December 30, 2002, January 17, 2003, April 30, 2003, September 17, 2003, and October 27, 2003, by the New York State Department of Environmental Conservation, which consists of control strategies that will achieve volatile organic compound emission reductions that will help achieve attainment of the national ambient air quality standard for ozone.

(i) Incorporation by reference:

(A) Regulations Part 226, ''Solvent Metal Cleaning Processes'' of Title 6 of the New York Code of Rules and Regulations (NYCRR), filed on April 7, 2003, and effective on May 7, 2003, Part 228, ''Surface Coating Processes'' of Title 6 NYCRR, filed on June 23, 2003, and effective on July 23, 2003, Part 235, ''Consumer Products'' of Title 6 NYCRR, filed on October 10, 2002, and effective on November 9, 2002, and Part 239, ''Portable Fuel Container Spillage Control'' of Title 6 NYCRR, filed on October 4, 2002, and effective on November 4, 2002.

■ 3. In § 52.1679, the table is amended by:

■ a. revising the entries under Title 6 for Parts 226 and 228, and

■ b. adding new entry under Title 6 for Parts 235 and 239, in numerical order to read as follows:

52.1679 EPA-approved New York State regulations

New York State regulation	State effective date	Latest EPA approval date	Comments
Title 6:			
* * *	*	*	* * *
Part 226, ''Solvent Metal Cleaning Processes''.	5/7/03	1/23/04	
* * *	*	*	* * *
Part 228, ''Surface Coating Processes''.	8/23/03	1/23/04	
* * *	*	*	* * *
Part 235, ''Consumer Products''.	11/9/02	1/23/04	The specific application of provisions associated with alternate test methods, variances, innovative products and alternate compliance plans, must be submitted to EPA as SIP revisions.
* * *	*	*	* * *
Part 239, ''Portable Fuel Container Spillage Control''.	11/4/03	1/23/04	The specific application of provisions associated with alternate test methods, variances and innovative products, must be submitted to EPA as SIP revisions.
* * *	*	*	* * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0373; FRL–7342–1]

Sulfuryl Fluoride; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of sulfuryl fluoride and inorganic fluoride from postharvest fumigation uses of sulfuryl fluoride in or on stored commodities. Dow AgroScience LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). This action reflects the first food use on sulfuryl fluoride in the United States. Sulfuryl fluoride has been registered for fumigation of structures for termites under the brand name Vikane for many years. Sulfuryl fluoride is considered to be a methyl bromide replacement for some of these post-harvest fumigation uses. Under the Profume product label, grain processing facilities and stored cereal grains, dried fruits and tree nuts will be fumigated at a maximum use rate of 1,500 ounces/hours/1,000 ft^3 (1,500 milligrams/hours/liter (mg/hr/L) or 200 mg-hr/L under vacuum conditions. Commodities treated with Profume must be aerated for at least 24 hours before entering commerce.

DATES: This regulation is effective January 23, 2004. Objections and requests for hearings, identified by docket ID number OPP–2003–0373, must be received on or before March 23, 2004.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Dennis McNeilly, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–6742; e-mail address: *mcneilly.dennis@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, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0373. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/ 40cfr1 80_00.html/*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background

In the **Federal Register** of February 15, 2002 (67 FR 7156) (FRL–6822–2), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 1F6312) by Dow AgroScience LLC, 9330 Zionsville Road, Indianapolis, IN 46268. That notice included a summary of the petition prepared by DowAgroScience, the registrant. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide sulfuryl fluoride and the metabolite fluoride, from sulfuryl fluoride postharvest use, in or on:

1. Fluoride in or on the following raw agricultural commodities: Date at 5 parts per million (ppm), fig at 5 ppm, plum, prune, dried at 5 ppm, grape, raisin at 5 ppm, fruit, dried at 5 ppm, almond at 10 ppm, pecan at 23 ppm, pistachio at 18 ppm, walnut at 30 ppm, beechnut; butternut; cashew; chestnut; chinquapin; filbert; nut, brazil; nut, hickory; and nut, macadamia at 30 ppm, barley, grain at 10 ppm, corn, field, grain; and corn, pop, grain at 7 ppm, oat, grain at 17 ppm, rice, grain at 10 ppm, wheat, grain at 25 ppm, millet, grain; rice, wild, grain; sorghum, grain; and triticale, grain at 25 ppm and on the processed products corn, field, flour at 26 ppm, corn, field, grits at 10 ppm, corn, field, meal at 28 ppm, corn, field, oil at 3 ppm, rice, brown at 14 ppm, rice, polished rice at 18 ppm, rice, bran at 31 ppm, rice, hulls at 35 ppm, wheat, bran at 40 ppm, wheat, flour at 10 ppm, wheat, germ at 98 ppm, wheat milled by products at 35 ppm, wheat, shorts at 38 ppm, corn, field, refined oil at 3 ppm.

2. Sulfuryl fluoride in or on the following raw agricultural commodities: Date at 0.03 ppm, fig at 0.05 ppm, plum, prune, dried at 0.01 ppm, grape, raisin at 0.01 ppm, fruit, dried at 0.05 ppm, almond at 0.2 ppm, pecan at 6.0 ppm, pistachio at 0.5 ppm, walnut at 6.0 ppm, beechnut; butternut; cashew; chestnut; chinquapin; filbert; nut, brazil; nut, hickory; and nut, macadamia at 6.0 ppm, barley, grain at 0.01 ppm, corn, field, grain and corn, pop, grain at 0.04 ppm, oat, grain at 0.01 ppm, rice, grain at 0.04 ppm, wheat, grain at 0.05 ppm, millet, grain; rice, wild, grain; sorghum, grain; triticale, grain at 0.05 ppm and on the processed products corn, field, flour at 0.01 ppm, corn, field, grits at 0.01 ppm, corn, field, meal at 0.01 ppm, corn, field, refined oil at 9.0 ppm, rice, brown at 0.01 ppm, rice, polished rice at 0.01 ppm, rice, bran at 0.01 ppm, rice, hulls at 0.08 ppm, wheat, bran at 0.01 ppm, wheat, flour at 0.03 ppm, wheat, germ at 0.01 ppm, wheat milled byproducts at 0.01 ppm, wheat, shorts at 0.01 ppm.

The Agency has previously established temporary tolerances for sulfuryl fluoride and fluoride on stored walnuts and raisins in connection an Experimental Use Permit (EUP) for post-harvest sulfuryl fluoride use (See 67 FR 5735, February 7, 2000) (FRL–6834–4). Sulfuryl fluoride has never been used on stored walnuts and raisins, however, because the California Department of Pesticide Regulation has not issued the necessary state authorization to allow the EUP to proceed. Because Dow Agrosciences has now requested that its EUP for sulfuryl fluoride use on walnuts and raisins be withdrawn and EPA, in today's action, is establishing permanent tolerances for sulfuryl fluoride on walnuts and raisins, these temporary tolerances are being revoked, also as a part of today's action. The Agency received a Hearing Request dated April 8, 2002 in response to the temporary tolerance final rule from Fluoride Action Network. Because the tolerances that were objected to have now been revoked, the objections are moot and are denied on that ground. EPA fully considered, however, all of the Fluoride Action Network's objections as a part of today's action and has responded to each significant objection lodged by the Fluoride Action Network.

The Agency received 17 sets of written comments (including 5 sets of late comments) on the notice of filing published on February 15, 2002 (67 FR 7156). In addition, the Agency had previously received comments on prior **Federal Register** tolerance documents related to the establishment of tolerances for sulfuryl fluoride and inorganic fluoride, including two sets of comments on the notice of filing of a pesticide petition to establish temporary tolerances for residues of fluoride and sulfuryl fluoride in or on walnuts and sulfuryl fluoride in or on raisins, and to establish an exemption from the requirement of a tolerance for inorganic fluoride in or on raisins published on June 15, 2001 (66 FR 32618) (FRL–6788–2), and 89 sets of comments (including 10 late comments) on the proposed rule to establish temporary tolerances for sulfuryl fluoride and inorganic fluoride residues resulting from application of sulfuryl fluoride in or on walnuts and raisins published on September 5, 2001 (66 FR 46415). In

addition, an objection and request for hearing was submitted in response to the establishment of temporary tolerances for sulfuryl fluoride and inorganic fluoride residues resulting from application of sulfuryl fluoride in or on walnuts and raisins published on February 7, 2002 (67 FR 5735).

The Agency has prepared a detailed response to the public comments regarding the establishment of tolerances for sulfuryl fluoride and inorganic fluoride on food including all public comments made to the documents noted above resulting from the application of sulfuryl fluoride as a post-harvest fumigant. This document has been made part of the public docket OPP–2003–0373 for this regulatory action, and is also available for review on the Internet (*http://www.epa.gov/fedrgstr/*).

In general, the comments addressed either procedural issues concerning the process of establishing tolerance levels for sulfuryl fluoride and total fluoride or substantive issues concerning the human health and other consequences that would result from the use of sulfuryl fluoride and increased human exposure to fluorides. Most of the comments relate to fluoride exposure, fluoride toxicology and issues related to the exposure to fluorides from fluoridated drinking water. The longest and most significant of these comments came from the Fluoride Action Network (FAN), which, among its comments, questioned the safety of the current Maximum Contaminant Level Goal (MCLG) and Secondary Maximum Contamination Level (SGML) for fluoride in drinking water established by the Agency's Office of Water, under the Safe Drinking Water Act. The Safe Drinking Water Act (SDWA) requires EPA to review each National Primary Drinking Water Regulation (NPDWR) at least once every 6 years and revise them, if appropriate. As part of this review process, the Office of Water, has requested the National Academy of Science (NAS) to review the current drinking water standards for fluoride. The project scope from the NAS website states:

A subcommittee of the National Research Council's (NRC) Committee on Toxicology (COT) will review toxicologic, epidemiologic, and clinical data, particularly data published since 1993, and exposure data on orally ingested fluoride from drinking water and other sources (e.g., food, toothpaste, dental rinses). Based on those reviews the subcommittee will evaluate independently the scientific basis of the EPA's maximum contaminant level goal (MCLG) of 4 milligram per liter (mg/L) and secondary maximum contaminant level (SMCL) of 2 mg/L in drinking water. The subcommittee will advise EPA on the adequacy of its fluoride MCLG and SMCL to protect children and others from adverse effects. The subcommittee will consider the relative contribution of various fluoride sources (e.g., food, dental-hygiene products) to total exposure. The subcommittee will also identify data gaps and make recommendations for future research relevant to setting the MCLG and SMCL for fluoride. The subcommittee will not address questions of economics, risk-benefit assessment, or water-treatment technology.

A previous NAS review of fluoride was published in 1993 (NRC 1993) and served as the basis for the retention of the 4 mg/L MCLG and 2 mg/L SMCL by EPA in 1993.

The comments cited a total of 120 scientific studies and other published articles and books (see Unit VII.); these citations have all been considered by the Agency and are discussed in further detail in the assessment of the toxic effects resulting from exposure to fluoride provided in Unit III. as well as within the detailed response to public comments document. The analysis of the acceptability of fluoride exposure is based on the current MCLG and SMCL for fluoride in drinking water. The NAS is currently reviewing the adequacy of the present drinking water standards for fluoride in light of relevant scientific data that has been published subsequent to the 1993 review (National Research Council (1993). Health effects of ingested fluoride. National Academy Press, Washington, DC.). In connection with the sulfuryl fluoride tolerance petition, EPA has separately reviewed the cited studies (Dellarco 2003; Baetcke et al. 2003) and concludes that the cited scientific data that has been published since 1993 does not support adopting a reference point for evaluating the adverse health effects of fluoride than that underlying the MCLG.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' 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.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of sulfuryl fluoride and fluoride on numerous commodities at the levels specified in the tables below. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by sulfuryl fluoride are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Study Type/Guideline No.	Results
2–Week inhalation study--rat	NOAEL = 83/89 (Male/Female) milligrams/kilogram/day (mg/kg/day) LOAEL = 249/267 (M/F) mg/kg/day based on slightly increased kidney weights, minimal histopathology in kidney. At 495/534 high mortality, decreased body weights, severe histopathology in the kidney, gross and histopathology in many tissues/organs (secondary to kidney effects); severe inflammation of respiratory tissues in one survivor. No treatment-related neurotoxicity).
2–Week inhalation study--dog	NOAEL = 26/27 (M/F) mg/kg/day LOAEL = 79/80 (M/F) mg/kg/day based on M&F intermittant tremors and tetany during exposure, minimal inflammatory changes in upper respiratory tract, decreased body weight (F only). Note: Increased serum fluoride at ≥ 26/27 mg/kg/day
2–Week inhalation study--rabbit	NOAEL = 30/30 (M/F) mg/kg/day LOAEL = 90/90 (M/F) mg/kg/day based on for both M&F malacia (necrosis) in cerebrum, vacuolation of cerebrum, moderate inflammation of respiratory tissues At 180/180 mg/kg/day for M&F convulsions, hyperactivity, malacia (necrosis) in cerebrum, vacuolation of cerebrum, moderate inflammation of respiratory tissues
90-Day inhalation toxicity--rat (870.3100)	NOAEL = 24/25 (M/F) mg/kg/day LOAEL = 80/83 (M/F) mg/kg/day based on dental fluorosis* At 240/250 (M/F) vacuolation of caudate-putamen nucleus and white fiber tracts of the internal capsule of the brain, decreased body weight, inflammation of nasal passages, alveolar histiocytosis; slight hyperplasia of renal collecting ducts (F only)
90-Day inhalation toxicity--mouse (870.3100)	NOAEL = 38/36 (M/F) mg/kg/day LOAEL = 125/121 (M/F) mg/kg/day based on for both M/F miscroscopic lesions in caudate-putamen nucleus and external capsule of the brain, decreased body weight, decreased body weight gain, follicular cell hypertrophy in thyroid. Note: Increased serum fluoride at ≥ 26/27 mg/kg/day
90-Day inhalation toxicity--dog (870.3150)	NOAEL = 25/26 (M/F) mg/kg/day LOAEL = 50/51 (M/F) mg/kg/day based on slight histopathology of the caudate nucleus of the basal ganglia, decreased body weight, decreased body weight gain, transient neurological signs (lateral recumbancy, tremors, incoordination, salivation, tetany, inactivity) starting at day 19 in one M
90-Day inhalation toxicity--rabbit (870.3150)	NOAEL = 8.6/8.5 (M/F) mg/kg/day LOAEL = 29/28 (M/F) mg/kg/day based on for both M&F decreased body weight, decreased liver weight, dental fluorosis*, vacuolation of white matter of the brain (F only). At 86/85 mg/kg/day for both M&F malacia (necrosis) and vacuolation of putamen, globus pallidus and internal and external capsules in the brain, decreased body weight gain, alveolar histiocytosis, histopathology in nasal epithelium.
Prenatal developmental--rat (870.3700)	*Maternal* NOAEL = 225 ppm or 243 (F) mg/kg/day LOAEL = >225 ppm or >243 (F) mg/kg/day based on no observed effects. *Developmental* NOAEL = 225 or 243 (F) mg/kg/day LOAEL = >225 ppm or 243 (F) mg/kg/day based on no observed adverse developmental effects
Prenatal developmental--rabbit (870.3700)	*Maternal* NOAEL = 75 ppm or 29 (F) mg/kg/day LOAEL = 225 ppm or 86 mg/kg/day based on decreased body weight and body weight gain during treatment *Developmental* NOAEL = 75 ppm or 29/29 (M/F) mg/kg/day LOAEL = 225 ppm or 86 (F) mg/kg/day based on decreased fetal body weight, decreased crown-rump length, possible increased fetal liver pathology (pale liver)
Reproduction and fertility effects (870.3800)	*Parental/Systemic* NOAEL = 5 ppm or 3.6/3.6 (M/F) mg/kg/day LOAEL = 20 ppm or 14/14 (M/F) mg/kg/day based on pale foci in lungs, increased alveolar macrophages in lungs *Reproductive* NOAEL = 14/14 (M/F) mg/kg/day LOAEL = >150 ppm or 108/108 (M/F) mg/kg/day based on no adverse effects up to 150 ppm *Offspring* NOAEL = 20 ppm or 14 mg/kg/day LOAEL = 150 ppm or 108 mg/kg/day based on decreased pup weight in the F1 and F2 generations (probably secondary to maternal body weight loss

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Study Type/Guideline No.	Results
Chronic toxicity--rodents (870.4100)	NOAEL = 3.5 for M and 16 for F mg/kg/day LOAEL = 20 ppm or 14 for M and 80 ppm or 62 for F mg/kg/day based on dental fluorosis* in males and for females greatly increased mortality (due mostly to severe kidney toxicity which led to kidney failure); and histopathology in brain (vacuolation in cerebrum and thalmus/hypothalmus), adrenal cortex, eyes, liver, nasal tissue and respiratory tract; and, dental fluorosis*. No evidence of carcinogenicity in M or F
1–Year chronic inhalation toxicity--dog (870.4100)	NOAEL = 5.0/5.1 (M/F) mg/kg/day LOAEL = 20/20 (M/F) mg/kg/day based on for both M/F decreased body weight gain, increased alveolar macrophages in lungs, dental fluorosis*. At 50/51 mg/kg/day for both M/F increased mortality, malacia (necrosis) in caudate nucleus of brain, follicular cell hypertrophy in thyroid, histopathology in lung.
18–Month carcinogenicity inhalation study--mouse (870.4200)	NOAEL = 25/25 (M/F) mg/kg/day LOAEL = 101/101 (M/F) mg/kg/day based on for both M/F cerebral vacuolation in brain, decreased body weight gain, follicular hypertrophy in thyroid (M only), increased mortality (F only), heart thrombus (F only), and lung congestion (F only) No evidence of carcinogenicity in M or F
2–Year combined chronic/carcinogenicity--rat (870.4300)	NOAEL = 3.5 for M and 16 for F mg/kg/day LOAEL = 20 ppm or 14 for M and 80 ppm or 62 for F mg/kg/day based on dental fluorosis* in males and for females greatly increased mortality (due mostly to severe kidney toxicity which led to kidney failure); and histopathology in brain (vacuolation in cerebrum and thalmus/hypothalmus), adrenal cortex, eyes, liver, nasal tissue and respiratory tract; and, dental fluorosis*. No evidence of carcinogenicity in M or F
Ames assay (870.5100)	Negative without and with S-9 activation
Cytogenetics (870.5395)	There was no significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow at any sulfuryl fluoride concentration or treatment time used in the study (520 ppm).
UDS Assay (870.5550)	There was no evidence of unscheduled DNA synthesis over negative controls up to 1,020 ppm of sulfuryl fluoride.
Acute inhalation neurotoxicity study--rat (special design) (870.6200)	*Systemic* NOAEL = 300 ppm or 354 (F) mg/kg/day LOAEL = >300 ppm or >354 (F) mg/kg/day based on highest dose tested *Neurotoxic* NOAEL = 354 (F) mg/kg/day LOAEL = >354 (F) mg/kg/day based on highest dose tested Note: study included electrophysiological parameters, but no microscopic pathology.
90–Day inhalation neurotoxicity study-rat (special design) (870.6200)	*Systemic* NOAEL = 24/25 (M/F) mg/kg/day LOAEL = 80/83 (M/F) mg/kg/day based on for both M and F pale foci in pleura and macrophages in lungs, dental fluorosis* *Neurotoxic* NOAEL = 24/25 (M/F) mg/kg/day LOAEL = 80/83 (M/F) mg/kg/day based on for both M and F disturbances in electro-physiological parameters (slowing of VER and SER waveforms in F and ABR waveforms in M
1–Year inhalation neurotoxicity study-rat (special design) (870.6200)	NOAEL = 3.5/3.9 (M/F) mg/kg/day LOAEL = 14/16 (M/F) mg/kg/day based on dental fluorosis*. At 52/62 mg/kg/day (M/F) increased kidney and liver weights, progressive kidney disease and histopathology in lung. *Neurotoxic* NOAEL = 56/62 (M/F) mg/kg/day LOAEL = 56/62 (M/F) mg/kg/day based on highest dose tested
Developmental neurotoxicity (870.6300)	No study available. Study will be a condition of registration.
Metabolism and pharmacokinetics (870.7485)	Waived, Reregistration Eligibility Document, 1993
Dermal penetration (870.7600)	No study available. Not required for a gas.

*As discussed later in this document, dental fluorosis is not considered an adverse health effect, and the identification of that effect in any of these toxicological studies has not served to define a safe level of exposure to sulfuryl fluoride under the FFDCA.

Technical grade sulfuryl fluoride (99.8% active ingredient) is marketed as a liquified gas in pressurized steel cylinders. The acute oral LD_{50} of sulfuryl fluoride has been estimated to be approximately 100 mg/kg in rats (Toxicity Category II). The acute inhalation LC_{50} in mice (4–hour exposure) is 660 ppm (2.56 mg/L) in males and 642 ppm (2.49 mg/L) in females. The acute inhalation LC_{50} in rats (1 hour exposure) is 4,512 ppm (17.5 mg/L). Based on the use pattern for sulfuryl fluoride and several reported incidences of human poisonings in the general toxicologic literature, the Agency has classified sulfuryl fluoride as Toxicity Category I for acute inhalation toxicity. When released from pressurized steel cylinders, sulfuryl fluoride causes freezing of skin and eye tissues on contact. Therefore, no dermal studies or eye irritation studies have been required to be submitted. The acute dermal toxicity study (assumed Toxicity Category IV), the primary skin irritation study (assumed Toxicity Category IV), the primary eye irritation study (assumed Toxicity Category I), and the dermal sensitization study (assumed to be a non-sensitizer) have been waived. In a non-guideline study in which rats were dermally exposed (with no inhalation exposure) to vapors of sulfuryl fluoride gas at an exposure concentration of 9,600 ppm (40.3 mg/L) for 4 hours, no treatment-related adverse effects were observed.

In 2–week inhalation studies in rats, dogs and rabbits, different target organs were affected. In rats, the primary target organ was the kidneys, in which severe histopathological lesions were observed. These lesions included papillary necrosis, hyperplasia of the epithelial cells of the papillae, and degeneration/ regeneration of collecting tubules and proximal tubules. In dogs, the primary target organ was the upper respiratory tract, in which minimal inflammation was observed. Intermittant tremors and tetany were also noted in dogs. In rabbits, the primary target organ was the brain, in which malacia (necrosis) and vacuolation were observed in the cerebrum. Inflammation of the upper respiratory tract was also noted in rabbits.

In subchronic (90–day) inhalation studies in rats, mice, dogs and rabbits, the brain was the major target organ. Malacia and/or vacuolation were observed in the white matter of the brain in all four species. The portions of the brain most often affected were the caudate-putamen nucleus in the basal ganglia, the white fiber tracts in the internal and external capsules, and the globus pallidus of the cerebrum. In dogs and rabbits, clinical signs of neurotoxicity (including tremors, tetany, incoordination, convulsions and/or hind limb paralysis) were also observed. Inflammation of the nasal passages and histiocytosis of the lungs were observed in rats and rabbits; but not in dogs, in which species inflammation of the upper respiratory tract was more prominent in the 2–week study. In rats, kidney damage was also observed. In mice, follicular cell hypertrophy was noted in the thyroid gland. Decreased body weights and body weight gains were also observed in rats, dogs and mice.

In chronic (1–2 year) inhalation studies in rats, dogs and mice, target organs were the same as in the 90–day studies. In rats, severe kidney damage caused renal failure and mortalities in many animals. Additional gross and histopathological lesions in numerous organs and tissues were considered to be secondary to the primary effect on the kidneys. Other treatment-related effects in rats included effects in the brain (vacuolation of the cerebrum and thalamus/ hypothalamus) and respiratory tract (reactive hyperplasia and inflammation of the respiratory epithelium of the nasal turbinates, lung congestion, aggregates of alveolar macrophages). In dogs and mice, increased mortalities, malacia and/or vacuolation in the white matter in the brain, histopathology in the lungs, and follicular cell hypertrophy in the thyroid gland were observed. Decreased body weights and body weight gains were also noted in all three species. No evidence of carcinogenicity was observed in either the combined chronic toxicity/carcinogenicity study in rats or in the 18–month carcinogenicity study in mice.

In specially designed acute and subchronic inhalation neurotoxicity studies in rats, several electrophysiological parameters (EEGs) were recorded in addition to observations for clinical signs of neurotoxicity, functional observational battery (FOB) and motor activity testing, and/or neurohistopathologic examination. Following two exposures on consecutive days for 6 hours/day at 300 ppm of sulfuryl fluoride (354 mg/ kg/day), no treatment-related neurotoxic effects were noted. In a 90–day study, changes in some EEG patterns were observed at 100 ppm (80 mg/kg/day) and in several additional patterns at 300 ppm (240 mg/kg/day). Vacuolation of the white matter in the cerebrum was also observed at 300 ppm in this study. In a specially designed 1–year chronic inhalation neurotoxicity study in rats, no treatment-related neurotoxic effects were observed at 80 ppm (56 mg/kg/ day). EEGs were not recorded in this study.

In a developmental toxicity inhalation study in rats, no developmental toxicity was observed in the pups. Although no maternal toxicity was observed in this study at the highest dose tested (225 ppm), significant maternal toxicity (decreased body weight, body weight gain and food consumption; increased water consumption and kidney weights; and gross pathological changes in the kidneys and liver) was observed in a previously conducted range-finding study at a slightly higher dose level (300 ppm). In a developmental toxicity inhalation study in rabbits, decreased fetal body weights were observed in the pups. At the same dose level, decreased body weight and body weight gain were observed in the dams. In a 2-generation reproduction inhalation study in rats, vacuolation of the white matter in the brain, pathology in the lungs (pale, gray foci; increased alveolar macrophages) and decreased body weights were observed in the parental animals. Decreased pup body weights in the F1 and F2 generations were observed in the offspring. No effects on reproductive parameters were noted in this study. No quantitative or qualitative evidence of increased susceptibility of fetuses or pups was observed in the developmental toxicity or reproduction studies on sulfuryl fluoride.

A battery of mutagenicity studies was negative for genotoxic potential. The studies included a reverse gene mutation assay in *Salmonella typhimurium*, an unscheduled DNA synthesis assay in primary rat hepatocytes, and a micronucleus assay in mouse bone marrow cells.

In carcinogenicity studies in male and female rats and in male and female mice, sulfuryl fluoride did not demonstrate evidence of carcinogenic potential. Sulfuryl fluoride is classified as ''not likely to be carcinogenic to humans'' according to the July 2, 1999 *EPA Draft Proposed Guidelines for Carcinogen Risk Assessment*.

Poisonings and fatalities have been reported in humans following inhalation exposure to sulfuryl fluoride. The severity of these effects has depended on the concentration of sulfuryl fluoride and the duration of exposure. Short-term inhalation exposure to high concentrations has caused respiratory irritation, pulmonary edema, nausea, abdominal pain, central nervous system depression, and numbness in the extremities. In addition, there have been two reports of deaths of persons entering houses treated with sulfuryl fluoride. One

person entered the house illegally and was found dead the next morning. A second person died of cardiac arrest after sleeping in the house overnight following fumigation. A plasma fluoride level of 0.5 mg/L (10 times normal) was found in this person following exposure. Prolonged chronic inhalation exposures to concentrations of sulfuryl fluoride gas significantly above the threshold limit value (TLV) of 5 ppm have caused fluorosis in humans because sulfuryl fluoride is converted to fluoride anion in the body. Fluorosis is characterized by binding of fluoride anion to teeth (causing mottling of the teeth) and to bone. Sulfuryl fluoride and fluoride anion are the residues of concern associated with sulfuryl fluoride.

Fluoride anion. In assessing the risks associated with exposure to fluoride, the Agency has relied on the toxicological assessment and Maximum Contaminant Levels (MCLs) and Maximum Contaminant Level Goals (MCLG) established by the Agency's Office of Water. The MCGL is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety. A MCL is an enforceable level that is set as closely as feasible to the MCLG of a contaminant. MCLGs are non-enforceable health goals. For fluoride, both the MCL and the MCLG have been set at 4.0 ppm in order to protect against crippling skeletal fluorosis. The Office of Water has also established a secondary MCL (SMCL) for fluoride at 2.0 ppm. The SMCL is a non-enforceable level established to be protective against the cosmetic and aesthetic effects of objectionable dental fluorosis.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors''; the ''special FQPA safety factor''; and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for data base deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for sulfuryl fluoride used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR SULFURYL FLUORIDE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary	None, UF = N/A	Not applicable	No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies on sulfuryl fluoride
Chronic dietary (all populations)	NOAEL = 8.5 mg/kg/day UF = 3,000 Chronic RfD = 0.003 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD/Special FQPA SF = 0.003 mg/kg/day	90–Day inhalation--rabbit LOAEL = 28 mg/kg/day based on vacuolation of white matter in the brain of females.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR SULFURYL FLUORIDE FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Incidental oral (all durations)	None	Not applicable	Due to sulfuryl fluoride being a gas and pattern of use, no significant incidental oral exposure is anticipated.
Dermal (all durations)	None	Not applicable	Due to sulfuryl fluoride being a gas and pattern of use, no significant incidental dermal exposure is anticipated. No hazard identified, therefore, no quantification is required.
Short-term inhalation (1 to 30 days)	Inhalation study NOAEL = 30 mg/kg/day (100 ppm; 0.42 mg/L)	Residential LOC for MOE = 1,000 Occupational LOC = 100	2-Week inhalation--rabbit LOAEL = 90 mg/kg/day (300 ppm; 1.25 mg/L) based on malacia (necrosis) and vacuolation in brain, inflammation of nasal tissue and trachea
Intermediate-term inhalation (1 to 6 months)	Inhalation study NOAEL = 8.5 mg/kg/day (100 ppm; 0.42mg/L)	Residential LOC for MOE = 1,000 Occupational LOC for MOE = 100	90–Day inhalation-rabbit LOAEL = 28 mg/kg/day (100 ppm; 0.42 mg/L) based on vacuolation of white matter in the brain of females.
Long-term inhalation (>6 months)	Inhalation study NOAEL = 8.5 mg/kg/day (30 ppm; 0.13 mg/L)	Residential LOC for MOE = 3,000 Occupational LOC for MOE = 300	90–Day inhalation--rabbit LOAEL = 28 mg/kg/day based on vacuolation of white matter in the brain of females
Cancer (oral, dermal, inhalation)	Classified as not likely to be carcinogenic to humans		

For sulfuryl fluoride, the end-point from an inhalation study is being used to calculate the chronic RfD which is used to perform risk assessments for oral exposure. In addition to being the only practical way to administer a gas test material, the Agency believes this is a very conservative methodology which is supported by the following considerations:

The absorption of test material from inhalation exposure is generally presumed to be 100%, where as absorption via oral exposure is often times determined to be less than 100%.

A higher and more persistent level of parent test material in the body may occur following inhalation exposure as compared to an oral exposure because the parent test material is immediately distributed throughout the circulatory system following inhalation, rather than the first being directly shunted to the liver (where most metabolism occurs) as in the case of oral exposure.

In addition, for sulfuryl fluoride, the NOAEL on which the chronic RfD was calculated is from a study in rabbits (which is the most sensitive species for the neurotoxic effects) and the LOAEL in this study was close to a threshold effect level (the effect was observed only in the female rabbit).

Fluoride anion. In assessing the risks associated with exposure to fluoride, the Agency relied on the toxicological assessment and MCLG established by the Agency's Office of Water for fluoride of 4.0 ppm. At this time, based on the information available to the Agency, EPA is not concluding that dental fluorosis associated with fluoride exposure is an adverse health effect under the FFDCA. The current arguments that dental fluorosis is more than a cosmetic effect are not sufficiently persuasive to warrant regulation as an adverse health effect under the FFDCA. Accordingly, consistent with the action taken by the Office of Water under the Safe Drinking Water Act, 50 FR 47142 (November 14, 1985) (WH–FRL–2913–8(b)), the Agency believes the appropriate endpoint for regulation under the FFDCA is skeletal fluorosis.

While the tolerance safety determination under the FFDCA is a health based standard, FIFRA requires the balancing of all costs, taking into account the economic, social, and environmental effects as well as health based risks, against the benefits associated with the pesticide use. Therefore, the Agency will consider dental fluorosis in determining whether sulfuryl fluoride meets the requisite standard under FIFRA.

Using body weight and water consumption estimates, the MCLG, expressed mg/kg/day, for the population groups addressed in the fluoride risk assessments are as follows:

U.S. population . . . . . 0.114 mg/kg/day
Infants (< 1 year old). . . . . 0.571 mg/kg/day
Children 1-2 years old. . . . . 0.308 mg/kg/day
Children 3-5 years old. . . . . 0.182 mg/kg/day
Children 6-12 years old . . . . . 0.100 mg/kg/day
Youth 13-19 years old . . . . . 0.133 mg/kg/day
Adults 20+ years old. . . . . 0.114 mg/kg/day
Females 13–49 years old . . . . . 0.131 mg/kg/day

For fluoride risk assessments addressed in this document, the term ''% of MCLG (as mg/kg/day)'' is analogous to a reference dose (RfD).

Percent of MCLG (expressed as mg/kg/day) use in acute risk assessments. None. The Agency has not identified any toxicological endpoint attributable to a single exposure of fluoride that would be applicable to females (13–50 years old) or to the general population (including infants and children).

Percent of MCLG (expressed as mg/kg/day) use in non-acute risk assessments. For all short-term, intermediate-term, and chronic assessments, the Agency

has converted the MCLG of 4.0 ppm to a mg/kg/day basis using standard water consumption estimates and body weight data from the NHANES III survey (U.S. EPA, 2000). Body weight data from the NHANES survey were matched as closely as possible to the population subgroups addressed by the DEEM-FCID dietary exposure modelling software. Use of the NHANES data, rather than the Agency default body weights, avoids setting dose levels too high due to underestimated body weights. These doses in Table 3 below were used for all risk assessment durations and pathways (oral, dermal, and inhalation) in a manner analogous to an RfD. That is, the Agency would have concerns about the level of estimated risk if the exposure estimates exceed 100% of ''MCLG (as mg/kg/day)'' as defined in this rule.

The Agency notes that the EPA's Integrated Risk Information System (IRIS) lists an oral RfD of 1 ppm fluoride in water for dental fluorosis (IRIS Database). That RfD is based on a NOEL of 1 ppm with an LOEL of 2 ppm and no modifying or uncertainty factors since the effect was noted in a sensitive population and the duration of exposure was appropriate for the effect and the population. The IRIS value has not been used in this action since dental fluorosis is a cosmetic effect, not a human health effect.

*Table 3.—Toxicological Doses Used in the Fluoride Risk Assessment**

Population Subgroup	Toxicological Effect	Water Conc. Protective of Effect, ppm	Water Consumption, L/day	Body Weight, kg	of MCLG (as mg/kg/day)
U.S. population (total)	Skeletal fluorosis	4	2	70	0.114
All infants (<1 year)	Skeletal fluorosis	4	1	7	0.571
Children (1–2 years)	Skeletal fluorosis	4	1	13	0.308
Children (3–5 years)	Skeletal fluorosis	4	1	22	0.182
Children (6–12 years)	Skeletal fluorosis	4	1	40	0.1
Youth (13–19 years)	Skeletal fluorosis	4	2	60	0.133
Adults (20+ years)	Skeletal fluorosis	4	2	70	0.114
Females (13–49 years)	Skeletal fluorosis	4	2	61	0.131

*Doses are used in a manner analogous to an RfD and are used for all exposure pathways

Carcinogenicity. In its assessment of the health effects of fluoride, the National Research Council (NRC) concluded that the available laboratory data are insufficient to demonstrate a carcinogenic effect of fluoride in animals. The NRC also concluded that the weight of the evidence from more than 50 epidemiological studies does not support the hypothesis of an association between fluoride exposure and increased cancer risk in humans. National Research Council, 1993.

The Agency for Toxic Substances and Disease Registry (ATSDR) and the World Health Organization have come to similar conclusions. Based on the findings of those bodies and the Agency's own review, the Agency believes fluoride poses a negligible cancer risk.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. This is the first food-use for sulfuryl fluoride. Temporary tolerances were established (40 CFR 180.575) for the residues of sulfuryl fluoride, in or on a walnuts and raisins. Tolerances already exist for fluoride residues in food in 40 CFR 180.145 to support use of cryolite in on on various raw agricultural commodities. This action involves adding a new section (1)(a)(3) to 40 CFR 180.145, i.e., an entry adding postharvest use of Profume on stored commodites. Risk assessments were conducted by EPA to assess dietary exposures from sulfuryl fluoride and inorganic fluoride in food as follows:

i. *Acute exposure*. Acute dietary risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies for either sulfuryl fluoride and/or fluoride; therefore, no acute dietary exposure analysis was conducted.

ii. *Chronic exposure*. In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID), which incorporates food consumption data as reported by respondents in the U.S. Department of Agriculture 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). The following assumptions were made for the chronic exposure assessments: The chronic analysis for sulfuryl fluoride used anticipated residues (average residue) from residue trials reflecting the maximum proposed use rate, percent market share estimates and a dilution factor for flour commodities to reflect the pre-fumigation draw down practice in grain mills. This assessment includes quantitative estimates of dietary exposure from background levels of fluoride in food, fluoride in water, and fluoride from the pesticidal food uses of cryolite and sulfuryl fluoride; non-dietary exposure from the use of fluoridated toothpaste, and non-dietary exposure from fluoride residues in air. For each of these pathways of exposure, residue estimates are conservative to moderately conservative in nature. Other potential sources of fluoride exposure have not been included in this assessment in a quantitative manner, primarily due to lack of demographic and/or exposure information. Non-quantified pathways of exposure are not expected to significantly increase exposure estimates for the various population subgroups at large.

The chronic analysis for sulfuryl fluoride used average residue values from residue trials reflecting the maximum proposed use, percent market share estimates, and a dilution factor for flour commodities to reflect the pre-fumigation draw-down practice in grain processing mills. Based on these

assumptions, the refined chronic dietary risk estimates for all population subgroups are less than 1% of the chronic population-adjusted dose (cPAD) of 0.003 mg/kg/day.

TABLE 4.—CHRONIC DIETARY EXPOSURE ASSESSMENT FOR SULFURYL FLUORIDE

Population Subgroup	Chronic PAD, mg/kg/day	Estimated Exposure, mg/kg/day	Risk, % of cPAD
U.S. population (total)	0.003	0.000003	<1
All infants (<1 year)	0.003	0.000002	<1
Children (1–2 years)	0.003	0.000004	<1
Children (3–5 years)	0.003	0.000004	<1
Children (6–12 years)	0.003	0.000003	<1
Youth (13–19 years)	0.003	0.000001	<1
Adults (20–49 yrs)	0.003	0.000003	<1
Adults (50+ years)	0.003	0.000004	<1
Females (13–49 years)	0.003	0.000003	<1

In addition to assessing the exposure to sulfuryl fluoride in food, EPA assessed fluoride exposure from residues in foods from the use of sulfuryl fluoride and/or cryolite as well as background levels in foods. Also addressed quantitatively are exposure from the use of fluoridated toothpaste, inhalation of fluoride from the atmosphere, and consumption of fluoride-containing water. Other known potential sources of fluoride exposure were not addressed quantitatively due to lack of data regarding residues and/or data regarding the demographics of exposure. Details regarding the residue profiles of the various fluoride sources are discussed below.

Background fluoride in foods. Monitoring studies indicate fluoride is ubiquitous in the food supply (e.g., World Health Organization. 2002; Rao,G. S. 1984; Sherlock, JC. 1984). The primary sources for residues used in this background food assessment were Taves, D.R. (1983) for plant-based foods, bovine and porcine commodities, and eggs; Fein, N.J. and Cerklewski F.L. (2001) for poultry; and residue trials for tree nuts and dried fruits (MRID 45510304). Average residue values were used when available. In cases were a range was listed, the maximum value in the range was used. In the 1983 study by Taves, 93 food items from a hospital in an area with fluoridated water were analyzed for fluoride content. The use of the Taves data accounts for the increase in fluoride residues that may occur when foods are processed/prepared in fluoridated water. Note that the residue estimates for dried fruits and tree nuts are at the LOQ for the residue trial method and are most likely overestimates of fluoride, based on the residue levels in other commodities. Overall, these should be considered to be conservative to slightly refined estimates of fluoride residues.

Cryolite. In evaluating the exposure to fluoride from the agricultural uses of cryolite, residue trial data were matched as closely as possible to the current maximum use patterns for this active ingredient. Empirically derived processing factors were used for processed commodities of grapes, citrus, mint, and tomato. Default processing factors from DEEM Version 7.81 were used for all other commodities. Overall, these should be considered to be moderately refined estimates of residues.

EPA has concluded that dietary exposure to fluoride will utilize 30% of the MCLG (expressed as mg/kg/day) for the U.S. population, 18% of the MCLG (expressed as mg/kg/day) for youth 13–19 years, 29% of the MCLG (expressed as mg/kg/day) for children 3-5 years, and 27% of the MCLG (expressed as mg/kg/day) for All infants less than 1 year. These risk estimates are below the Agency's level of concern.

TABLE 5.—TOTAL CHRONIC EXPOSURE AND RISK ESTIMATES FOR FLUORIDE FROM DIETARY SOURCES

Population Subgroup	Tox. Dose, mg/kg/day	Dietary Fluoride Anion Exposure Estimates, mg/kg/day					Risk, % of MCLG (as mg/kg/day)
		Sulfuryl Fluoride	Cryolite	Food	Water	Total Dietary	
U.S. population (total)	0.114	0.0004	0.0006	0.0068	0.0269	0.0347	30
All infants (<1 year)	0.571	0.0005	0.0009	0.0093	0.1424	0.1531	27
Children (1–2 years)	0.308	0.0013	0.0031	0.0175	0.0407	0.0626	20
Children (3–5 years)	0.182	0.0012	0.0020	0.0149	0.0338	0.0519	29
Children (6–12 years)	0.100	0.0007	0.0008	0.0094	0.0227	0.0336	34
Youth (13–19 years)	0.133	0.0004	0.0003	0.0062	0.0176	0.0245	18

TABLE 5.—TOTAL CHRONIC EXPOSURE AND RISK ESTIMATES FOR FLUORIDE FROM DIETARY SOURCES—Continued

Population Subgroup	Tox. Dose, mg/kg/day	Dietary Fluoride Anion Exposure Estimates, mg/kg/day					Risk, % of MCLG (as mg/kg/day)
		Sulfuryl Fluoride	Cryolite	Food	Water	Total Dietary	
Adults (20–49 years)	0.114	0.0003	0.0004	0.0057	0.0252	0.0316	28
Adults (50+ yrs)	0.114	0.0003	0.0005	0.0050	0.0256	0.0314	28
Females (13–49 years)	0.131	0.0003	0.0005	0.0054	0.0238	0.0300	23

iii. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of FFDCA, EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

A routine chronic dietary exposure analysis for the postharvest fumigant Profume was based on 20% of the nut crop, 40% of dried fruit, 2% of the stored grain will be treated postharvest with Profume.

The Agency believes that the three conditions previously discussed have been met. With respect to Condition 1, EPA finds that the PCT information described in this document for Profume used on postharvest use on stored commodities is reliable and has a valid basis. Profume is a postharvest fumigant of stored commodities that will replace methyl bromide uses for which the Agency has good information about the actual amounts used. It is also possible that Profume could replace other fumigant products for which there are also use data available, although not as refined as for MeBr. This has been considered when making the percent crop treated estimates which are considered to be conservative, i.e., estimating the upper range of the stored commodity market that will likely be treated with Profume.

Tree nuts. Methyl bromide is used on nearly all walnuts and about 3% of almonds. Dow estimated sulfuryl fluoride use will not exceed 10% on almonds and 20% on other nuts. The Agency used a PCT of 20% for all tree nuts.

Dried fruit. Methyl bromide is used on 64% of prunes and 28% of raisins. Sulfuryl fluoride and phosphine are expected to share the market as a replacement for methyl bromide used to treat dried fruit. The Agency used a PCT of 40% for all dried fruits.

Stored grains. (1) At flour mills: Wheat flour mills are typically fumigated 2 to 3 times per year, and there is enough stored grain to support 2 days of production at a typical flour mill facility. Three fumigations per year would mean 6 days of exposed production or 6/350 = 1.7% of the grain handled by the mill would be exposed to sulfuryl fluoride, assuming that all flour mill fumigations were done with sulfuryl fluoride. (2) Other stored grains. Phosphine is used to fumigate stored grain, and 10% to 15% of stored grain is presently fumigated. It is expected that sulfuryl fluoride will replace only 10% of the phosphine usage because some phosphine products may be easier for some users than sulfuryl fluoride (one formulation of phosphine only requires that you drop pellets compared to the application and monitoring equipment required for sulfuryl fluoride), phosphine is less expensive than sulfuryl fluoride, and many grain fumigations do not require the faster fumigation of sulfuryl fluoride. Sulfuryl fluoride is likely to used for resistance management in many situations. Overall, it is expected only 1% to 1.5% of other stored grains will be treated with sulfuryl fluoride. The Agency used a PCT of 2% for all stored grains.

As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which Profume may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency has determined that because of the use pattern and physicochemical characteristics of sulfuryl fluoride, neither residues of sulfuryl fluoride nor of inorganic fluoride are expected to reach surface water or ground water due to the postharvest fumigation (an indoor use) of the commodities listed in Unit II. Residues of inorganic fluoride may be in drinking water due to intentional fluoridation.

Monitoring data based on 16 states from 1983 to 1998 that has been extrapolated to the U.S. (U.S. EPA, 2003) indicate that approximately 99% of the U.S. population is supplied with water containing, on average, less than 2 ppm fluoride anion. In the current risk

assessment, the Agency has assumed a residue level of 2 ppm for tap water and 1 ppm for water sources other than tap water. The optimal fluoridation level for water is approximately 1 ppm. This residue level is reflected in the final product (e.g., soft drinks) when production is in areas with fluoridated water. Because of the inclusion of all non-tap water at 1 ppm, these should be considered to be slightly refined overall estimates of fluoride residues. The use of 2 ppm fluoride in tap water and 1 ppm in other water sources likely results in an overestimation of exposure for the general population, especially those on public water systems (93% of the U.S. population based on 2002 Census figures). However, it may underestimate the level of residues present in drinking water for certain regional populations in the U.S. who are supplied by well water that is naturally high in fluoride. In monitoring data (1991-2002) from the National Water Quality Assessment (NAWQA) Program (*http://water.usgs.gov/nawqa/*), the concentration of fluoride in groundwater samples designated as being used for domestic purposes exceeded 2 ppm in at least one sample from 13 of 49 study units. Study units are major river basins and aquifers across the nation and typically encompass approximately 4000 square miles. Examination of data from each of those 13 study units indicates that there is a fair degree of spatial variability in fluoride levels. Similar finding regarding spatial difference in fluoride concentration have been noted in local monitoring studies. For example, data from Lakewood Township, Minnesota show a fluoride concentration of 0.4 ppm in a well located at a similar depth and only a few hundred feet from a well with a fluoride concentration of 14.0 ppm (Hastreiter, et al., 1992). Similar variations in fluoride levels over small geographic areas were noted. Data are not available describing fluoride levels for a specific source over time, and it is unclear whether or not there is temporal, as well as spatial, variability in well water fluoride concentrations. If temporal variability is similar in magnitude to the spatial variability, then the 2-ppm estimate for fluoride in tap water is conservative for even those populations living in high-fluoride areas. Overall, the conservative values used for both fluoride residues in drinking water and drinking water consumption as well as conservative assumptions on exposure to fluoride through food and other non-dietary sources should not understate exposure to the general population or any major identifiable population subgroup.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (i.e., for sulfuryl fluoride, termiticide use).

Sulfuryl fluoride is currently registered for use on the following residential non-dietary sites: fumigation of residential sites for termites. The risk assessment was conducted using the following residential exposure assumptions: Sulfuryl fluoride is registered for fumigation of domestic structures. Exposure could occur when residents re-occupy a fumigated home; however, the label restricts reentry to the residence until the measured levels of sulfuryl fluoride are very low. The Agency has determined, based the available exposure data supporting the Vikane registration and the Vikane label restriction on reentry that there is negligible exposure to sulfuryl fluoride from home fumigation (B. Daiss, May 15, 2001, DP Barcode 274960).

Fluoride exposure may occur from non-dietary sources, including incidental ingestion of toothpaste and inhalation of airborne fluoride. Other non-dietary exposures may occur; however, the Agency has included only these two in its quantitative assessment due to lack of data regarding residue levels and/or exposure demographics. In order to take into account these other sources of non-dietary exposure, the Agency has used conservative assumptions when estimating exposure from toothpaste and air in an effort to ensure that exposures are not underestimated. Exposure estimates for fluoride from toothpaste and air for all of the population subgroups (i.e., in DEEM-FCID) are addressed.

Toothpaste. A number of studies available in the open literature have been conducted to determine the exposure to fluoride from the incidental ingestion of toothpaste (e.g., Levy et al., 1995; Naccache et al., 1992, 1990; Simard et al., 1989; Bruun and Thylstrup, 1988; Barnhart et al., 1974). Due to the different techniques used to assess toothpaste ingestion and the different foci in those studies, the estimates of fluoride exposure from toothpaste are quite varied. A few common threads can be found, however: (1) incidental toothpaste ingestion decreases with age as children gain better control of the swallowing reflex; and, (2) ingestion of toothpaste can be a significant contributor to overall fluoride exposure.

Despite the variability in the estimates of ingested toothpaste, maximum exposures to fluoride observed in those studies appear to converge to approximately 3 mg/day. In assessing fluoride from toothpaste, HED has used this maximum estimate of 3 mg/day and normalized to body weight using the NHANES dody weight data for the various population subgroups. The exposure estimates range from 0.005 to 0.03 mg/kg/day and should be considered conservative in nature; especially for older population subgroups since exposure estimates were not adjusted for the age-related decrease in toothpaste ingestion.

Air. Estimates of fluoride residues in air are presented in a number of review articles (e.g., World Health Organization, 2002; Burt, 1992). In the U.S., airborne fluoride concentrations are highest around smelters and industrialized area. In such areas, the fluoride concentration does not typically exceed 3 µg/m^3. The Agency has used standard respiration rates derived from OPP/HED Science Advisory Council for Exposure Policy No. 12 (2/22/2001) and body weights to convert 3 µg/m^3 to a mg/kg/day basis. Exposure estimates range from 0.0006 to 0.0026 mg/kg/day. As with toothpaste, the risk estimates derived from these exposure estimates are below the Agency's level of concern.

TABLE 6.—ESTIMATED FLUORIDE EXPOSURE FROM NON-DIETARY SOURCES

Population Subgroup	Body Weight, kg	Standard Respiration, m^3/day	Estimated Exposure, mg/kg/day	
			Toothpaste	Air
U.S. population (total)	70	13.3	0.0043	0.0006
All infants (<1 year)	7	4.5	0.0429	0.0019
Children (1–2 years)	13	8.7	0.0231	0.0020

TABLE 6.—ESTIMATED FLUORIDE EXPOSURE FROM NON-DIETARY SOURCES—Continued

Population Subgroup	Body Weight, kg	Standard Respiration, m^3/day	Estimated Exposure, mg/kg/day	
			Toothpaste	Air
Children (3–5 years)	22	8.7	0.0136	0.0012
Children (6–12 years)	40	8.7	0.0075	0.0007
Youth (13–19 years)	60	13.3	0.0050	0.0007
Adults (20–49 years)	70	13.3	0.0043	0.0006
Adults (50+ years)	70	13.3	0.0043	0.0006
Females (13–49 years)	61	11.3	0.0049	0.0006

In response to the EUP for sulfuryl fluoride, the Agency received comments regarding, among other things, sources of fluoride that were not considered in the EUP assessment. Most of those sources have been addressed quantitatively above; however, the use of fluoride supplements and the potential for increased exposure following food preparation in Teflon-treated cookware were specific issues that were not addressed numerically. Fluoride supplements are prescribed only by a health care professional. The community of health care professionals is aware of the potential for fluorosis and the use of supplements is only advocated when aggregate exposure is insufficient to provide protection against dental caries. Because the amount of fluoride prescribed is made in consideration of other fluoride sources, the use of fluoride supplements would not result in overexposure to fluoride. With respect to increased exposure to fluoride from the use of Teflon-treated cookware, Full and Parkins (1975) report an approximately 3-fold increase in the fluoride concentration of water boiled in a Teflon-coated pan relative to that of stainless steel or Pyrex glass. Due to their experimental design and the manner in which final fluoride concentrations are expressed, it is not possible to discern whether or not the increased fluoride concentration was due to leaching of fluoride from the Teflon or differential evaporation noted for the Teflon cookware versus other materials. Given the inert nature of Teflon and the strength of the covalent C-F bonds in the tetrafluoroethylene polymer, it is unlikely that fluoride would be released in sufficient quantities to increase its concentration in the water by 3 times. Based on the uncertainties associated with the experimental data and the properties of Teflon, the Agency does not believe that Teflon-treated cookware is a significant source of fluoride exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether sulfuryl fluoride or fluoride has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to sulfuryl fluoride or fluoride and any other substances. Sulfuryl fluoride does produce the metabolite fluoride also produced by the insecticide cryolite and this risk assessment has included exposure from both exposure sources. For the purposes of this tolerance action, therefore, EPA has not assumed that sulfuryl fluoride and/or fluoride has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold 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 data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. In the sulfuryl fluoride developmental toxicity study in rats, neither quantitative nor qualitative evidence of increased susceptibility of fetuses to in utero exposure to sulfuryl fluoride was observed. In the sulfuryl fluoride developmental study in rabbits, neither quantitative nor qualitative evidence of increased susceptability of fetuses to *in utero* exposure to sulfuryl fluoride was observed. In the sulfuryl fluoride 2-generation reproductive study in rats, neither quantitative nor qualitative evidence of increased susceptability of fetuses to sulfuryl fluoride was observed.

A very large body of information regarding the toxicology of fluoride is available in the open literature. A complete review or re-presentation of that information is beyond the scope of this assessment. For a comprehensive review of the toxicology of fluoride, the reader is referred to publications by the World Health Organization (2002), the National Research Council (1993), the Medical Research Council (1992), and

the Department of Health and Human Services (Draft Document 1993). In conducting the assessment for fluoride, the Agency has used the toxicological assessment and Maximum Contaminant Level Goals (MCLGs) established by the Agency's Office of Water. The MCLG was established in 1986 and is based on an LOAEL of 20 mg/day, a safety factor of 2.5, and an adult drinking water intake of 2 L/day. The use of a safety factor of 2.5 ensures public health criteria while still allowing sufficient concentration of fluoride in water to realize its beneficial effects in protecting against dental caries.

3. *Conclusion*. There is a complete toxicity data base for sulfuryl fluoride with the exception of a developmental neurotoxicity (DNT) study in rats. The exposure data are sufficiently complete or are estimated based on data that reasonably accounts for potential exposures. Based on the available evidence, the Agency is requiring an inhalation developmental neurotoxicity (DNT) study in rats (Guideline No. 870.6300) as a condition of registration in order to more clearly and fully characterize the potential for neurotoxic effects in young animals.

The Agency has determined that a 10X FQPA safety factor in the form of a data base uncertainty factor (UFDB) is needed to account for the lack of the DNT study since the available data provide no basis to support reduction or removal of the default 10X factor. The following points were considered in this determination:

- The current regulatory dose for chronic dietary risk assessment is the NOAEL of 8.5 mg/kg/day (30 ppm; 0.13 mg/L) selected from a 90–day inhalation toxicity study in rabbits. This dose is also used for intermediate- and long-term inhalation exposure risk assessments. The current dose for the short-term inhalation exposure risk assessment is the NOAEL of 30 mg/kg/day (100 ppm; 0.42 mg/L) from a 2–week inhalation toxicity study in rabbits.
- After considering the dose levels used in the neurotoxicity studies and in the 2-generation reproduction study, it is assumed that the DNT study with sulfuryl fluoride will be conducted at dose levels similar to those used in the 2-generation reproduction study (0, 5, 20, 150 ppm; 0, 0.02, 0.08, 0.6 mg/L). It is considered possible that the results of the DNT study could impact the endpoint selection for risk assessments because the lowest dose that may be tested in the DNT (5 ppm or 0.02 mg/L), based on the Agency's dose analysis, could become an effect level which would necessitate an additional factor resulting in doses which would then be lower than the current doses used for chronic dietary (8.5 mg/kg/day), intermediate and long-term inhalation (30 ppm or 0.13 mg/L) and short term inhalation (100 ppm or 0.42 mg/L) risk assessments. Given these circumstances, the Agency does not have sufficient reliable data justifying selection of an additional safety factor for the protection of infants and children lower than the default value of 10X. Therefore, a UFDB of 10X will be applied to repeated dose exposure scenarios (i.e. chronic RfD, and residential short, intermediate and long term inhalation) to account for the lack of the DNT study with sulfuryl fluoride.

The Agency has determined that there is no need for a special FQPA safety factor (i.e., 1X) since there are no residual uncertainties for pre- and/or post-natal toxicity based on the following:

- In the developmental toxicity study in rats, neither quantitative nor qualitative evidence of increased susceptibility of fetuses to in utero exposure to sulfuryl fluoride was observed.
- In the developmental toxicity study in rabbits, neither quantitative nor qualitative evidence of increased susceptibility of fetuses to *in utero* exposure to sulfuryl fluoride was observed.
- In the 2-generation reproduction toxicity study in rats, neither quantitative nor qualitative evidence of increased susceptibility of fetuses to sulfuryl fluoride was observed.

Fluoride. Given the wealth of reliable human data on fluoride, EPA believes no additional safety factor for the protection of children is necessary (1X). Relying on the extensive data bearing on skeletal fluorosis, EPA's Office of Water reduced the traditional intraspecies safety factor to 2.5X. This is reasonable, especially given that the NAS has recommended that a safe dose for fluoride should be set using no intraspecies safety factor or any other safety factor.

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies for either sulfuryl fluoride and/or fluoride; therefore, no acute risk is expected from exposure to these compounds.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that aggregate exposure to sulfuryl fluoride food will utilize less than 1% of the cPAD for the U.S. population, less than 1% of the cPAD for all population subgroups.

EPA has concluded that aggregate exposure to fluoride from food will utilize 35% of the MCLG (as mg/kg/day) for the U.S. population, 23% of the MCLG (as mg/kg/day) for youth 13–19 years, 37% of the MCLG (as mg/kg/day) for children 3–5 years, 35% of the MCLG (as mg/kg/day) for all infants less than 1 year, and 28% of the MCLG (as mg/kg/day) for children 1-2 years. These risk estimates are below the Agency's level of concern.

TABLE 7.—AGGREGATE EXPOSURE AND RISK ESTIMATES FOR FLUORIDE

Population Subgroup	MCL/ SMCL, mg/kg/ day	Estimated Fluoride Exposure by Source, mg/kg/day							% of MCLG
		Sulfuryl Fluoride	Cryolite	Back-ground Food	Water	Tooth-paste	Air	Total	
U.S. population (total)	0.114	0.0004	0.0006	0.0068	0.0269	0.0043	0.0006	0.0397	35
All infants (<1 year)	0.571	0.0005	0.0009	0.0093	0.1424	0.0429	0.0019	0.1980	35
Children (1–2 years)	0.308	0.0013	0.0031	0.0175	0.0407	0.0231	0.0020	0.0877	28
Children (3–5 years)	0.182	0.0012	0.0020	0.0149	0.0338	0.0136	0.0012	0.0668	37
Children (6–12 years)	0.1	0.0007	0.0008	0.0094	0.0227	0.0075	0.0007	0.0419	42

TABLE 7.—AGGREGATE EXPOSURE AND RISK ESTIMATES FOR FLUORIDE—Continued

Population Subgroup	MCL/ SMCL, mg/kg/ day	Estimated Fluoride Exposure by Source, mg/kg/day							% of MCLG
		Sulfuryl Fluoride	Cryolite	Back-ground Food	Water	Tooth-paste	Air	Total	
Youth (13–19 years)	0.133	0.0004	0.0003	0.0062	0.0176	0.0050	0.0007	0.0302	23
Adults (20–49 years)	0.114	0.0003	0.0004	0.0057	0.0252	0.0043	0.0006	0.0365	32
Adults (50+ years)	0.114	0.0003	0.0005	0.0050	0.0256	0.0043	0.0006	0.0364	32
Females (13–49 years)	0.131	0.0003	0.0005	0.0054	0.0238	0.0049	0.0006	0.0355	27

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

The Agency determined there is no need to quantify the inhalation risk resulting from a single residential or occupational inhalation exposure to sulfuryl fluoride. No treatment-related neurotoxic or other effects were observed in a specially designed acute neurotoxicity inhalation study in which rats were exposed on two consecutive days for 6 hours/day to concentrations up to 300 ppm of sulfuryl fluoride (equivalent to 1.25 mg/L). Further, no appropriate endpoints resulting from a single inhalation exposure were identified in any of the available toxicity studies on sulfuryl fluoride. Therefore, no hazard attributable to a single inhalation exposure was identified and quantification of risk for single inhalation exposures was determined to be unnecessary. The Agency notes that poisonings and fatalities have been reported in humans following inhalation exposure to sulfuryl fluoride. The severity of these effects has depended on the concentration of sulfuryl fluoride and the duration of exposure. Short-term inhalation exposure to high concentrations has caused respiratory irritation, pulmonary edema, nausea, abdominal pain, central nervous system depression, and numbness in the extremities. In addition, there have been two reports of deaths of persons entering houses treated with sulfuryl fluoride. One person entered the house illegally and was found dead the next morning. A second person died of cardiac arrest after sleeping in the house overnight following fumigation. A plasma fluoride level of 0.5 mg/L (10 times normal) was found in this person following exposure. These acute poisonings in humans, however, occurred only after label directions were grossly violated and persons were subsequently exposed to extremely high concentrations of sulfuryl fluoride. Therefore, based on the best available data and current policies, potential risks do not exceed the Agency's level of concern if label directions and precautions are followed.

Fluoride is not expected to pose a short-term risk.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Intermediate-term residential exposure is not expected to occur with the use of sulfuryl fluoride. Furthermore, sulfuryl fluoride residues will not occur in water due to its extreme volatility as a gas; and based on the toxicology of fluoride and the behaviors associated with fluoride exposure a chronic risk assessment is appropriate not an intermediate-term risk assessment. Therefore, based on the best available data and current policies, potential risks do not exceed the Agency's level of concern.

Fluoride is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population*. Sulfuryl fluoride and fluoride are not expected to pose a cancer risk.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to sulfuryl fluoride and inorganic fluoride residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology are available to enforce the tolerance expressions. The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no CODEX MRLs established. These are the first food tolerances for sulfuryl fluoride in the United States.

C. Conditions

The conditions for registration are discussed in the Profume Notice of Registration. The Agency does note that the current MCLG and SMCL are under review by the National Academy of Science as requested by the Office of Water. This review is expected to be completed in 2005. Should there be a change in the MCLG and/or SMCL by the Office of Water then the registration of Profume may require revision.

V. Conclusion

Therefore, tolerances are established for sulfuryl fluoride and inorganic fluoride residues of sulfuryl fluoride, in or on various commodities at the level specified in the tables below.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0373 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before March 23, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0373, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have

''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: January 13, 2004.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—AMENDED

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

■ 2. Section 180.145 is amended by revising paragraph (a)(3) to read as follows:

§ 180.145 Flourine compounds; tolerances for residues.

(a) * * *

(3) Tolerances are established for residues of fluoride in or on the following commodities from the postharvest fumigation with sulfuryl fluoride for the control of insects:

Commodity	Parts per million
Barley, bran, postharvest	45.0
Barley, flour, postharvest	45.0
Barley, grain, postharvest	15.0
Barley, pearled, postharvest	45.0
Corn, aspirated grain fractions, postharvest	55.0
Corn, field, flour, postharvest	35.0
Corn, field, grain, postharvest	10.0
Corn, field, grits, postharvest	10.0
Corn, field, meal, postharvest	30.0
Corn pop, grain, postharvest	10.0
Fruit, dried , postharvest (other than raisin)	3.0
Grape, raisin, postharvest	7.0
Millet, grain, postharvest	40.0
Nut, tree, Group 14, postharvest	10.0
Oat, flour, postharvest	75.0
Oat, grain, postharvest	25.0
Oat, rolled, postharvest	75.0
Pistachio, postharvest	10.0
Rice, bran, postharvest	31.0
Rice, grain, postharvest	12.0
Rice, hulls, postharvest	35.0
Rice, polished, postharvest	25.0
Rice, wild, grain, postharvest	25.0
Sorghum, grain, postharvest	40.0
Triticale, grain, postharvest	40.0
Wheat, bran, postharvest	40.0
Wheat, flour, postharvest	125.0
Wheat, germ, postharvest	130.0
Wheat, grain, postharvest	40.04
Wheat, milled byproducts, postharvest	130.0
Wheat, shorts, postharvest	40.0

* * * * *

■ 3. Section 180.575 is amended by revising paragraph (a) to read as follows:

§ 180.575 Sulfuryl fluoride; tolerance for residues.

(a)(1) *General.* Tolerances are established for residues of sulfuryl fluoride in or on the following commodities from the postharvest fumigation with sulfuryl fluoride for the control of insects:

Commodity	Parts per million
Barley, bran, postharvest	0.05
Barley, flour, postharvest	0.05
Barley, grain, postharvest	0.1
Barley, pearled, postharvest	0.05
Corn, aspirated grain fractions, postharvest	0.05
Corn, field, flour, postharvest	0.01
Corn, field, grain, postharvest	0.05
Corn, field, grits, postharvest	15.0
Corn, field, meal, postharvest	0.01
Corn pop, grain, postharvest	0.05
Fruit, dried, postharvest	0.05
Millet, grain, postharvest	0.1
Nut, tree, Group 14, postharvest	3.0
Oat, flour, postharvest	0.05
Oat, grain, postharvest	0.1
Oat, rolled, postharvest	0.1
Pistachio, postharvest	3.0
Rice, bran, postharvest	0.01
Rice, grain, postharvest	0.04
Rice, hulls, postharvest	0.1
Rice, polished, postharvest	0.01
Rice, wild, grain, postharvest	0.05
Sorghum, grain, postharvest	0.1
Triticale, grain, postharvest	0.1
Wheat, bran, postharvest	0.05
Wheat, flour, postharvest	0.05
Wheat, germ, postharvest	0.02
Wheat, grain, postharvest	0.1
Wheat, milled byproducts, postharvest	0.05
Wheat, shorts, postharvest	0.05

(2) To assure safe use of this pesticide commodities treated with sulfuryl fluoride must be aerated for at least 24 hours prior to entering commerce.

* * * * *

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 2, 15, 97, and 101

[WT Docket No. 02–146; RM–10288; FCC 03–248]

Allocations and Service Rules for the 71–76 GHz, 81–86 GHz, and 92–95 GHz Bands; Loea Communications Corporation Petition for Rule Making

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission adopts service rules to promote the private sector development and use of the ''millimeter wave'' spectrum in the 71–76 GHz, 81–86 GHz and 92–95 GHz bands pursuant to parts 15 and 101 of our rules. This action follows an initiative by the Commission's Office of Engineering and Technology to spawn possible commercial development of these bands under the Communications Act of 1934, as amended.

DATES: Effective February 23, 2004.

FOR FURTHER INFORMATION CONTACT: Jennifer Burton regarding legal matters, and/or Gerardo Mejia regarding engineering matters via phone at (202) 418–0680, via TTY (202) 418–7233, via e-mail at *Jennifer.Burton@fcc.gov*; *Gerardo.Mejia@fcc.gov*, respectively, or via regular mail at Federal Communications Commission, Wireless Telecommunications Bureau, 445 12th Street, SW., Washington, DC 20554.

SUPPLEMENTARY INFORMATION: This is a summary of the Federal Communications Commission's *Report and Order*, FCC 03–248, adopted on October 16, 2003, and released on November 4, 2003. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center, Room CY–A257, 445 12th Street, SW., Washington, DC 20554. The complete text may be purchased from the Commission's copy contractor, Qualex International, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. The full text may also be downloaded at: *www.fcc.gov*. Alternative formats are available to persons with disabilities by contacting Brian Millin at (202) 418–7426 or TTY (202) 418–7365.

Report and Order: In this *Report and Order*, the Commission makes the following major decisions:

- It will reallocate the 71–76 GHz, 81–86 GHz and 92–95 GHz bands to update the current allocations, which were established at the World Administrative Radio Conference in 1992 (WARC–92, Malaga-Torremolinos) and the World Radiocommunication Conference in 1997 and 2000 (WRC–97, Geneva, and WRC–2000, Istanbul).

- It will divide the 71–76 GHz and 81–86 GHz bands into four unpaired 1.25 GHz segments each (eight total), without mandating specific channels within the segment. The segments may be aggregated without limit. In order to maximize the number of possible users in a given location, the Commission will divide the 71–76 GHz and 81–86 GHz bands into unpaired 1.25 GHz segments (without mandating specific channels within the segment) with no aggregation limit. It will permit pairing, but only in a standardized manner (*e.g.*, 71–72.25