over the science question of whether severe dental fluorosis results in the pitting of dental enamel. As Dow AgroSciences has pointed out, it is EPA's responsibility to make the legal determination of whether this effect should be categorized as an adverse health effect.

Third, Dow AgroSciences argues that EPA is not authorized to aggregate fluoride added to drinking water for therapeutic purposes with fluoride from sulfuryl fluoride because fluoride from water fluoridation is neither a "pesticide chemical" under FFDCA nor an "other related substance." Dow AgroSciences claims that FFDCA's reference to "other related substances" means other related "pesticidal" substances. EPA disagrees with Dow AgroSciences' interpretation of FFDCA section 408 for several reasons. First, there is no exclusion from the aggregate exposure requirements for substances that have a therapeutic effect at certain levels. Second, there is no serious dispute that at certain levels exposure to fluoride is not therapeutic but harmful, and Dow AgroSciences cannot be contending that exposure to fluoride for water fluoridation does not aggregate within the body with fluoride from other exposures. Third, a significant portion of the U.S. population is exposed to fluoride in water that is naturally-occurring rather than added for therapeutic purposes. Finally, EPA has previously rejected attempts to limit the plain meaning of "other related substances" and does not believe that Dow AgroSciences has offered any compelling legal, policy, or scientific reasoning for adopting an interpretation that would bar EPA from considering the full effects of aggregate exposure to a substance. (*See* 69 FR 30042, 30073, May 26, 2004)(FRL–7355–7).

Dow AgroSciences also claims that EPA overestimated exposure to fluoride from use of sulfuryl fluoride. EPA agrees with this comment and, as described

previously, EPA has incorporated information from Dow AgroSciences on sulfuryl fluoride usage in its sulfuryl fluoride/fluoride exposure assessment.

VI. EPA's Proposed Response to Requests for Hearing

Because EPA is agreeing with the Objectors that the sulfuryl fluoride tolerances do not meet the safety standard and is proposing to grant their objections to the establishment of those tolerances, no further action is needed with regard to the Objectors' hearing requests. At this point, there is no material dispute of fact with regard to the Objectors' claims that warrants a hearing.

VII. EPA's Proposed Response to Request for a Stay and EPA's Proposed Expiration Date for Tolerances

Following release of the NRC Report, the Objectors filed a motion with EPA requesting a stay of the sulfuryl fluoride tolerances. (Ref. 2). In arguing for a stay, the Objectors relied on the four factors contained in *Virginia Petroleum Jobbers Ass'n* v. *FPC,* 259 F.2d 921 (DC Cir. 1958):

(1) Has the petitioner made a strong showing that it is likely to prevail on the merits;

(2) Has the petitioner shown that without such relief it will be irreparably harmed;

(3) Would issuance of the stay substantially harm other parties interested in the proceedings;

(4) Wherein lies the public interest.

In prior tolerance proceedings EPA has indicated it would consider the criteria in FDA's regulations pertaining to stay requests. (*See, e.g.,* 61 FR 39528, 39540, July 29, 1996). Those regulations provide that a stay shall be granted if a petitioner can show all of the following:

(1) The petitioner will otherwise suffer irreparable injury.

(2) The petitioner's case is not frivolous and is being pursued in good faith.

(3) The petitioner has demonstrated sound public policy grounds supporting the stay.

(4) The delay resulting from the stay is not outweighed by public health or other public interests.

(21 CFR 10.35).

The criteria under either approach are quite similar. Thus, in evaluating the stay request EPA will concentrate on an amalgam of the four factors:

- What are the merits of the Objectors' claims;
- Have the Objectors' shown that irreparable harm will occur in the absence of a stay;
- Would a stay substantially harm other parties or cause other effects on the public health; and
- Wherein lies the public interest.

EPA also believes that these factors are relevant in choosing an effective date for its proposed grant of the objections.

A. Merits of the Objectors' Claims

As indicated, EPA agrees with the Objectors that the sulfuryl fluoride tolerances do not meet the safety standard when aggregate fluoride exposure is considered and thus this factor supports granting the stay and making EPA's proposed grant of the objections effective relatively quickly.

B. Irreparable Harm to Objectors

The Objectors argue that the public is irreparably harmed by the sulfuryl fluoride tolerances because aggregate exposure to fluoride poses a long litany of threats to health. According to the Objectors, the NRC Report linked fluoride not just to adverse effects on bones and teeth but also other effects ranging from neurological impacts to cancer. (Ref. 2 at 11, 13–15). The weight of this argument, however, is undermined by two factors.

First, it is beyond dispute that NRC, after a comprehensive evaluation of all of the possible adverse effects of fluoride, recommended that OW lower the fluoride MCLG due to only three very specific health risks: severe dental fluorosis; stage II skeletal fluorosis; and bone fractures. (Ref. 17 at 345–346, 352). Although the NAS recommended further research on some of the other health risks cited by the Objectors, the NAS did not find sufficient evidence on any of them to support a lowering of the MCLG.

Second, and more importantly, the threat that fluoride poses to teeth and bones is due to aggregate exposure to fluoride not the fluoride in food resulting from use of sulfuryl fluoride when viewed in isolation. Use of sulfuryl fluoride is responsible for a tiny fraction of aggregate fluoride exposure. For example, for the most highly-exposed age groups in the populations examined in the revised risk assessment, fluoride from sulfuryl fluoride accounts for about 2 to 3% of aggregate fluoride exposure. Given the aggregate level of fluoride exposure, termination of the use of sulfuryl fluoride would not change the fact that aggregate fluoride levels would still exceed the safe level for highly-exposed subpopulations.

C. Harm to Others/Other Public Health Harms

1. *Overview.* Immediate termination of sulfuryl fluoride tolerances will lead to some combination of the following negative consequences depending how food processors and distributors for the various affected commodities respond: an increase in the use of inventories of the stratospheric ozone-depleting pesticide, methyl bromide; a disruption in the amount and availability of certain commodities; an increase in contamination of commodities with insect parts and waste posing potential health risks; and/or increased short-term and long-term costs for food processors, distributors, and consumers. To the extent that methyl bromide cannot be obtained in sufficient quantities to fill the void left by the absence of sulfuryl fluoride, the other potential negative impacts will be heightened.

In the following discussion, EPA first describes the likely effects that would occur in individual food markets if sulfuryl fluoride use is terminated. Then EPA presents more general information on the availability of methyl bromide, the potential disruption that can occur when food is contaminated with insect parts and waste, and potential health effects from such contamination.

2. *Likely effects in specific markets.* OPP analyzed three uses of sulfuryl fluoride that provide a representative view of how the food industries relying on sulfuryl fluoride may respond to a loss of that pesticide and the impacts of that response:

- Use of sulfuryl fluoride as a structural treatment in flour mills;
- Use of sulfuryl fluoride as a food fumigant for cocoa beans; and
- Use of sulfuryl fluoride as a food fumigant for walnuts.

Each of these uses is discussed in more detail in the next section. (Refs. 25 and 26).

a. *Flour mills.* Generally, flour mills and other food processing facilities are fumigated two to three times per year to control insect populations (the primary pests are the red flour beetle and the confused flour beetle). In the absence of sulfuryl fluoride, there are potentially three possible alternative options whose costs and efficacy differ from sulfuryl fluoride: (1) Use of another chemical pesticide; (2) use of non-chemical controls; or (3) complete removal of all food from the facility during fumigation with sulfuryl fluoride.

i. *Chemical control.* The only chemical alternative for use throughout food processing facilities is methyl bromide. As explained later in this document, mills and food processing

structures that do not have approved critical uses for a given year may not obtain methyl bromide produced under a critical use exemption. To the extent facilities have an approved critical use or can obtain methyl bromide from pre-phase-out inventories, mills will likely switch to methyl bromide if sulfuryl fluoride uses are immediately eliminated. Costs for use of methyl bromide and sulfuryl fluoride appear to be fairly similar at this time. No other chemical pesticides are a viable alternative. Phosphine is a commonly-used food fumigant that could be used in some portions of a flour mill; however, phosphine is highly corrosive to silver and copper metals and their alloys and thus cannot be used in the production areas of mills that contain electronic and electrical equipment which heavily rely on these metals. In terms of total area, the portion of a mill devoted to production is substantial and a failure to effectively dis-infest the production area would quickly result in re-infestation of the entire facility. Thus, phosphine is not an alternative to the use of sulfuryl fluoride. (Ref. 25 at 6–7).

ii. *Non-chemical control.* The leading non-chemical control option for use in flour mills is temperature manipulation. Either heat or cold can be used to destroy insect pests. Use of cooling to control pests in flour mills, however, is unlikely because cold temperatures can damage electronic equipment in production areas. Use of heat is a more likely option. Temperatures of 120–130 degrees Fahrenheit will kill most stored-product insect pests. Heat, however, would not be appropriate for mills principally constructed of wood because heat at these levels will shrink, crack, and warp wood. This can result in structural damage to the facility and may also render the heat treatment ineffective due to leakage of heat from the facility. Approximately 25% of the total number of flour mills in the United States fall in this category. These tend to be the older and smaller mills and thus probably represent less than 25% of mill capacity. Newer mills are generally constructed primarily of concrete or similar materials which would be appropriate for use with heat disinfestation techniques. Initially, use of heat will involve higher costs due to capital investment in heaters and plant modifications. However, in the long run, use of heat may be less costly than chemical pesticides. Switching to heat will also require transition time for the industry. Not only will mills have to purchase (or rent) heaters but modifications may be necessary to the mill to insure that heat is evenly distributed. Individual mills will have to go through a trial and error process to determine how the heating technique can be effective in each unique facility. Because disinfestations are commonly needed only two to three times per year, mills are likely to need an extended transition time to implement the technology effectively. If chemical alternatives are not available during that timeframe, processed food contaminated with insect parts and waste due to failure of initial attempts at heat disinfestation will have to be destroyed. (Ref. 25 at 6).

iii. *Product removal.* A third option that combines chemical and non-chemical control would be complete removal of all food from a facility before fumigation with sulfuryl fluoride. Currently, the sulfuryl fluoride label requires that food in facilities be minimized prior to fumigation. Only food that is not practical to remove may remain during the fumigation. Removal of food is also essential to the efficacy of sulfuryl fluoride. However, if all food is removed such that use of sulfuryl fluoride would not result in fluoride residues in food, no pesticide tolerance would be needed for this use and aggregate exposure to fluoride would not be increased. Currently, Canada has imposed restrictions on the use of sulfuryl fluoride for the fumigation of food processing facilities that are designed to insure that no residues result in food. Two obstacles remain, however, to adoption of this alternative. First, OPP's analysis of this alternative indicates there may be substantial costs. Second, at this time, sulfuryl fluoride's FIFRA label does not contain application instructions sufficient to eliminate residues on food. Thus, if the objections are granted as is proposed, EPA will pursue cancellation of all uses associated with the tolerances which are removed. Unless Dow AgroSciences, the registrant for sulfuryl fluoride, were to seek an amendment of its registration that imposes label restrictions insuring no residues in food, and OPP can determine that the proposed registration changes would achieve that result, this use would not be available to flour mills in the United States. (Ref. 25 at 10).

b. *Fumigation of cocoa and walnuts.* Any food that is stored, processed, or packaged is subject to attack by insects, generally beetles or moths. Phosphine is the dominant fumigant in the commodity market for use against such pests because it is efficacious, cost-effective, and easy to apply. However, phosphine fumigation takes 4 to 7 days to be effective. A fumigant that can work much more quickly, such as sulfuryl fluoride, is used when rapid fumigation is necessary.

Fumigation of harvested walnuts to destroy pests is primarily used for in-shell walnuts. Fumigation can kill pests in in-shell walnuts that are otherwise eliminated from shelled walnuts by shelling and processing of the nutmeat. The available data indicate that a high percentage of in-shell walnuts are fumigated one or more times. Fumigation is primarily not conducted with phosphine because, at peak harvest time, existing fumigation chambers do not have sufficient capacity to allow timely fumigation. Although historically most of this rapid fumigation was done with methyl bromide under a CUE, more recent information suggests that the industry is using sulfuryl fluoride almost entirely. (Ref. 26 at 4).

For cocoa beans, rapid fumigation is necessary due to the circumstances where fumigation is conducted. Cocoa beans are imported to the United States from Africa and South America. Upon arrival, they are taken to a warehouse at the port and fumigated under tarpaulins. To minimize risk to port employees, fumigations typically occur over weekends when the ports and warehouses are closed. One hundred percent of cocoa beans are fumigated with sulfuryl fluoride. (*Id.* at 5). In 2009, approximately $1.2 billion worth of cocoa beans were imported to the United States.

The primary chemical alternative to sulfuryl fluoride for walnuts and cocoa is phosphine. However, as indicated, there are insufficient fumigation chambers for walnuts at peak harvest time. For cocoa, existing facilities do not allow for use of phosphine because they are part of an ongoing port operation and cannot be shut down for more than 2 days at a time and often contain other articles that may be affected by phosphine's corrosive properties. Non-chemical alternatives either take too long (cold, modified atmosphere), may damage the stored commodity (heat), lack market acceptability (irradiation), or are largely untested for the commodities and pests in question (heat). Construction of fumigation chambers for walnuts and cocoa may take several years. (*Id.* at 5).

EPA requests information on whether other commodities treated in the United States or other imported commodities would be affected by elimination of sulfuryl fluoride.

3. *Availability of methyl bromide.* Due to the constraints of CAA and the Montreal Protocol, pesticide users would have very limited ability to use methyl bromide in lieu of sulfuryl fluoride if the sulfuryl fluoride

tolerances were abruptly withdrawn. Methyl bromide is an ozone depleting substance whose production has been banned under the Clean Air Act for domestic use since 2005. Along with other developed countries, the United States is also subject to the methyl bromide production phase-out under the Montreal Protocol. Production of methyl bromide for U.S. use other than for quarantine and preshipment purposes is not allowed under the Montreal Protocol and EPA's Clean Air Act implementing regulations unless the Parties to the Montreal Protocol agree to authorize additional new production for uses that have been demonstrated to be critical under the criteria adopted by the Parties.

The criteria for critical use exemptions (CUEs) are demanding and not easily met. Under Decision IX/6 of the Parties to the Montreal Protocol "a use of methyl bromide should qualify as 'critical' only if the nominating Party determines that: (i) The specific use is critical because the lack of availability of methyl bromide for that use would result in a significant market disruption; and (ii) there are no technically and economically feasible alternatives or substitutes available to the user that are acceptable from the standpoint of environment and public health and are suitable to the crops and circumstances of the nomination." Decision IX/6 para. 1(a). Additionally, Decision IX/6 specifies that:

> [P]roduction and consumption, if any, of methyl bromide for critical uses should be permitted only if:
>
> (i) All technically and economically feasible steps have been taken to minimize the critical use and any associated emission of methyl bromide;
>
> (ii) Methyl bromide is not available in sufficient quantity and quality from existing stocks of banked or recycled methyl bromide, also bearing in mind the developing countries' need for methyl bromide;
>
> (iii) It is demonstrated that an appropriate effort is being made to evaluate, commercialize and secure national regulatory approval of alternatives and substitutes.* * *
>
> Decision IX/6 para. 1(b).

EPA's stratospheric protection regulations contain essentially the same criteria (40 CFR 82.3). Decisions on these criteria are made following a careful review by both the United States and the Parties to the Montreal Protocol.[1] Importantly, because the CUE process is an exception to the phase-out, it has been implemented in a manner that recognizes the importance of the technical substantiation of critical need relative to the criteria agreed upon by the Parties. Between the 2005 and 2011 CUE Nominations, the United States post harvest CUE amount authorized by the Parties has declined by nearly 80% (784,936 kilograms (kg) to 161,394 kg). (Ref. 27). Given the potential availability of alternatives in a few years, taking into consideration the full suite of chemical and non-chemical pest control options for post harvest uses, technical and economic substantiation for methyl bromide would be limited under CUE criteria for uses that had transitioned to sulfuryl fluoride.

Finally, the ability of any given user group to use methyl bromide will also be constrained in any given year by a number of other factors. First, it is impermissible for any person to sell critical use methyl bromide to an end user without receiving a certification that it will be used for an approved critical use. (40 CFR 82.4(p)(1)(i)). Second, although there is no legal restriction on a non-critical user purchasing and using pre-phase-out stocks (the quantity of stored methyl bromide produced prior to the U.S. phase-out in 2005), (75 FR 23167, 23181, May 3, 2010) (FRL–9144–5), whether or not such stocks could be commercially obtained quickly given long-term contracting for stocks is another question. In any event, pre-phase-out inventory has declined substantially and it is unclear at this time how much of it could be purchased for use in the post-harvest market.

Thus, in the short-term, production and import of methyl bromide is restricted with no opportunities for immediate change. In the longer term, given the historical trajectory of the critical use exemption under the Montreal Protocol, there likely will be less, not more, methyl bromide available. Current users of sulfuryl fluoride may attempt to purchase methyl bromide from pre-phase-out inventories if sulfuryl fluoride becomes unavailable; however, the feasibility of obtaining significant quantities from this source is uncertain.

4. *Disruption of the marketplace.* Food containing insect parts and waste may be considered adulterated under FFDCA section 402(a)(4) and subject to seizure by FDA. (21 U.S.C. 342(a)(4); *see* 21 CFR 110.110 (Defect Action Levels)). As the recent recall of the infant formula Similac shows, contamination with insect parts can result in extensive disruption of the market for consumers and significant costs for the food industry. (Ref. 28 ("Worried parents have bombarded the maker of Similac with phone calls and peppered Facebook and Twitter pages over fears about insects in the top-selling baby formula after millions of cans were recalled."); Refs. 29 and 30 (reporting that recall involved "up to 5 million Similac-brand powder formulas" and "Abbot expects to lose $100 million in connection with the recall.")).

5. *Harm to health.* There is a real potential for adverse human health impacts if sulfuryl fluoride is not available for treatment of food commodities, food mills, and other food processing facilities where sulfuryl fluoride is used. Without sulfuryl fluoride, there would be re-infestation of those commodities or facilities if facilities are not able to find suitable alternatives and thus more contamination of food products by the pests controlled by sulfuryl fluoride. Contamination would include whole insects, insect body parts, and insect waste, mainly from various flour beetles, moths, and cockroaches. Some of these contaminants (*e.g.,* from cockroaches) have been identified as allergens. (Ref. 31). Other beetles have been associated with gastrointestinal illness and discomfort. (Ref. 32 and 33). Contamination also could include food-borne pathogens that cause disease, such as *E. coli* or *Salmonella,* introduced by flies that would no longer be controlled by sulfuryl fluoride. (*Id.*)

6. *Conclusion.* In the absence of sulfuryl fluoride tolerances, current sulfuryl fluoride users will, in the first instance, turn to methyl bromide if methyl bromide can be obtained. Users' ability to obtain methyl bromide will depend on a complex mix of factors including: when a final decision is made on the sulfuryl fluoride tolerances; whether the use is an approved critical use for a given year and, if so, the amount of methyl bromide available either from new

[1] Before U.S. production may legally occur, a specific use must receive a CUE through the authorization of the Parties to the Montreal Protocol and then through EPA's regulations. The CUE process takes three years to complete for one control period (one calendar year). Methyl bromide users who wished to obtain a CUE to allow production in 2011 submitted their applications to EPA in 2008. The U.S. Government reviewed those applications and submitted a Critical Use Nomination to the United Nations Environment Programme Ozone Secretariat in early 2009. During 2009, the Methyl Bromide Technical Options Committee (MBTOC) and the Technology and Economic Assessment Panel (TEAP), which are independent advisory bodies to the Parties to the Montreal Protocol, reviewed the Critical Use Nomination and made recommendations to the Parties. In the fall of 2009, the Parties met and approved CUEs for the following post-harvest uses in the U.S.: mills and food processing structures; country ham; dried fruit; and nuts. In 2010, EPA initiated notice-and-comment rulemaking to exempt the approved uses from its regulatory ban on methyl bromide production. The final rule will address what uses qualify for the exemption in 2011 and what amounts may be produced or imported for approved critical uses.

production or from pre-phase-out inventory under the CUE Rule for that year; and whether users have access to pre-phase-out inventory sold for non-critical exemption uses. To the extent that methyl bromide is used as a sulfuryl fluoride replacement, such a reversion to a stratospheric-ozone depleting chemical is a negative public health impact because it will add to damage to the ozone layer and contribute to additional health effects caused by exposure to ultraviolet radiation, including skin cancers and cataracts.

If both sulfuryl fluoride and methyl bromide are unavailable, or supplies are limited, there is likely to be some disruption of the food supply as to the affected commodities and/or there is a greater likelihood of contaminated food being released for public consumption. The extent of disruption and/or contamination varies based on the type of processing facility and the commodities involved. For newer flour mills and other food processing facilities (*i.e.,* ones made principally of concrete), use of heat should eventually be a successful alternative to sulfuryl fluoride. In the interim, food may become contaminated with insect parts and waste as facility owners use trial and error in adapting heat technology to their individual facilities.

Older processing facilities constructed mainly of wood may have no options other than to cease production unless Dow AgroSciences seeks and obtains a registration amendment for sulfuryl fluoride that insures that sulfuryl fluoride is used in a manner not resulting in residues in food. Even so, it is unknown whether use of sulfuryl fluoride under such an approach is economically feasible. EPA expects similar impacts on other food handling facilities that rely on sulfuryl fluoride or methyl bromide fumigation to control pests.

As to cocoa, impacts are likely to be very substantial. Currently, 100% of the imported cocoa in the United States is disinfested using sulfuryl fluoride. The likelihood of switching to methyl bromide is quite low. As of June 29, 2007 for the 2009 CUE control period, cocoa bean users of methyl bromide ceased seeking CUEs. Cocoa is not currently an approved critical use, and thus any methyl bromide produced under a CUE cannot be used on cocoa. Cocoa importers' only avenue for using methyl bromide would be to purchase methyl bromide from the dwindling pre-phase-out inventories. Eventually, fumigation chambers for phosphine could be constructed for cocoa but it may be a matter of years before they are operational and phosphine use is not feasible at existing sulfuryl fluoride fumigation sites. In the absence of an alternative to sulfuryl fluoride for disinfestation of cocoa, cocoa imports (which in 2009 were valued at approximately $1.2 billion) would be lost due to either destruction or refusal of shipments by warehouse operators to comply with FDA regulations. Walnuts may also face significant impacts because of the need for rapid fumigation with either methyl bromide or sulfuryl fluoride. Without sulfuryl fluoride or methyl bromide, a significant portion of the crop may be lost simply due to insufficient fumigation capacity given the relatively long time needed for fumigation with phosphine. Other commodities facing a similar situation to walnuts include dried fruits other than raisins.

D. The Public Interest

Determining where the public interest lies in this matter involves a complex weighing of inter-related environmental and health impacts and cost effects upon commercial interests and consumers. OPP attempts to capture each of these impacts in the following summary, some of which have been described previously. Others are discussed for the first time because they do not neatly fit under factors discussed previously.

1. *Harm from fluoride exposure.* Aggregate exposure to fluoride exceeds the safe level for several major identifiable population subgroups. Of principal concern here are children up to the age of 7.

2. *Sulfuryl fluoride's contribution to fluoride exposure.* Use of sulfuryl fluoride results in a minimal contribution to fluoride exposure. Elimination of sulfuryl fluoride does not solve, or even significantly decrease, the fluoride aggregate exposure problems identified earlier.

3. *Increase in the use of methyl bromide inventories.* There is a worldwide consensus that the use of chemicals that deplete the stratospheric ozone, such as methyl bromide, should be eliminated. Termination of sulfuryl fluoride will increase demand for methyl bromide and may result in an increase of use of methyl bromide inventories.

4. *Impacts on the food supply.* To the extent that neither methyl bromide nor sulfuryl fluoride is available, there are likely to be impacts on the food supply, either through disruption of food availability or contamination of food with insect parts and waste, because other feasible alternatives to sulfuryl fluoride and methyl bromide will not be immediately available.

5. *Other atmospheric effects of sulfuryl fluoride.* EPA acknowledges that recent research has identified the potential for sulfuryl fluoride to contribute to the greenhouse effect; however there does not appear to be consensus yet in the scientific community on its global warming potential.

6. *International consequences.* As explained previously, the United States agreed to end domestic production of methyl bromide in 2005, along with other developed countries that are Parties to the Montreal Protocol. Since 2005, the United States has—along with a handful of other developed countries—been requesting limited continued amounts of methyl bromide to satisfy needs that Parties agree to be 'critical'. Also since 2005, U.S. requests for continued uses have been large, relative to those of other countries. At the beginning of the post-phase-out period, in 2005, 17 developed countries requested and obtained such exemptions; currently, the United States is one of only four developed countries that have not yet eliminated methyl bromide CUEs. (Ref. 27). The United States historically used a majority of the world's methyl bromide; therefore, the challenge faced by U.S. agriculture in this transition has been formidable. Still, enormous progress has been made in adopting alternatives for all major uses, allowing the United States to substantially reduce the size and number of its CUE requests. Sulfuryl fluoride has been an important component to this process. A sudden reversal by the United States in its efforts to reduce the use of methyl bromide may have broad ramifications on the success of the treaty. U.S. authorizations have been reduced further by the Parties to the Montreal Protocol, based on recommendations from the relevant technical committees of the Montreal Protocol. Rapid termination of sulfuryl fluoride tolerances would be at odds with the careful, deliberate, and well-established CUE process. The process is protracted and the relevant criteria demand technical justifications that require time to develop and substantiate. In reality, the multi-step CUE process is not designed with the expectation that it would allow a Party to the Montreal Protocol requesting a CUE for a given year to rapidly adjust either to the introduction of a new alternative or to the withdrawal of an existing alternative. An additional international consequence is that the lack of sulfuryl fluoride to treat imported commodities

such as cocoa could lead to shipments of imported commodities being rejected and trade with some economically vulnerable countries may be negatively affected.

E. Conclusion

Taking all of these factors into account involves weighing EPA's proposed conclusion that Objectors' have meritorious objections and the potential beneficial impacts on the public interest if a stay was granted against the negative impacts on the public interest from a stay approval. The beneficial impacts from granting a stay would be a slight reduction in fluoride exposure and other potential atmospheric effects. On the other hand, granting a stay would potentially cause the following negative impacts:

1. A possible increase in use of methyl bromide inventories, with attendant negative known atmospheric effects;

2. An undermining of the substantial progress made in reducing methyl bromide critical use exemptions in the postharvest market and potential disruption in implementation of an important international treaty, and

3. Significant impacts on several food industries and related effects on the public, including potential health effects on the public.

Despite the health risks posed by overall aggregate fluoride exposure and the Objectors' likelihood of success on the merits, OPP believes that each of the potential negative impacts on the public interest outweigh the beneficial public effects from a stay. Viewed in this light, EPA concludes that the public interest strongly, in fact overwhelmingly, supports denial of the Objectors' stay request.

VIII. Proposed Effective Date of Order

EPA proposes to make this order effective 60 days following publication. However, EPA is also proposing a staggered implementation for withdrawal of the affected tolerances in 40 CFR 180.145(c) and 180.575 taking into account the discussion in Unit VII. concerning the Objectors' stay request. This staggered implementation is proposed to be accomplished by including an expiration/revocation date in 40 CFR 180.145(c) and 180.575 for each of the tolerances not proposed for withdrawal upon the effective date of the order. Given the potential disruption or contamination of some commodities in the food supply, severely limited availability of methyl bromide, and prospect of difficulties in implementing an important international treaty, EPA is proposing to withdraw tolerances under the following implementation or phaseout schedule:

1. *Tolerances for canceled uses: immediately.* For uses that have been removed from the sulfuryl fluoride registration, there is no reason the proposed order should not take effect upon the effective date of the order. These tolerances are: Dried eggs; milk, powdered.

2. *Tolerances for commodities where there is little to no use of sulfuryl fluoride: 90 days.* EPA's analysis and information from Dow AgroSciences indicate that sulfuryl fluoride is not currently used in significant amounts, if at all, on numerous commodities for which direct fumigation is allowed under the sulfuryl fluoride registration. EPA is proposing a termination of tolerances associated with these uses 90 days from the effective date of the order. Ninety days should be sufficient for all affected parties to come into compliance with the revised situation. Tolerances in this category are: barley, bran, postharvest; barley, flour, postharvest; barley, grain, postharvest; barley, pearled barley, postharvest; cattle, meat, dried; cheese; coconut, postharvest; coffee, bean, green, postharvest; corn, field, flour, postharvest; corn, field, grain, postharvest; corn, field, grits, postharvest; corn, field, meal, postharvest; corn, pop, grain, postharvest; cotton, undelinted seed, postharvest; ginger, postharvest; grain, aspirated fractions, postharvest; grape, raisin, postharvest; herbs and spices group 19, postharvest; hog, meat; millet, grain, postharvest; nut, pine, postharvest; nut, tree, Group 14, postharvest (revised to cover only walnuts, postharvest); oat, flour, postharvest; oat, grain, postharvest; oat, groat/rolled oats; peanut, postharvest; pistachio, postharvest; sorghum, grain, postharvest; triticale, grain, postharvest; vegetable, legume, group 6, postharvest; wheat, bran, postharvest; wheat, flour, postharvest; wheat, germ, postharvest; wheat, grain postharvest; wheat, milled byproducts, postharvest; wheat, shorts, postharvest.

3. *Tolerances for commodities directly treated where there is significant sulfuryl fluoride use and no readily-available alternative: 3 years.* For several commodities, sulfuryl fluoride is used on all, or a substantial portion, of the crop and there is no readily-available alternative. These commodities are cocoa, walnuts, and dried fruits other than raisins. Although there is a feasible alternative available for sulfuryl fluoride in the long-term, phosphine, in the short-term that alternative is not available due to the lack of fumigation capacity. The situation for cocoa is perhaps the most dire in that 100% of the crop is treated, the space used for sulfuryl fluoride fumigation is not appropriate for phosphine use, and, given that cocoa is not currently an approved critical use, methyl bromide produced under a CUE may not be used on cocoa. While not facing quite such catastrophic consequences, walnuts are nonetheless in essentially the same situation because the only realistic treatment option in the near term (*i.e.,* methyl bromide) can only be obtained, if at all, from pre-phase-out inventories or from production under the sharply-limited postharvest CUE, and another alternative will not be available until additional fumigation capacity is created. The situation appears similar for dried fruits other than raisins as well; however, EPA requests that information be submitted during the comment period documenting the amount of sulfuryl fluoride use on dried fruits and the availability of alternatives including the availability of capacity for alternative fumigations. EPA is proposing termination of tolerances associated with these uses 3 years from the effective date of the order. Construction of fumigation chambers may take several years.

4. *Tolerances for commodities receiving residues from incidental treatment during structural fumigation—3 years.* The situation for foods requiring tolerances as a result of incidental treatment from structural fumigations is more complicated. Different types of facilities will face different hurdles in transitioning from sulfuryl fluoride to other methods of pest control. For most facilities, use of heat may prove an adequate pest control strategy. However, implementation of heat technology is not expected to be seamless and the availability of sulfuryl fluoride as a backup to avoid potential disruption or contamination is important. OPP expects that, after the first year, use of sulfuryl fluoride in these facilities will be the exception rather than the rule as the technology comes online and facility operators gain experience with it. In other words, sulfuryl fluoride would only be used when difficulties arise in perfecting the use of heat technology in individual facilities. Given the cost of sulfuryl fluoride treatment, facility operators, having invested in heat technology, will have a strong incentive to avoid use of sulfuryl fluoride unless absolutely necessary. A relatively short transition period may be appropriate for these facilities. For wooden structures, however, where heat is not an option,

no chemical or non-chemical alternative is immediately available. These facilities face an uncertain future with perhaps the best alternative being pursuit by Dow AgroSciences of restrictions on the sulfuryl fluoride registration that would eliminate the possibility of residues in food and thus permit continued use of sulfuryl fluoride as a structural fumigant in food handling facilities. Nonetheless, even this approach is in question due to feasibility issues. Thus, to some degree, owners of wooden food handling facilities face the most serious consequences of any producer group and, due to their relatively large share of the market, there could be similarly serious consequences for the public. For that reason, EPA is proposing termination of tolerances associated with these uses 3 years from the effective date of the order. To insure that this extended transition period will not encourage owners of concrete facilities to maintain the status quo, EPA plans to pursue registration modifications for sulfuryl fluoride that differentiate between sulfuryl fluoride use in concrete and wooden structures. EPA's goal would be to allow sulfuryl fluoride use in concrete facilities for a period no longer than necessary to accomplish the transition to heat technology.

EPA specifically requests comment on the potential impacts from the loss of sulfuryl fluoride including any available and additional information on pest control alternatives to sulfuryl fluoride. Such information is important to EPA's decision on the proposed effective dates for this order. Further, EPA recognizes that sulfuryl fluoride is only one of many sources of exposure to fluoride. To the extent that new information indicates that overall fluoride exposure has decreased, including as a result of other government actions, EPA would consider revisiting the determinations in this proposed order.

IX. Request for Public Comment

EPA requests public comment on all aspects of this proposed order: Its hazard, exposure, and risk assessments of fluoride; its evaluation of the factors bearing on whether a stay should be granted; and its proposed effective dates for the order.

X. Regulatory Assessment Requirements

As indicated previously, this action announces the Agency's proposed order regarding objections filed under section 408 of FFDCA. As such, this action is an adjudication and not a rule. The regulatory assessment requirements imposed on rulemaking do not, therefore, apply to this action.

XI. Submission to Congress and the Comptroller General

The Congressional Review Act, (5 U.S.C. 801 *et seq.*), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply to this order because this action is not a rule for purposes of 5 U.S.C. 804(3).

XII. References

As indicated under **ADDRESSES**, a docket has been established for this rulemaking under docket ID number EPA–HQ–OPP–2005–0174. The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

1. Fluoride Action Network and Beyond Pesticides/National Coalition Against the Misuse of Pesticides, Written Objections and Request for Hearing in the matter of: Sulfuryl Fluoride; Pesticide Tolerance; Final Rule. (March 23, 2004).

2. Motion of Objectors for Stay of Final Rules Establishing Tolerances For Residues of Sulfuryl Fluoride and Fluoride Anion; (Docket Nos. OPP–2005–0174 and OPP–2003–0373) (June 1, 2006).

3. Objectors' Consolidated Objections to Final Rules Establishing Tolerances for Residues of Sulfuryl Fluoride and Fluoride Anion (November 6, 2006).

4. USEPA, *A User's Guide to Available EPA Information on Assessing Exposure to Pesticides in Food* (June 21, 2000).

5. USEPA. Office of Research and Development. 2000. Benchmark Dose Technical Guidance Document. Draft report. Risk Assessment Forum, Office of Research and Development, U.S. Environmental Protection Agency. Washington, DC. EPA/630/R–00/001.

6. FIFRA Science Advisory Panel. 2002. Methods Used to Conduct a Preliminary Cumulative Risk Assessment for Organophosphate Pesticides. Final Report from the FIFRA Scientific Advisory Panel Meeting of February 5–7, 2002 (Report dated March 19, 2002). FIFRA Scientific Advisory Panel, Office of Science Coordination and Policy, Office of Prevention, Pesticides and Toxic Substances, U.S. Environmental Protection Agency. Washington, DC. SAP Report 2002–01.

7. FIFRA Science Advisory Panel. 2005b. Final report on Preliminary *N*-Methyl Carbamate Cumulative Risk Assessment. Final Report from the FIFRA Scientific Advisory Panel Meeting of August 23–25, 2005 (Report dated October 13, 2005). Available at: *http://www.epa.gov/scipoly/sap/2005/august/minutes.pdf.*

8. Office of Pesticide Programs, USEPA, Office of Pesticide Programs' Policy on the Determination of the Appropriate FQPA Safety Factor(s) For Use in the Tolerance Setting Process (February 28, 2002).

9. USEPA, Residue Chemistry Test Guidelines: OPPTS 860.1500 Crop Field Trials (August 1996).

10. Office of Pesticide Programs, USEPA and Pest Regulatory Management Agency, Health Canada, NAFTA Guidance Document for Guidance for Setting Pesticide Tolerances Based on Field Trial Data (September 28, 2005).

11. Office of Pesticide Programs, USEPA, Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern (March 16, 2000).

12. Office of Pesticide Programs, USEPA, Standard Operating Procedures (SOPs) for Residential Exposure Assessments (Draft December 19, 1997).

13. Office of Prevention, Pesticides, and Toxic Substances, USEPA, "Response To Public Comments Concerning The Use Of Sulfuryl Fluoride As A Post-Harvest Fumigant" (January 16, 2004).

14. Baetcke *et al.,* Office of Pesticide Programs, USEPA, "A Preliminary Evaluation of Articles Related to Fluoride Cited by the Fluoride Action Network (FAN) as Objections to the Sulfuryl Fluoride Pesticide Tolerance Rule" (November 18, 2003).

15. Office of Prevention, Pesticides, and Toxic Substances, USEPA, Memorandum from Vicki L. Dellarco to Dennis McNeilly, Review of Five Recent Papers on Fluoride Submitted by the Fluoride Action Network (January 8, 2004).

16. Office of Prevention, Pesticides, and Toxic Substances, USEPA, "Response to Public Comments Concerning the Use of Sulfuryl Fluoride In Food Handling Facilities" (July 14, 2005).

17. National Research Council of the National Academies, "Fluoride in Drinking Water: A Scientific Review of EPA's Standards" (March 2006).

18. Objectors' Submission to Docket: 18 IQ Studies (posted February 17, 2009).

19. Dow AgroSciences LLC, "Response to Request for Public Comments; Sulfuryl Fluoride; Request for Stay of Tolerances; Public Docket Identification Numbers: EPA–HQ–OPP–2005–0174 and EPA–HQ–OPP–2003–0373 (August 4, 2006).

20. Dow AgroSciences LLC, Memorandum, "Standard for Granting a Hearing under the Federal Food, Drug, and Cosmetic Act Concerning Objections to Tolerances Established by EPA for Profume™ Gas Fumigant" (October 31, 2006).

21. Health and Ecological Criteria Division, Office of Water, USEPA, "Fluoride: Dose-Response Analysis for Non-cancer Effects" (December 2010).

22. Health and Ecological Criteria Division, Office of Water, USEPA, "Fluoride: Exposure and Relative Source Contribution Analysis" (December 2010).

23. Office of Chemical Safety and Pollution Prevention, US EPA, Memorandum from Michael A. Doherty to Meredith Laws, "Sulfuryl Fluoride—Revised Human Health

Risk Assessment for Fluoride to Incorporate New Hazard and Exposure Information" (January 7, 2011).

24. Office of Prevention, Pesticides, and Toxic Substances, US EPA, Memorandum from Colwell A. Cook, Jonathan Becker, and Elisa Rim to Kable Davis/Venus Eagle and Michael Doherty/Christina Swartz, "Revised Assessment of Percent Commodity Treated Values used in the Registrant's Dietary Exposure Assessment for Fluoride (DP# 361041)" (May 1, 2009).

25. Office of Chemical Safety and Pollution Prevention, US EPA, Memorandum from Michelle Ranville and Colwell Cook to Meredith Laws, "Assessment of Impacts on Flour Mills Operators of a Stay in Sulfuryl Fluoride Food Tolerances" (January 7, 2011).

26. Office of Chemical Safety and Pollution Prevention, US EPA, Memorandum from Colwell Cook and Michelle Ranville to Meredith Laws, "Assessment of Impacts of a Stay of Food Tolerances for Sulfuryl Fluoride on Selected Post-Harvest Commodities" (January 7, 2011).

27. Office of Chemical Safety and Pollution Prevention, US EPA, Memorandum from Colwell Cook and Michelle Ranville to Jonathan Fleuchaus, Post Harvest Methyl Bromide Grant to the United States by the Parties to the Montreal Protocol, 2005–2011 (December 16, 2010).

28. Washington Post, "Bugs in Baby Formula? Parents Worried About Recall" (September 24, 2010) (available at *http://www.washingtonpost.com/wp-dyn/content/article/2010/09/24/AR2010092402044.html?waporef=obinsite*).

29. U.S. FDA Consumer Update, "Abbott Recalls Some Similac Formulas (September 23, 2010) (available at *http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm226941.htm*).

30. Washington Post, "Bug Contamination Sparks Baby Formula Recall" (September 23, 2010) (available at *http://www.washingtonpost.com/wp-dyn/content/article/2010/09/22/AR2010092206070.html?waporef=obinsite*).

31. Olsen *et al.,* Regulatory Action Criteria for Filth and Other Extraneous Materials, V. Strategy for Evaluating Hazardous and Nonhazardous Filth (Jan. 12, 2001).

32. U.S. FDA Consumer Update, "Abbott Recalls Some Similac Formulas" (September 23, 2010) (available at *http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm226941.htm*).

33. Olsen, Alan, FDA Teamwork Uncovers Insect Infestation, FDA Consumer, Vol. 25, Jul.–Aug. 1991).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

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