Sulfuryl fluoride; Pesticide Tolerance

[Federal Register: July 15, 2005 (Volume 70, Number 135)]
[Rules and Regulations]
[Page 40899-40908]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr15jy05-11]

ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 180
[OPP-2005-0174; FRL-7723-7]

Sulfuryl fluoride; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of sulfuryl fluoride and of fluoride anion in or on commodities in food processing facilities. Dow AgroSciences LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective July 15, 2005. Objections and requests for hearings must be received on or before September 13, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the SUPPLEMENTARY INFORMATION. EPA has established a docket for this action under docket identification (ID) number OPP-2005-0174. All documents in the docket are listed in the EDOCKET index at http://www.epa.gov/edocket. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., 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.

FOR FURTHER INFORMATION CONTACT: Daniel Kenny, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7546; e-mail address: kenny.dan@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 code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.

• Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.

• Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.

• Pesticide manufacturing (NAICS code 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 Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (http://www.epa.gov/edocket/), 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 E-CFR Beta Site Two at http://www.gpoaccess.gov/ecfr/. EXIT Disclaimer To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

II. Background and Statutory Findings

In the Federal Register of March 4, 2005 (70 FR 10621) (FRL-7701-8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F6573) by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fumigant sulfuryl fluoride, and of fluoride anion (also referred to as ``fluoride'' in this document), from the fumigation use of sulfuryl fluoride in food processing facilities, as follows:

1. The petition requested that 40 CFR 180.145 be amended by establishing tolerances for residues of fluoride in or on the following raw agricultural commodities (RAC): Animal feed at 130 parts per million (ppm); beef, meat at 40 ppm; cheese, postharvest at 5 ppm; cocoa bean, postharvest at 12 ppm; coconut, postharvest at 40 ppm; coffee, postharvest at 12 ppm; cottonseed, postharvest at 13 ppm; egg at 850 ppm; ginger, postharvest at 13 ppm; grain, cereal, forage, fodder and straw group 16, postharvest at 130 ppm; grass, forage, fodder and hay group 17, postharvest at 130 ppm; ham at 20 ppm; herbs and spices group 19, postharvest at 50 ppm; milk at 3 ppm; nut, pine, postharvest at 10 ppm; other processed food at 70 ppm; peanut, postharvest at 13 ppm; rice flour, postharvest at 98 ppm; and vegetable, legume, group 06, postharvest at 6 ppm. As a result of the residue data, and in order to provide more adequate coverage of all commodities that may be involved in the use of sulfuryl fluoride in food processing facilities, the proposed tolerances were subsequently revised to tolerances for residues of fluoride in or on all processed food commodities where a separate tolerance is not already established at 70 ppm; cattle, meat, dried at 40 ppm; cheese at 5.0 ppm; cocoa bean, postharvest at 20 ppm; coconut, postharvest at 40 ppm; coffee, postharvest at 15 ppm; cottonseed, postharvest at 70 ppm; eggs, dried at 900 ppm; ginger, postharvest at 70 ppm; ham at 20 ppm; herbs and

spices, group 19 postharvest at 70 ppm; milk, powdered at 5.0 ppm; nut, pine, postharvest at 20 ppm; peanut, postharvest at 15 ppm; rice, flour, postharvest at 45 ppm; and vegetables, legume, group 6, postharvest at 70 ppm.

[[Page 40900]]

2. The petition requested that 40 CFR 180.575 be amended by establishing tolerances for residues of sulfuryl fluoride in or on the following RACs: Animal feed at 2.0 ppm; beef, meat at 0.01 ppm; cheese, postharvest at 0.5 ppm; cocoa bean, postharvest at 0.8 ppm; coconut, post harvest at 1.0 ppm; coffee, postharvest at 0.8 ppm; cottonseed, postharvest at 0.2 ppm; egg at 0.7 ppm; ginger, postharvest at 0.2 ppm; grain, cereal, forage, fodder and straw group 16, postharvest at 2.0 ppm; grass, forage, fodder and hay group 17, postharvest at 2.0 ppm; ham at 0.01 ppm; herbs and spices group 19, postharvest at 0.3 ppm; milk at 1.5 ppm; nut, pine, postharvest at 3.0 ppm; other processed food at 1.2 ppm; peanut, postharvest at 0.2 ppm; rice flour, postharvest at 0.08 ppm; and vegetable, legume, group 06, postharvest at 0.02 ppm. As a result of the residue data, and in order to provide more adequate coverage of all commodities that may be involved in the use of sulfuryl fluoride in food processing facilities, the proposed tolerances were subsequently revised to a tolerance for residues of sulfuryl fluoride in or on all processed food commodities where a separate tolerance is not already established at 2.0 ppm; cattle, meat, dried at 0.01 ppm; cheese at 2.0 ppm; cocoa bean, postharvest at 0.2 ppm; coconut, postharvest at 1.0 ppm; coffee, postharvest at 1.0 ppm; cottonseed, postharvest at 0.5 ppm; eggs, dried at 1.0 ppm; ginger, postharvest at 0.5 ppm; ham at 0.02 ppm; herbs and spices, group 19 postharvest at 0.5 ppm; milk, powdered at 2.0 ppm; nut, pine, postharvest at 0.2 ppm; peanut, postharvest at 0.5 ppm; rice, flour, postharvest at 0.05 ppm; and vegetables, legume, group 6, postharvest at 0.5 ppm.

That notice included a summary of the petition prepared by Dow AgroSciences LLC, the registrant. The Agency received 19 sets of written comments on this notice. In general, the comments addressed either procedural issues concerning the process of establishing tolerance levels for sulfuryl fluoride and total fluoride or addressed issues concerning the human health and other consequences that would result from the use of sulfuryl fluoride and increased human exposure to fluorides. In addition, numerous questions and requests for additional information were raised concerning issues related to EPA's human health risk assessment process and to possible secondary fluoride exposures. Most of the comments and questions relate to fluoride exposure and fluoride toxicology. The Agency has separately reviewed these comments and concludes that the information contained within does not support adopting a change in EPA's current evaluation of the adverse health effects of fluoride. The Agency has prepared a detailed response to the public comments regarding the establishment of tolerances for sulfuryl fluoride and for fluoride anion on food resulting from the application of sulfuryl fluoride as a fumigant in food processing facilities. This document has been made part of the public docket OPP-2005-0067 for this regulatory action.

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 in the Federal Register of November 26, 1997 (62 FR 62961) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

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 on all processed food commodities where a separate tolerance is not already established at 2.0 ppm; cattle, meat, dried at 0.01 ppm; cheese at 2.0 ppm; cocoa bean, postharvest at 0.2 ppm; coconut, postharvest at 1.0 ppm; coffee, postharvest at 1.0 ppm; cottonseed, postharvest at 0.5 ppm; eggs, dried at 1.0 ppm; ginger, postharvest at 0.5 ppm; ham at 0.02 ppm; herbs and spices, group 19 postharvest at 0.5 ppm; milk, powdered at 2.0 ppm; nut, pine, postharvest at 0.2 ppm; peanut, postharvest at 0.5 ppm; rice, flour, postharvest at 0.05 ppm; and vegetables, legume, group 6, postharvest at 0.5 ppm, and residues for fluoride anion on all processed food commodities where a separate tolerance is not already established at 70 ppm; cattle, meat, dried at 40 ppm; cheese at 5.0 ppm; cocoa bean, postharvest at 20 ppm; coconut, postharvest at 40 ppm; coffee, postharvest at 15 ppm; cottonseed, postharvest at 70 ppm; eggs, dried at 900 ppm; ginger, postharvest at 70 ppm; ham at 20 ppm; herbs and spices, group 19 postharvest at 70 ppm; milk, powdered at 5.0 ppm; nut, pine, postharvest at 20 ppm; peanut, postharvest at 15 ppm; rice, flour, postharvest at 45 ppm; and vegetables, legume, group 6, postharvest at 70 ppm.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. Since residues of concern for sulfuryl fluoride are sulfuryl fluoride, per se, and fluoride anion, the Agency assessed the human health risk associated with both sulfuryl fluoride and fluoride anion in connection with this action. Due to the different toxicological effects elicited by these two chemicals, their risks have been assessed separately. The nature of the toxic effects caused by sulfuryl fluoride and by fluoride anion as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed are discussed in the Federal Register of January 23, 2004 (69 FR 3240) (FRL-7342-1).

B. Toxicological Endpoints

The dose at which 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

[[Page 40901]]

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 UFs may be used: ``Traditional UFs,'' the ``special FQPA safety factor,'' and the ``default FQPA safety factor.'' By the term ``traditional UF,'' EPA is referring to those additional UFs used prior to FQPA passage to account for database deficiencies. These traditional UFs 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 UF 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 (aRfD or cRfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional UFs 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 x 10-5), one in a million (1 x 10-6), or one in ten million (1 x 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.

In assessing the risks associated with exposure to fluoride, EPA has relied on the toxicological assessment and Maximum Contaminant Levels (MCLs) established by the Agency's Office of Water and the hazard analysis performed by the Institute of Medicine of the National Academy of Science. A MCL is an enforceable level that is set as closely as feasible to the Maximum Contaminant Level Goal (MCLG) of a contaminant. The MCLG 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. MCL goals are non-enforceable health goals. For fluoride, both the MCL and the MCLG have been set at 4.0 ppm (4 milligrams/liter (mg/L)). EPA chose the MCL value to protect against cripplying skeletal fluorosis effects that were only seen where there was daily consumption of 20 mg or more of fluoride for 20 or more years. (50 FR 47142) (November 14, 1985). A 4 mg/L level in water is designed to limit total daily exposure to approximately 8 milligrams day (mg/day).

The Institute of Medicine (IOM) examined fluoride in 1997 and recommended a NOAEL for use in evaluating the risk posed by fluoride exposure. Its examination of the available data identified a NOAEL of

10 mg/day as relates to fluoride intake and skeletal fluorosis. The IOM further pointed out that exposures of 10 or more years are required to develop this condition and therefore concluded that skeletal fluorosis is not a concern for children under the age of 8. Their analysis results in a tolerable upper intake level of 10 mg/day for children age 8 and above and adults. In deriving a recommended upper limit for exposure, the IOM used an UF of 1, noting that the NOAEL is derived from human studies and that symptomatic skeletal fluorosis is not observed at intakes of 10 mg/day. As noted in the general discussion of fluoride toxicity, the FQPA safety factor can also be reduced to 1X; therefore, the safe dose level for skeletal fluorosis based on the IOM analysis is 10 mg/day.

A summary of the toxicological endpoints for sulfuryl fluoride and for fluoride anion used for use in human risk assessment is discussed in Unit III.B. of the final rule published in the Federal Register of January 23, 2004 (69 FR 3240) (FRL-7342-1).

C. Exposure Assessment

1. Dietary exposure from food and feed uses. Tolerances have been established (40 CFR 180.575) for the residues of sulfuryl fluoride, in or on a variety of RACs. Tolerances currently exist for sulfuryl fluoride on cereal grains, dried fruits, and tree nuts as a result of postharvest fumigation application to grain processing and storage facilities. Tolerances have been established (40 CFR 180.145) for the residues of fluoride, in or on a variety of RACs as a result of applications of sulfuryl fluoride and cryolite on food. With this action, tolerances are established in association with the use of sulfuryl fluoride for the fumigation of dried beef, cheese, coffee, cottonseed, cocoa bean, coconuts, coffee, powdered eggs, ginger, ham,herbs and spices, powdered milk, pine nuts, peanuts, rice flour, and legume vegetables for the control of insects, and all other processed foods as a result of the treatment of areas and equipment within food and feed processing plants with sulfuryl fluoride for the control of insects. The term food and feed processing plant includes those facilities specifically listed under the Food and Feed Processing Plants subgroup within pesticide use site group 12 in Appendix A to 40 CFR part 158. Risk assessments were conducted by EPA to assess dietary exposures from sulfuryl fluoride and from fluoride anion 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 on sulfuryl fluoride or the fluoride anion. Therefore, acute dietary exposure assessments were not conducted.

ii. Chronic exposure. In conducting the chronic dietary risk assessment, EPA used the Dietary Exposure Evaluation Model (DEEM) software with the Food Commodity Intake Database (FCID),

[[Page 40902]]

which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. Due to the potential for serial fumigation of a commodity or ingredient, first as part of a postharvest or grain mill fumigation and then again due to food processing facility fumigation, dietary exposure estimates from the previous assessment are combined with those from the current assessment. The actual probability of this occurring is likely to be very small; therefore, this assumption results in an overestimate of exposure. The following assumptions were made for the chronic exposure assessments.

For sulfuryl fluoride, the chronic analysis used average residue values from residue trials reflecting the maximum proposed use, percent market share estimates, and an estimate of the amount of yearly production that might be within the processing facility during fumigation.

In addition to assessing the exposure to sulfuryl fluoride in food, EPA included quantitative estimates of fluoride exposure from residues in foods from the use of sulfuryl fluoride and/or cryolite, background levels in foods, and consumption of fluoride-containing water. Also addressed quantitatively are exposure from the use of fluoridated toothpaste and inhalation of fluoride from the atmosphere. For each of these pathways of exposure, residue estimates are conservative to moderately conservative in nature. After assessing these pathways of exposure, drinking water and background levels in food are the principal sources of dietary exposure to fluoride.

iii. Cancer. Sulfuryl fluoride has been classified as ``not likely to be carcinogenic to humans'' and there is no evidence showing an increased risk of cancer following exposure to fluoride. Therefore, EPA has not conducted an assessment of cancer risk from dietary exposures for either sulfuryl fluoride or fluoride anion.

iv. Anticipated residue and percent crop treated (PCT) information. Section 408(b)(2)(E) of the 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 pursuant to section 408(f)(1) 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. For the present action, EPA will issue such data call-ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such data call-ins will be required 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:

EPA has estimated that 40% of the commodities for which an individual, specific tolerance is established by this action will be fumigated with sulfuryl fluoride. The exceptions are cocoa beans and ham, which were estimated at 100%. Sulfuryl fluoride is intended to be used as a methyl bromide alternative that is used to target pests in commodities and food processing facilities. Usage information indicates that an estimated 20 to 40% of the fumigated commodity market is fumigated using methyl bromide. Assuming full market penetration by sulfuryl fluoride, and using the upper bound percentage and applying it to the entire U.S. market as opposed to only the fumigated market, EPA believes that 40% PCT is a highly conservative over-estimation of actual potential usage of sulfuryl fluoride for these commodities.

For processed foods that may be present while fumigating areas and equipment within food processing facilities (i.e., the commodities covered by the catchall provision in the tolerance ``all processed foods not otherwise listed''), EPA has estimated the percentage of food processing facilities that will likely be fumigated, the frequency of

fumigation, as well as the extent of a given facility's production that would be exposed during fumigation. Of the processing facilities in the U.S., it is estimated that approximately 40% would receive sulfuryl fluoride fumigation with, on average, 2.5 fumigations per year. Approximately one day's worth of production could be stored on-site and the facilities typically operate over 300 days per year. Assuming 3 fumigations per year, that gives a percent commodity treated estimate of 0.4 x 3 / 300 = 0.004. For this assessment, it was assumed that rice mills could be fumigated 6 times per year, yielding a factor of 0.008. Since commodities would be exposed in their ``final'' form, processing factors were not used in this assessment. In the case of milk and egg, only dried food forms were included in the analysis since that is the form that would be present in the processing facility.

The Agency believes that the three conditions listed in this Unit have been met. With respect to condition 1, EPA finds that the PCT information described in this document for sulfuryl fluoride used in food processing facilities is reliable and has a valid basis. Sulfuryl fluoride is a postharvest fumigant in food processing facilities that will replace methyl bromide uses for which the Agency has good information about the actual amounts used. It is also possible that sulfuryl fluoride could replace other fumigant products for which there are also use data available, although not as refined as for methyl bromide. 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 in food processing facilities that will likely be treated with sulfuryl fluoride. 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

[[Page 40903]]

have available information on the regional consumption of food to which sulfuryl fluoride 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 fluoride anion may be in drinking water due to intentional fluoridation. The nature of fluoride residues in drinking water and fluoride exposure estimates are discussed in the Federal Register of January 23, 2004 (69 FR 3240) (FRL-7342-1).

3. From non-dietary exposure. The term ``residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

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 for the sulfuryl fluoride product that is used for fumigation of domestic structures (Vikane) restricts reentry to the residence until the measured levels of sulfuryl fluoride are very low. The Agency has determined, based on 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.

Fluoride exposure may also 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 exposure from toothpaste and the air in its quantitative assessment due to lack of data indicating that other sources of exposure are significant. The nature of non-dietary exposures to fluoride and non-dietary exposure estimates are discussed in the Federal Register of January 23, 2004 (69 FR 3240) (FRL-7342-1).

4. Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of the 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.''

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 and any other substances and sulfuryl fluoride does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that sulfuryl 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 Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using UF (safety) 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. The toxicity database for sulfuryl fluoride is complete 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 DNT study in rats (OPPTS Harmonized Guideline 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 database (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 milligrams/kilogram/day (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-term and long-term inhalation exposure risk assessments. The current dose for the short-term inhalation exposure risk

[[Page 40904]]

assessment is the NOAEL of 30 mg/kg day (100 ppm; 0.42 mg/L) from a 2-week inhalation toxicity study in rabbits. In addition, 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-term, intermediate-term, and long-term inhalation) to account for the lack of the DNT study with sulfuryl 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 exposure to sulfuryl fluoride from food will utilize 2.4% of the cPAD for the U.S.

population, 5.3% of the cPAD for infants less than 1 year of age, and 3.3% of the cPAD for children 6-12 years of age. There are no residential uses for sulfuryl fluoride that result in chronic residential exposure to sulfuryl fluoride. In addition, as discussed above, residues of sulfuryl fluoride will not occur in drinking water. Therefore, drinking water does not contribute to aggregate exposure, leaving residues in or on food as the only quantifiable exposure pathway for estimating aggregate risks. Estimated chronic dietary risks represent chronic aggregate risks, and are no more than 2.4% of the cPAD for the U.S. population or any subgroup. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 1:

Table 1.-Aggregate Risk Assessment for Chronic Exposure to Sulfuryl

Population Subgroup	cPAD, mg/kg/day	Estimated Exposure (Current Request), mg/kg/day	Estimated Exposure (Previous Estimate) mg/kg/day
U. S. population	0.003	0.000070	0.00000
All infants (< 1 year)	0.003	0.000156	0.0000
Children (1-2 years)	0.003	0.000236	0.00000
Children (3-5 years)	0.003	0.000178	0.00000
Children (6-12 years)	0.003	0.000096	0.00000
Youth (13-19 years)	0.003	0.000052	0.00000
Adults (20-49 years)	0.003	0.000056	0.00000
Adults (50+ years)	0.003	0.000046	0.00000
Females (13-49 years)	0.003	0.000052	0.00000

As discussed previously in this Unit, to assess aggregate risk for fluoride, EPA included quantitative estimates of dietary exposure from background levels of fluoride in food, fluoride in water, 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. Total estimated aggregate exposures were calculated for the U.S. population and each subgroup and are shown in the following Table 2:

[[Page 40905]]

Table 2.-Estimated Aggregate Exposure to

Population Subgroup	From Sulfuryl Fluoride mg/kg/day	From Cryolite kg/day
U.S. population	0.0093	0.00
All infants (< 1 year)	0.0114	0.0
Children (1-2 years)	0.0231	0.00
Children (3-5 years)	0.0204	0.00

Children (6-12 years)	0.0130	0.00
Youth (13-19 years)	0.0078	0.00
Adults (20-49 years)	0.0078	0.00
Adults (50+ years)	0.0072	0.00
Females (13-49 years)	0.0073	0.00

In a prior tolerance action involving sulfuryl fluoride, aggregate exposure estimates expressed in milligrams per kilogram of body weight per day were then compared to the MCL for the U.S. population and each subgroup. Because the MCL was expressed in terms of an allowable level of fluoride in milligrams per liter of water, EPA converted the MCL into a reference dose-type number relying on standard age group body weights and water consumption figures. The IOM's conclusion that exposures to fluoride must continue for at least 10 years has convinced EPA that its prior risk assessment approach using the MCL to calculate a reference dose-type number mischaracterizes the risk by focusing attention on daily or yearly exposure rather than looking at total exposure over a 10-year period. In fact, the MCL, itself, was based on a concern that fluoride could cause skeletal fluorosis if there was exposure at a 20 mg/day level over a period of 20 years. Setting the MCL at 4 mg/L was based on the conclusion that value would limit exposure to 8 mg/day (assuming 2 liters of water consumed per day) over the long-term and would therefore, provide an adequate margin of exposure. Accordingly, in this action, EPA has characterized the risk by comparing total exposure for various age groups to the value deemed safe in choosing the MCL (8 mg/day) and identifying the 10-year span most likely to produce the highest exposure. Because the MCL was based on the finding that exposures over 8 mg/day would have to occur for 20 years or more, EPA believes it is appropriate to use the 8 mg/day figure to evaluate exposure for all populations subgroups, including infants and children. Nonetheless, out of an abundance of caution, and because the EPA document establishing the MCL value did not specifically address the level of exposure in children that could contribute to crippling skeletal fluorosis later in life, EPA has also evaluated children's exposure to fluoride by comparing it to the expected exposure under the MCL for children of 4 mg/day (assuming consumption of 1 liter of water a day).

As Table 3 shows, each of the age groups's exposure is well below the exposure value deemed safe by the MCL and the highest exposure over a 10-year period is for adults and their exposure is likely to be no greater than 38% of the safe level. Even when it is assumed that the maximum exposure for infants, children, and youths should be 4 mg/day, the highest 10-year period, which would be for the ages of 2-12, would only increase to 50% of the safe level. EPA conducted the same exercise using the IOM safe level of 10 mg/day. Although the IOM did not suggest that skeletal fluorosis could be a problem for children under the age of 8, neither did IOM state that exposure under the age of 8 could contribute to skeletal fluorosis later in life. Accordingly, as a conservative measure, EPA evaluated children under the age of 8 under the 10 mg/day exposure level as well. EPA did not conduct an alternative evaluation assuming a lower acceptable exposure level for children in relying on the IOM analysis because the IOM clearly applied its safe exposure level of 10 mg/day to children and adults. The results using the IOM safe level of 10 mg/day are presented in Table 4. It shows that exposure during the highest 10-year period is 31% of the safe dose.

Table 3.-Aggregate Exposure and Risk Estimates for Skeletal Fluorosis R

	Total

Population Subgroup	Allowable Exposure in mg/day under MCL	Total Flouride Exposure, mg/kg/day	Body Weight, k
U.S. population (total)	8	0.049	70.000
All infants (< 1 year)	8	0.209	7.00
Children (1-2 years)	8	0.110	13.000
Children (3-5 years)	8	0.086	22.000

[[Page 40906]]

Children (6-12 years)	8	0.054	40.000
Youth (13-19 years)	8	0.038	60.000
Adults (20-49 years)	8	0.044	70.000
Adults (50+ years)	8	0.043	70.000
Females (13-49 years)	8	0.043	61.000

Table 4.--Aggregate Exposure and Risk Estimates for Skeletal Fluorosis Based on Ana Medicine of the National Academies

Population Subgroup	IOM-selected NOAEL, mg/day	Total Fluoride Exposure, mg/kg/day	Body Weight, k
U.S. population (total)	10	0.049	7
Infants (< 1 year)	10	0.209	
Children (1-2 years)	10	0.110	1
Children (3-5 years)	10	0.086	2
Children (6-12 years)	10	0.054	4
Youth (13-19 years)	10	0.038	6
Adults (20-49 years)	10	0.044	7
Adults (50+ years)	10	0.043	7
Females (13-49 years)	10	0.043	6

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).

Sulfuryl fluoride is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

Residential exposure could occur with fluoride anion. However, as stated above, the endpoint of concern for fluoride anion has been identified as crippling skeletal fluorosis, which is a chronic effect. Therefore, fluoride anion 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).

Sulfuryl fluoride is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

Residential exposure could occur with fluoride anion. However, as stated above, the endpoint of concern for fluoride anion has been identified as crippling skeletal fluorosis, which is a chronic effect. Therefore, fluoride anion is not expected to pose an intermediate-term risk.

5. Aggregate cancer risk for U.S. population. Sulfuryl fluoride has been classified as ``not likely to be carcinogenic to humans'' and there is no evidence showing an increased risk of cancer following exposure to fluoride. Therefore, EPA has not conducted an aggregate assessment of cancer risk for either sulfuryl fluoride or fluoride anion.

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 fluoride anion residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. The method 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 for sulfuryl fluoride or fluoride anion.

V. Conclusion

Therefore, the tolerance is established for residues of sulfuryl fluoride in or on all processed food commodities where a separate tolerance is not already established at 2.0 ppm; cattle, meat, dried at 0.01 ppm; cheese at 2.0 ppm;

[[Page 40907]]

cocoa bean, postharvest at 0.2 ppm; coconut, postharvest at 1.0 ppm; coffee, postharvest at 1.0 ppm; cottonseed, postharvest at 0.5 ppm; eggs, dried at 1.0 ppm; ginger, postharvest at 0.5 ppm; ham at 0.02 ppm; herbs and spices, group 19 postharvest at 0.5 ppm; milk, powdered at 2.0 ppm; nut, pine, postharvest at 0.2 ppm; peanut, postharvest at 0.5 ppm; rice, flour, postharvest at 0.05 ppm; and vegetables, legume, group 6, postharvest at 0.5 ppm. In addition, tolerances are estalished for residues of fluoride anion in or on all processed food commodities where a separate tolerance is not already established at 70 ppm; cattle, meat, dried at 40 ppm; cheese at 5.0 ppm; cocoa bean, postharvest at 20 ppm; coconut, postharvest at 40 ppm; coffee, postharvest at 15 ppm; cottonseed, postharvest at 70 ppm; eggs, dried at 900 ppm; ginger, postharvest at 70 ppm; ham at 20 ppm; herbs and spices, group 19 postharvest at 70 ppm; milk, powdered at 5.0 ppm; nut, pine, postharvest at 20 ppm; peanut, postharvest at 15 ppm; rice, flour, postharvest at 45 ppm; and vegetables, legume, group 6, postharvest at 70 ppm.

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-2005-0174 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 September 13, 2005.

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 (1900L), 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 Suite 350, 1099 14th St., NW., Washington, DC 20005. 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 (202) 564-6255.

2. 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 ADDRESSES. Mail your copies, identified by docket ID number OPP-2005-0174, 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 ADDRESSES. 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,

[[Page 40908]]

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 (59 FR 22951, 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: July 1, 2005
Lois Rossi,
Director, Registration Division, 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), 346a and 371.

• 3. Section 180.145 is amended by adding alphabetically the following commodities to the table in paragraph (a)(3) to read as follows:

Sec. 180.145 Flourine compounds; tolerances for residues.

(a) * * *
(3) * * *

Commodity	Parts per million
All processed food commodities not otherwise listed	70
* * * * *	
Cattle, meat, dried	40
Cheese	5.0
Cocoa bean, postharvest	20
Coconut, postharvest	40
Coffee, postharvest	15
* * * * *	
Cottonseed, postharvest	70
Eggs, dried	900
* * * * *	
Ginger, postharvest	70
* * * * *	
Ham	20
Herbs and spices, group 19, postharvest	70
* * * * *	
Milk, powdered	5.0
Nut, pine, postharvest	20
* * * * *	

Peanut, postharvest	15
* * * * *	
Rice, flour, postharvest	45
* * * * *	
Vegetables, legume, group 6, postharvest	70
* * * * *	

* * * * *

• 5. Section 180.575 is amended by alphabetically adding the following commodities to the table in paragraph (a)(1) to read as follows:

Sec. 180.575 Sulfuryl fluoride; tolerances for residues.

(a)(1) General. * * *

Commodity	Parts per million
All processed food commodities not otherwise listed	2.0
* * * * *	
Cattle, meat, dried	0.01
Cheese	2.0
Cocoa bean, postharvest	0.2
Coconut, postharvest	1.0
Coffee, postharvest	1.0
* * * * *	
Cottonseed, postharvest	0.5
Eggs, dried	1.0
* * * * *	
Ginger, postharvest	0.5
Ham	0.02
Herbs and spices, group 19, postharvest	0.5
* * * * *	
Milk, powdered	2.0
Nut, pine, postharvest	0.2
* * * * *	
Peanut, postharvest	0.5
* * * * *	
Rice, flour, postharvest	0.05
* * * * *	
Vegetables, legume, group 6, postharvest	0.5
* * * * *	

* * * * *

[FR Doc. 05-13982 Filed 7-14-05; 8:45 am]
BILLING CODE 6560-50-S