application if the reference identifying the prior application by provisional application number was unintentionally delayed. A petition to accept an unintentionally delayed claim under 35 U.S.C. 119(e) for the benefit of a prior-filed provisional application must be accompanied by:

(i) The surcharge set forth in § 1.17(t); and

(ii) A statement that the entire delay between the date the claim was due under paragraph (a)(5)(ii) of this section and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional.

* * * * *

3. Section 1.311 is amended by revising paragraph (a) to read as follows:

§ 1.311 Notice of allowance.

(a) If, on examination, it appears that the applicant is entitled to a patent under the law, a notice of allowance will be sent to the applicant at the correspondence address indicated in § 1.33. The notice of allowance shall specify a sum constituting the issue fee which must be paid within three months from the date of mailing of the notice of allowance to avoid abandonment of the application. The sum specified in the notice of allowance may also include the publication fee, in which case the issue fee and publication fee (§ 1.211(e)) must both be paid within three months from the date of mailing of the notice of allowance to avoid abandonment of the application. This three-month period is not extendable.

* * * * *

4. Section 1.434 is amended by revising paragraph (d)(2) to read as follows:

§ 1.434 The request.

* * * * *

(d) * * *

(2) A reference to any prior-filed national application or international application designating the United States of America, if the benefit of the filing date for the prior-filed application is to be claimed.

5. Section 1.491 is revised to read as follows:

§ 1.491 National stage commencement and entry.

(a) Subject to 35 U.S.C. 371(f), the national stage shall commence with the expiration of the applicable time limit under PCT Article 22(1) or (2), or under PCT Article 39(1)(a).

(b) An international application enters the national stage when the applicant has filed the documents and fees required by 35 U.S.C. 371(c) within the period set in § 1.494 or § 1.495.

Dated: August 29, 2001.

Nicholas P. Godici,

Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office.

[FR Doc. 01–22273 Filed 9–4–01; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MD078–3078b; FRL 7049–4]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Control of VOC Emissions From Marine Vessel Coating Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a revision to the Maryland State Implementation Plan (SIP) revision. The revision establishes and imposes reasonably available control technology to reduce volatile organic compound (VOC) emissions from marine vessel coating operations. In the ''Rules and Regulations'' section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by October 5, 2001.

ADDRESSES: Written comments should be addressed to Makeba Morris, Chief, Permits and Technical Assessment Branch, Mailcode 3AP11, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; and the Maryland Department of the Environment, 2500 Broening Highway, Baltimore, Maryland, 21224.

FOR FURTHER INFORMATION CONTACT: Makeba Morris, (215) 814–2182, at the EPA Region III address above, or by e-mail at makeba.morris@epa.gov. Please note that while questions may be posed via telephone and e-mail, formal comments must be submitted, in writing, as indicated in the **ADDRESSES** section of this document.

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action that is located in the ''Rules and Regulations'' section of this **Federal Register** publication.

Dated: August 28, 2001.

Thomas C. Voltaggio,

Regional Administrator, Region III.

[FR Doc. 01–22268 Filed 9–4–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301166; FRL–6799–6]

RIN 2070–AC18

Sulfuryl Fluoride; Proposed Pesticide Temporary Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to establish temporary tolerances for sulfuryl fluoride and inorganic fluoride residues resulting from application of sulfuryl fluoride in or on walnuts and raisins under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. This fumigant is being proposed as a methyl bromide alternative in the post-harvest fumigation of stored walnuts and raisins. These temporary tolerances would support a proposed 3–year experimental use permit (EUP) effective between September 24, 2001 and September 24, 2004, conducted by Dow AgroSciences entirely in the state of California. The temporary tolerances will expire April 1, 2006. This will allow approximately 18 months after the end of the EUP, for all the treated commodities to clear commerce.

DATES: Comments, identified by docket control number OPP–301166 must be received on or before October 5, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–301166 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Dennis McNeilly, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460; 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 affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301166. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–301166 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described in this unit. Do not submit any information electronically that you consider to be CBI. Electronic comments must be submitted as an ASCII file avoiding use of special characters and any form of encryption. Comments and data will also be accepted on standard disks in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP–301166. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the proposed rule or collection activity.

7. Make sure to submit your comments by the deadline in this document.

8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background and Statutory Findings

In the **Federal Register** of June 15, 2001 (66 FR 32618) (FRL–6788–2), EPA

issued a notice under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a announcing the filing of an Experimental Use Permit (EUP) and associated request for temporary tolerances by Dow AgroSciences LLC. Dow AgroSciences requested temporary tolerances for sulfuryl fluoride residue of the insecticide sulfuryl fluoride, in or on walnuts and raisins at 2.0 and 0.004 part per million (ppm), respectively. The June 15, 2001 Notice inadvertently omitted reference to the requested 2.0 ppm tolerance for walnuts. In addition, the company has since submitted a revised limit of quantitation (LOQ) for sulfuryl fluoride in raisins of 0.004 ppm instead of 0.003 ppm. Dow AgroSciences also requested a temporary tolerance for fluoride residue of the insecticide sulfuryl fluoride, in or on walnuts at 12.0 part per million (ppm) and an exemption from the requirement of a tolerance for fluoride residues in or on raisins resulting from treatment with the insecticide sulfuryl fluoride under the USEPA's Threshold of Regulation Policy - Deciding Whether a Pesticide with a Food Use Pattern Needs a Tolerance. EPA is issuing this action as a proposal (rather than a final rule) because after review of the initial petitions and Notice of Filing the Agency has determined that:

1. The original Notice of Filing did not include the 2.0 ppm tolerance for sulfuryl fluoride residues in or on walnuts. In addition, the company has revised the limit of quantitation of fluoride residues in or on raisins from 0.003 ppm to 0.004 ppm.

2. The Agency wanted to publish its planned approach for regulating fluoride residues in or on raisins. This approach differs from that proposed by Dow AgroSciences. Although Dow AgroSciences has submitted data indicating that post-harvest use of sulfuryl fluoride is not expected to result in finite residues of either sulfuryl fluoride or fluoride in or on raisins, that data is limited and may not accurately reflect residues that may occur in actual use. EPA also notes that the existing 7.0 ppm tolerance in 40 CFR 180.145 established to regulate fluoride residues in or on grapes from use of cryolite might be affected by fluoride residues in or on raisins from sulfuryl fluoride use. The enforcement analytical methods for both cryolite and sulfuryl fluoride measure fluoride anion and cannot distinguish fluoride resulting from cryolite application to grapes, sulfuryl fluoride application to raisins, or even fluoride which may be a natural constituent of grapes. Because this existing tolerance is expressed in §180.145 as parts per million of cryolite, the Agency will add a new paragraph (a)(3) to 40 CFR 180.145 expressing the temporary tolerances for raisins and walnuts as parts per million fluoride, in order to reduce the potential for confusion. The tolerance expression will clarify that the tolerance for fluoride residues in or on raisins covers residues from application of both cryolite to grapes, expected to be the major source of fluoride residue, and residues of fluoride from post-harvest treatment with sulfuryl fluoride. The fluoride tolerance for raisins must also account for naturally occurring levels of fluoride in raisins. Residues of fluoride from use of sulfuryl fluoride on raisins are expected to be at most trace levels with most raisins having non-detectable (1.1 ppm) residue levels.

3. Sulfuryl fluoride is a fumigant that is being proposed as a methyl bromide alternative for the post-harvest control of pests in stored walnuts and raisins. In the future, it is likely that other commodities may be proposed for post-harvest, stored commodity fumigation using this fumigant.

Section 408(r) of the FFDCA authorizes EPA to establish a temporary tolerance or exemption for pesticide chemical residues resulting from use of a pesticide pursuant to a FIFRA section 5 experimental use permit (EUP). Section 408(b)(2)(A)(i) of the 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) 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) 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....'' Additionally, section 408(b)(2)(D) requires that 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 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 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).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), 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), for tolerances for residues of sulfuryl fluoride on walnuts and raisins at 2.0 and 0.004 ppm, respectively. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for temporary tolerances for inorganic fluoride residues of sulfuryl fluoride on walnuts and raisins at 12.0 and 30.0 ppm, respectively. 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 and fluoride are discussed in the following discussion.

Acute, subchronic, chronic, and other toxicity. Technical grade sulfuryl fluoride (Profume® Gas Fumigant, 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 (milligrams/kilogram (mg/kg) in rats (Toxicity Category II). The acute inhalation LC_{50} in mice (4 hour exposure) is 660 ppm (2.56 milligram/liter (mg/L) in males and 642 ppm (2.49 mg/L) in females. The acute inhalation LC_{50} in rats (1 hour exposure) is 17.5 mg/L. Based on the use pattern for sulfuryl fluoride and several reported incidences of human poisonings in the Sulfuryl Fluoride Reregistration Eligibility Decision (RED) (September, 1993) and elsewhere in the general toxicologic literature, the Agency has classified sulfuryl fluoride as Toxicity Category I for acute inhalation toxicity. The acute dermal

toxicity study (assumed Toxicity Category of IV), the primary skin irritation study (assumed Toxicity Category of IV), the primary eye irritation study (assumed Toxicity Category of I), and the dermal sensitization study (assumed to be a non-sensitizer) have been waived. These studies were waived because they would not change the overall signal word from DANGER, and/or alter personal protective equipment requirements. In addition, the insecticide is a volatile gas. 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 9,599 ppm 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, dogs, rabbits and mice, 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 many subchronic and chronic inhalation studies in rats, dogs, and rabbits, dental fluorosis was the most sensitive toxic effect observed in the study. In two 90–day studies in rats and rabbits, in which serum fluoride levels were determined, an increased serum level of fluoride anions was observed at even lower dose levels. The increased serum fluoride levels were due to the conversion of sulfuryl fluoride to fluoride anions in the body.

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 F_1 and F_2 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 an Ames assay in *Salmonella typhimurium*, an unscheduled DNA synthesis assay in primary rat hepatocytes, and a micronucleus assay in mouse bone marrow cells.

Sulfuryl fluoride is classified as a ''not likely'' human carcinogen according to the EPA Draft Guidelines for Carcinogen Risk Assessment (July, 1999)

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 exposure to concentrations of sulfuryl fluoride gas significantly above the 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.

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 intra species differences. There are no additional uncertainty factors (other than the 3X FQPA Safety Factor) used in this assessment, except a 3X factor used in long-term occupational inhalation exposure/risk assessment. A 3X factor is used there, rather than a 1X factor, because the toxicological endpoint is based on a 90–day inhalation study rather than a chronic study.

For dietary risk assessment (other than cancer) the Agency calculates an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such an additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) EPA determines a 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.

A summary of the toxicological endpoints for sulfuryl fluoride used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SULFURYL FLUORIDE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario[1]	Dose (mg/kg/day)	Endpoint	Study
Acute Dietary (General Population including Infants and Children)	None UF = N/A FQPA Factor = N/A	No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies on sulfuryl fluoride. Acute RfD = Not Required	None
Chronic Dietary (General Population including Infants and Children)	NOAEL = 8.5; UF = 300; FQPA Factor = 3	Vacuolation of white matter in the brain of females. Chronic RfD = 0.028 mg/kg/day Chronic Population-Adjusted Dose (cPAD) = 0.0093 mg/kg/day	90–Day inhalation-rabbits
Oral, Incidental (All Durations)	None; UF = N/A; FQPA Factor = N/A	Due to sulfuryl fluoride being a gas and its use pattern, no significant incidental oral exposure is anticipated.	None
Dermal (All Durations)	None; UF = N/A; FQPA Factor = N/A	Due to sulfuryl fluoride being a gas and its use pattern, no significant dermal exposure is anticipated.	None
Inhalation Short-Term (Occupational)	NOAEL = 30; MOE = 100; FQPA Factor = N/A	Malacia (necrosis) and vacuolation in the cerebrum, inflammation of nasal tissues and trachea.	2–Week inhalation-rabbits
Inhalation Short-Term (Residential)	NOAEL = 30; MOE = 300; FQPA Factor = 3	Malacia (necrosis) and vacuolation in the cerebrum, inflammation of nasal tissues and trachea.	2– Week inhalation-rabbits
Inhalation Intermediate-Term (Occupational)	NOAEL = 8.5; MOE = 100; FQPA Factor = N/A	Vacuolation of white matter in the brain of females.	90–Day inhalation-rabbits
Inhalation Intermediate-Term (Residential)	NOAEL = 8.5; MOE = 300; FQPA Factor = 3	Vacuolation of white matter in the brain of females.	90–Day inhalation-rabbits
Inhalation Long-Term (Occupational)	NOAEL = 8.5; MOE =300; FQPA Factor = N/A	Vacuolation of white matter in the brain of females.	90–Day inhalation-rabbits

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SULFURYL FLUORIDE FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario[1]	Dose (mg/kg/day)	Endpoint	Study
Carcinogenicity Chronic Exposure	Classified as a ''not likely'' human carcinogen	Negative for carcinogenicity in carcinogenicity studies in rats and mice	Chronic toxicity/carcinogenicity, rats and Carcinogenicity, mice

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

[1] The only significant route of exposure for inorganic fluoride is dietary exposure, which includes residues in drinking water. This risk assessment uses the maximum concentration limit goal (MCLG) of 4.0 ppm for fluoride as the basis for a maximum allowable exposure to inorganic fluoride (see the Cryolite Reregistration Eligibility Decision, 8/96, EPA- 738–R–96–016). Using the Agency default values of body weight (70 kg) and water consumption (2 liters/day), the MCLG converts to an exposure limit of 0.114 mg/kg/day. This exposure is used as the cPAD for inorganic fluoride in this risk assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* No tolerances have ever been established in the United States for sulfuryl fluoride. This is the first food use for sulfuryl fluoride in the U.S. tolerances have been established for the insecticide cryolite (40 CFR 180.145) for residues of fluoride, in or on a variety of raw agricultural commodities. Cryolite degrades after application, with the metabolite of toxicological concern being fluoride. Section 180.145 already contains a tolerance for fluoride resulting from the use of cryolite in or on grapes, measured as fluoride but expressed as 7 ppm cryolite equivalents. Section 180.145 does not set a specific tolerance for raisins, the 7.0 ppm tolerance for the raw agricultural commodity grapes would apply to residues in the processed commodity raisins. See 40 CFR 180.1(f). A tolerance for fluoride (55 ppm expressed as Cryolite) residue in or on raisins was proposed but has not been finalized. See 62 FR 42546 (Aug 7, 1997). There is also uncertainty concerning the extent of naturally occurring levels of fluoride in raisins; and, a major purpose of this experimental use permit is to generate comprehensive residue data collected from different storage facilities. It is for these reasons that the Agency proposes setting a 30 ppm tolerance for fluoride (55 ppm cryolite divided by 1.84 conversion factor) that would adequately address residues from cryolite application to grapes, sulfuryl fluoride application to raisins, and naturally occurring background levels of fluoride in raisins. Risk assessments were conducted by EPA to assess dietary exposures from sulfuryl fluoride and the metabolite 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 one day or single exposure. No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies on sulfuryl fluoride or inorganic fluoride (Cryolite RED) that would be applicable for an acute dietary exposure.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992–nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. This survey indicates the following average daily consumption for the total U.S. population for the commodities involved in this EUP: 0.0000253 mg/kg/day for raisins and 0.0000040 mg/kg/day for walnuts. To determine the estimated daily average consumption for a ''U.S. population'' individual, simply multiple the daily average times the body weight in kg.

The existing tolerance for cryolite on grapes (40 CFR 180.145) is in fact a tolerance for fluoride, because the approved analytical method for enforcement tests only for fluoride, and not cryolite. There is no analytical method for distinguishing between cryolite and sulfuryl fluoride as the source of inorganic fluoride in or on grapes or raisins, nor is there any toxicological reason to distinguish between such residues.

In order to assess compliance with the tolerances in 40 CFR 180.145, measured levels of fluoride in grapes are converted to cryolite equivalents by multiplying the concentration (in parts per million) of fluoride by a factor of 1.84 (molecular weight of cryolite divided by molecular weight of fluoride, divided by the number of fluoride atoms in cryolite; (210 amu) ÷ (19 amu) x 6 = 1.84). A tolerance for fluoride (55 ppm expressed as Cryolite) residue in or on raisins was proposed but has not yet been finalized, see 62 FR 42546 (Aug 7, 1997). The Agency is proposing a 30 ppm tolerance for fluoride (55 ppm cryolite divided by 1.84 conversion factor) that would adequately address residues from cryolite use on grapes, sulfuryl fluoride use on raisins, and background levels.

In order to provide additional data concerning the residues of fluoride in grapes treated with sulfuryl fluoride, the petitioner has agreed to monitor fluoride levels in all batches of raisins fumigated pursuant to the EUP and to provide the data to the Agency. The exposure and risk estimates for Sulfuryl Fluoride and Fluoride Anion from the fumigation of raisins and walnuts with Sulfuryl Fluoride are indicated in the following Table 2:

TABLE 2.—EXPOSURE AND RISK ESTIMATES FOR SULFURYL FLUORIDE AND FLUORIDE ANION FROM THE FUMIGATION OF RAISINS AND WALNUTS WITH SULFURYL FLUORIDE

Population Subgroup	Sulfuryl Fluoride		Fluoride Anion	
	Risk, % cPAD[a]	Exposure, mg/kg/day	Exposure, mg/kg/day	Risk, % MCLG[b]
U.S. Population	0.000008	<1	0.000808	<1

TABLE 2.—EXPOSURE AND RISK ESTIMATES FOR SULFURYL FLUORIDE AND FLUORIDE ANION FROM THE FUMIGATION OF RAISINS AND WALNUTS WITH SULFURYL FLUORIDE—Continued

Population Subgroup	Sulfuryl Fluoride		Fluoride Anion	
	Risk, % cPAD[a]	Exposure, mg/kg/day	Exposure, mg/kg/day	Risk, % MCLG[b]
All Infants (<1 Year)	0.000000	<1	0.000065	<1
Children (1–6 Years of Age)	0.000016	<1	0.002447	2
Children (7–12 Years of Age)	0.000014	<1	0.000862	<1
Females (13–50 Years of Age)	0.000009	<1	0.000600	<1
Males (13–19 Years of Age)	0.000005	<1	0.000420	<1
Males (20+ Years of Age)	0.000005	<1	0.000547	<1
Seniors (55+ Years of Age)	0.000007	<1	0.000870	<1

[a] Exposure ÷ cPAD (0.009 mg/kg/day) x 100
[b] Exposure ÷ Max. Conc. Limit Goal for fluoride anion (0.114 mg/kg/day) x 100

iii. *Cancer*. Sulfuryl fluoride is classified as ''not likely to be carcinogenic to humans.'' This classification is based on the lack of evidence of carcinogenicity in male and female rats as well as male and female mice and on the lack of genotoxicity in an acceptable battery of mutagenicity studies performed on the technical grade material.

iv. *Anticipated residue and percent crop treated information*. For the purposes of these temporary tolerances, the Agency is assuming 100% of the walnut and raisin crops will be treated with sulfuryl fluoride, and that residues will be at the proposed tolerance levels. These conservative assumptions over state the actual exposure but because this is an experimental use permit reliable data on the actual percent crop treated and residues are not available. The registrant estimates that this experimental use permit may entail treatment of up to 14% and 32% of the domestically produced walnuts and raisins, respectively. In this risk assessment, all walnuts are assumed to contain 2.0 ppm residues of sulfuryl fluoride and 12.0 ppm residue of fluoride, and raisins are assumed to contain 0.004 ppm residues of sulfuryl fluoride and 30.0 ppm residues of fluoride.

2. *Dietary exposure from drinking water*. The Agency has determined that because of the indoor use pattern and physicochemical characteristics of sulfuryl fluoride (such as low water solubility and high volatility), neither residues of sulfuryl fluoride nor of inorganic fluoride are expected to reach surface or groundwater due to the post harvest fumigation of walnuts and raisins. There are no other anticipated sources of sulfuryl fluoride in surface or ground water, and EPA believes that it is not present in drinking water. Any releases to wastewater treatment plants would be ''stripped'' from the wastewater during the aeration of the activated sludge or trickling filter processes (secondary treatment). Residues of inorganic fluoride may be in drinking water due to intentional fluoridation or to natural sources. Dietary exposure to fluoride from drinking water is estimated to average 0.057 mg/kg/day (Cryolite RED, 8/96, EPA–738–R–96–016).

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). The Agency has determined that exposure of residents to sulfuryl fluoride resulting from home fumigation is negligible. The only significant exposure pathway for inorganic fluoride is via the diet (food + drinking water).

Structural pest control, a residential non-dietary site, is the only currently registered use of sulfuryl fluoride. Details concerning residential exposure from the structural pest control use of sulfuryl fluoride are discussed in the Sulfuryl Fluoride Reregistration Eligibility Decision (RED) issued in September 1993 (EPA 738–R–93–016). The Agency does note that this insecticide is a Restricted Use Pesticide and there are no homeowner products registered.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) 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 per se has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, EPA has not assumed that sulfuryl fluoride has a common mechanism of toxicity with other substances. On this basis, the petitioner must submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether sulfuryl fluoride shares a common mechanism of toxicity with any other substance and, if so, whether any tolerances for sulfuryl fluoride need to be modified or revoked.

Crop protection uses of cryolite, intentional fluoridation of municipal drinking water, and the proposed uses of sulfuryl fluoride appear to share a common mechanism of toxicity through residues of their common degradate, inorganic fluoride. Exposure to fluoride from chronic ingestion of cryolite-treated commodities combined with residues of inorganic fluoride in drinking water is estimated to be 0.085 mg/kg/day. This is derived using 0.028 mg/kg/day for fluoride from cryolite treated commodities + 0.057 mg/kg/day from fluoride intentionally added to drinking water (Cryolite RED). Aggregate exposure to inorganic fluoride from sulfuryl fluoride, cryolite, and

water fluoridation is estimated to be 0.087 mg/kg/day for the most highly exposed population subgroup (children 1–6 years of age). This exposure estimate is approximately 75% of the exposure-converted MCLG for fluoride and indicates that the sulfuryl fluoride contributes a negligible amount to the cumulative exposure estimate for inorganic fluoride.

The Agency has determined that because the use pattern and physicochemical characteristics of sulfuryl fluoride, neither residues of sulfuryl fluoride nor of inorganic fluoride are expected to reach surface or ground water due to the post-harvest fumigation of walnut and raisins. Specifically, the indoor use of this highly volatile compound is not expected to result in residues in either surface or ground water.

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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general*. FFDCA section 408 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 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. Neither quantitative not qualitative evidence of increased susceptibility of fetuses or pups to sulfuryl fluoride was demonstrated in the prenatal developmental toxicity studies in rats and rabbits or in the 2-generation reproduction study in rats.

3. *Conclusion*. There is an adequate toxicity database for sulfuryl fluoride, for the purposes of this experimental use permit only. Adequate exposure data for the purposes of this experimental use permit are available or are estimated based on data that reasonably account for potential exposures. The Agency has reduced the FQPA Safety Factor from 10X to 3X in assessing the toxicity from exposure to sulfuryl fluoride from all sources. The FQPA Safety factor was reduced because:

(i) There is no qualitative or quantitative evidence of increased susceptibility following *in utero* exposure to rats and/or following pre-/postnatal exposure to rats.

(ii) The dietary (food and drinking water) and non-occupational exposure assessments will not underestimate the potential exposure to infants, children, and/or women of childbearing age. The FQPA Safety Factor was not reduced to 1X because of the lack of a developmental neurotoxicity study in rats.

E. Aggregate Risks and Determination of Safety

The potential exists for exposure to sulfuryl fluoride from dietary and residential pathways. However, the risk from exposure to sulfuryl fluoride via the residential pathway is considered negligible. Accordingly, EPA has considered only dietary exposure as contributing to the aggregate risk from sulfuryl fluoride. As explained in Unit III. C.1.ii. of this preamble, chronic exposure was estimated using DEEM and assuming 100% of the raisin and walnut crops would be treated and contain tolerance level residues. The resulting dietary risk estimates are less than 1% of the cPAD, except for ''Children (1–6 years of age)''. The Agency's level of concern is risks > 100% of the cPAD. No acute dietary risks were assessed since no toxicological endpoint attributable to a single exposure could be identified.

The only significant exposure pathway for inorganic fluoride is via the diet (food + drinking water). EPA notes that anticipated fluoride exposure resulting from post-harvest use of sulfuryl fluoride on walnuts and raisins is negligible in comparison to fluoride levels permitted under the Safe Drinking Water Act. The Agency's Office of Water has set a MCLG of 4.0 ppm for fluoride. The Office of Pesticides Programs has used this number as the exposure level in drinking water. This concentration is a level that provides no known or anticipated adverse health effects. The MCLG has been reviewed and is supported by the Surgeon General. Risks from dietary exposure to inorganic fluoride from the post-harvest fumigation of raisins and walnuts are estimated to be less than 1% of the MCLG for fluoride when the MCLG is converted to an exposure equivalent using Agency default values of body weight and drinking water consumption. Total exposure to fluoride, including that from fluoridated water, cryolite uses and from the proposed uses of sulfuryl fluoride are discussed in Unit III.C.4. of this preamble. As noted there, aggregate fluoride exposure for the most highly exposed population is about 75% of the MCLG converted to an exposure equivalent.

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 methods of analysis for both sulfuryl fluoride and fluoride anion are available. The methods are considered adequate as tolerance enforcement methods for the purposes of these temporary tolerances during the EUP. For a Section 3 registration, the registrant will need to submit independent laboratory validations for both the proposed sulfuryl fluoride and inorganic fluoride methods. For sulfuryl fluoride, the method consists of blending the sample for 5 minutes in an air-tight Eberbach blending device, equilibrating the sample for 5 minutes, and analyzing 30mL of headspace from the sample container by gas chromatography. For fluoride anion, analysis is done by ion-specific electrodes using a double standard addition procedure. Spike and recovery submitted with the request show acceptable recoveries for both sulfuryl fluoride and inorganic fluoride for raisins and walnuts.

Adequate enforcement methodology (example: gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. Magnitude of Residues

The petitioner submitted data describing residues of sulfuryl fluoride and inorganic fluoride in raisins and walnuts following a number of fumigation regimes including: ''To Determine and Evaluate the Significance of Sulfuryl Fluoride Residues in Dried Fruits and Tree Nuts Following Fumigation Treatments with Sulfuryl Fluoride at Different Temperatures, Sample Locations, Desorption Rates, Repeated fumigations, and A

Comparison of Treatments Done Under Vacuum or Normal Atmospheric Pressure Phase 1.'' Unpublished study sponsored by Dow AgroSciences LLC 6/1/2000. MRID 45170401.

The fumigation of walnuts and raisins consisted of treatments at either 10, 21, or 32 °C, multiple fumigations (up to 5) at 21 °C, or fumigation under vacuum versus ambient atmospheric pressure (21 °C). As part of the studies, samples were collected from the top, middle, and bottom of the fumigation chamber; additionally, samples were collected at post-aeration intervals of up to 11 days depending upon the treatment. For all treatments to raisins, residues of sulfuryl fluoride were <1 LOQ (<0.004 ppm) and most residues were <1 LOD (<0.0011 ppm); residues of inorganic fluoride were <1 LOQ (2.2 ppm) with approximately half falling below the LOD (< 0.75 ppm). Finite residues of sulfuryl fluoride and inorganic fluoride were found in/on walnuts and are summarized in Table 3 below.

The proposed use pattern specifies a maximum cumulative per batch rate of 2,500 oz-hours/1,000 ft^3 for ambient pressure fumigations and 250 oz-hours/1,000 ft^3 for vacuum fumigations. The multiple-fumigation data submitted with the EUP reflect use rates of 2,500 oz- hours/1,000 ft^3 for each fumigation; thus, a batch fumigated 5 times represents a 5X rate. In determining appropriate tolerance levels for walnuts, only data from single fumigations were considered. The data summarized below indicate that a 2.0 ppm tolerance for sulfuryl fluoride and 12.0 ppm tolerance for inorganic fluoride in or on walnuts are appropriate for the use rate being proposed in this experimental use permit. In Table 3, only those commodities treated once reflect the use rate proposed in this experimental use permit. The other data, those samples reflecting more than one application, provide additional information but reflect a higher use rate than proposed in the experimental use permit and therefore are not directly used in determining appropriate tolerances.

TABLE 3.—SUMMARY OF RESIDUE DATA FOR SULFURYL FLUORIDE AND INORGANIC FLUORIDE IN/ON WALNUTS

Temp., °C	No. of Treatments[a]	Pressure	PAT, days[b]	Sulfuryl Fluoride, ppm		Fluoride Anion, ppm	
				Mean	Max.	Mean	Max.
10	1	Ambient	4	0.184	0.259	2.9	3.1
10	1	Ambient	4	0.332	0.387	2.9	3.2
10	1	Ambient	4	0.271	0.289	3.1	3.4
21	1	Ambient	4	0.044	0.051	7.1	7.5
21	1	Ambient	7	0.006	0.007	5.8	6.1
32	1	Ambient	4	0.212	0.229	8.0	8.8
32	1	Ambient	7	0.062	0.073	9.6	10.5
21	1	Ambient	1	1.535	1.767	NS[c]	-
21	1	Ambient	4	0.124	0.135	NS	-
21	1	Ambient	7	0.007	0.010	<**2.3**	2.3
21	3	Ambient	1	4.794	5.303	NS	-
21	3	Ambient	4	0.884	0.927	NS	-
21	3	Ambient	7	0.211	0.231	10.2	38.6
21	5	Ambient	1	4.811	6.282	NS	-
21	5	Ambient	4	2.069	2.355	NS	-
21	5	Ambient	7	0.666	0.742	25.8	30.2
21	5	Ambient	11	0.214	0.252	NS	-
21	1	Vacuum	4	1.629	1.705	4.5	4.6
21	1	Vacuum	7	0.540	0.719	5.8	6.2

[a] Each fumigation was conducted at a treatment rate of 2,500 oz-hours/1,000 ft^3. The proposed use pattern is for the cumulative treatment rate not to exceed 2,500 oz-hours/1,000 ft^3 for ambient fumigations or 250 oz-hours/1,000 ft^3 for vacuum fumigations.
[b] PAT = Post-aeration Time.
[c] NS = No sample

Proposed tolerances - raisins. The data submitted with the EUP request indicate that, at the proposed use rate, only trace residues of sulfuryl fluoride are present in or on raisins, all below the LOQ. Based on these data, a tolerance for sulfuryl fluoride in or on raisins set at the LOQ, or 0.004 ppm, would not be exceeded through post-harvest application of sulfuryl fluoride.

C. International Residue Limits

There are no U.S. tolerances and/or CODEX MRLs established.

D. Conditions

The proposed temporary tolerances are to support an experimental use permit only. The registrant has agreed to analyzing every batch of raisins for fluoride levels to verify tolerance levels for fluoride are not exceeded. Other conditions may be specified on the Profume label. The Agency will not complete a final label review until comments on the proposed temporary tolerances are received and reviewed.

The Agency reserves the right to make additional data requirements for a Section 3 registration; however, the Agency knows that at least the following additional data will be required:

(1) Additional residue data to further define magnitude of the residue for both sulfuryl fluoride and inorganic fluoride (background levels vs. residues from Cryolite use).

(2) Residue data to define background levels of fluoride naturally occurring in both walnuts and raisins.

(3) Residue dissipation data examining residue levels in/on walnuts and raisins under post-fumigation storage conditions as a function of time.

(4) A comprehensive air monitoring study in and around the fumigation chambers.

(5) A Developmental Toxicity Study.

V. Conclusion

Temporary tolerances are proposed for sulfuryl fluoride residues of sulfuryl fluoride in walnuts and raisins at 2.0 and 0.004 ppm, respectively.

A temporary tolerance is also proposed for inorganic fluoride residues of sulfuryl fluoride in walnuts and raisins at 12.0 and 30.0 ppm, respectively.

VI. Regulatory Assessment Requirements

This proposed rule establishes a tolerance under FFDCA section 408(d) 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 proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed 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 proposed 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 FFDCA section 408(d), such as the tolerance in this proposed 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 proposed 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 FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this proposed 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 proposed 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 proposed rule.

List of Subjects in 40 CFR Part 180

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

Dated: August 22, 2001.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be 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.

1. Section 180.145 is amended by adding paragraph (a)(3) to read as follows:

§ 180.145 Fluorine compounds; tolerances for residues.

(a) * * *

(3) Temporary tolerances are established for residues of fluoride resulting from the post-harvest treatment with sulfuryl fluoride. The tolerances are measured and expressed as ppm of fluoride. Total residues of fluoride in or on raisins from use of cryolite on grapes (addressed in paragraph (a)(1) of this section) or sulfuryl fluoride on raisins shall not exceed the tolerance list in the following table.

Commodity	Parts per million	Expiration/ Revocation Date
Raisins	30.0	4/01/06
Walnuts	12.0	4/01/06

* * * * *

2. Section 180.575 is added to read as follows:

§ 180.575 Sulfuryl fluoride; tolerances for residues.

(a) *General.* Temporary tolerances are established for residues of sulfuryl fluoride resulting from the post harvest treatment with sulfuryl fluoride.

Commodity	Parts per million	Expiration/Revocation Date
Raisins	0.004	4/01/06
Walnuts	2.0	4/01/06

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 01–22283 Filed 9–4–01; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–2001; MM Docket No. 01–205; RM–10212]

Radio Broadcasting Services; Weinert, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition for rule making filed by Jeraldine Anderson, requesting the allotment of Channel 266C3 to Weinert, Texas, as that community's first local aural transmission service. This proposal requires a site restriction 13.8 kilometers (8.6 miles) south of the community at coordinates 33–12–15 NL and 99–37–35 WL.

DATES: Comments must be filed on or before October 15, 2001, and reply comments on or before October 30, 2001.

ADDRESSES: Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, as follows: Jeraldine Anderson, 1702 Cypress Drive, Irving, Texas 75061.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 01–205, adopted August 15, 2001, and released August 24, 2001. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center (Room CY–A257), 445 Twelfth Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800.

Provisions of the Regulatory Flexibility Act of l980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR § 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Weinert, Channel 266C3.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 01–22201 Filed 9–4–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–2004, MM Docket No. 01–196, RM–10208]

Radio Broadcasting Services; Childress, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Jeraldine Anderson requesting the allotment of Channel 281C2 at Childress, Texas. The coordinates for Channel 281C2 at Childress are 34–12–44 and 100–15–55. There is a site restriction 23.6 kilometers (14.6 miles) south of the community.

DATES: Comments must be filed on or before October 15, 2001, and reply comments on or before October 30, 2001.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, S.W., Washington, DC. 20554. In addition to filing comments with the FCC, interested parties should serve the petitioners, as follows: Jeraldine Anderson, 1702 Cypress Drive, Irving, Texas 75061. Katherine Pyeatt, 6655 Aintree Circle, Dallas, Texas 75214.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 01–196, adopted August 15, 2001, and released August 24, 2001. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Information Center, 445 Twelfth Street, SW, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 1231 20th Street, NW.,