Commodity	Parts per million
Canola, seed	0.05
Vegetable, legume, group	0.05

(2) Tolerances are established for the combined residues of the herbicide imazamox, and its metabolite AC263284 [(±)2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(hydroxymethyl)-3-pyridinecarboxylic acid in or on the raw agricultural commodities:

Commodity	Parts per million
Wheat, grain	0.30
Wheat, forage	0.30
Wheat, hay	0.30
Wheat, straw	0.20
Wheat, bran	1.0
Wheat, shorts	0.80
Wheat, germ	0.60

(3) Tolerances are established for the combined residues of the herbicide imazamox, and its metabolite AC263284 (free and conjugated), and AC312622, [(±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-3,5-pyridinecarboxylic acid in or on the raw agricultural commodities:

Commodity	Parts per million
Alfalfa, seed	0.40
Alfalfa, forage	2.0
Alfalfa, hay	4.0

* * * * *

[FR Doc. 01–31799 Filed 12–26–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301197; FRL–6816–1]

RIN 2070–AB78

Halosulfuron-methyl; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of Halosulfuron-methyl in or on asparagus. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on asparagus. This regulation establishes a maximum permissible level for residues of halosulfuron-methyl in this food commodity. The tolerance will expire and is revoked on December 31, 2003.

DATES: This regulation is effective December 27, 2001. Objections and requests for hearings, identified by docket control number OPP–301197, must be received by EPA on or before February 25, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301197 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Meredith Laws, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9366; and e-mail address: laws.meredith@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS Codes	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/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301197. 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, 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.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl) amino]carbonylaminosulfonyl-3-chloro-1-methyl-1H-pyrazole-4-carboxylate, in or on asparagus at 2.0 parts per million (ppm). This tolerance will expire and is revoked on 12/31/03. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations (CFR).

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Halosulfuron-methyl on Asparagus and FFDCA Tolerances

Washington, Idaho and Oregon requested the use of halosulfuron-methyl to control nutsedge infesting asparagus fields. Michigan requested the use of halosulfuron-methyl to control nutsedge and pigweed infesting asparagus fields. In the Pacific Northwest nutsedge has spread throughout the asparagus growing region and has been declared a Class B noxious weed in Washington. Asparagus growers are especially vulnerable to nutsedge because of the difficulty in controlling a perennial monocot weed in a perennial monocot crop. The information provided by the four applicant states indicates that nutsedge is reducing asparagus yields and reducing the life span of the crop. EPA agrees that heavily infested fields can have severe yield losses. Additionally, EPA expects that yield reductions in Michigan due to redroot pigweed could be quite high due to coverage of the crop during the harvest period. EPA has authorized under FIFRA section 18 the use of halosulfuron-methyl on asparagus for control of nutsedge in Washington, Idaho, Oregon and Michigan and also for control of pigweed in Michigan. After having reviewed the submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of halosulfuron-methyl in or on asparagus. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 2003, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on asparagus after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether halosulfuron-methyl meets EPA's registration requirements for use on asparagus or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of halosulfuron-methyl by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Washington, Idaho, Oregon and Michigan to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for halosulfuron-methyl, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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).

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 halosulfuron-methyl and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of halosulfuron-methyl in or on asparagus at 2.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

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

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference

dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety facto is retained due to concerns unique to the FQPA, 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 FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (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 is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for halosulfuron-methyl used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR HALOSULFURON-METHYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13+, Infants and Children)	NOAEL = 50 mg/kg/day UF = 100 Acute RfD = 0.5 mg/kg/day	FQPA SF = 1x aPAD = acute RfD ÷ FQPA SF = 0.5 mg/kg/day	Developmental - rabbit LOAEL = 150 mg/kg/day based on decreased mean litter size, increased resorptions, and increased postimplantation loss.
Acute dietary (Adult male)	None	No appropriate endpoint was selected	A dose and endpoint was not identified for this subpopulation since there were no toxicological effects applicable to adult males and attributable to a single exposure (dose) observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits.
Chronic dietary all populations	NOAEL= 10 mg/kg/day UF = 100 Chronic RfD = 0.1 mg/kg/day	FQPA SF = 1x cPAD = chronic RfD ÷ FQPA SF = 0.1 mg/kg/day	Chronic toxicity - dog LOAEL = 40 mg/kg/day based on decrease in body weight gain and alterations in hematology and clinical chemistry parameters
Short-term dermal (1 to 7 days) (Residential)	Oral study NOAEL= 50 mg/kg/day (dermal absorption rate = 75%)	LOC for MOE = 100 (Residential)	Developmental - rabbit LOAEL = 150 mg/kg/day based on decreased mean litter size, increased resorptions, and increased postimplantation loss
Intermediate-term dermal (1 week to several months) (Residential)	Oral study NOAEL= 10 mg/kg/day (dermal absorption rate = 75%	LOC for MOE = 100 (Residential)	Chronic toxicity - dog LOAEL = 40 mg/kg/day based on decrease in body weight gain during weeks 0–13
Long-term dermal (several months to lifetime) (Residential)	Oral study NOAEL= 10 mg/kg/day (dermal absorption rate = 75% when appropriate)	LOC for MOE = 100 (Residential)	Chronic toxicity - dog LOAEL = 40 mg/kg/day based on decrease in body weight gain and alterations inhematology and clinical chemistry parameters
Inhalation (any time period) (Residential)	None	-	Low toxicity and use pattern do not indicate a need for risk assessment for this route.
Cancer (oral, dermal, inhalation)	-	-	Classified as a ''Not-likely'' human carcinogen based on the lack of evidence of carcinogenicity in male and female mice and rats.

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

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.479) for the residues of halosulfuron-methyl, in or on a variety of raw agricultural commodities. The established tolerances include tree nuts (crop group 14); sugarcane; corn rice and cotton, and their associated commodities. Additionally, tolerances are established for residues of halosulfuron-methyl and its metabolites determined as 3-chloro-1-methyl-5-sulfamoylpyrazole-4-carboxylic acid (also referred to as CSA, expressed as parent equivalents) in/on meat by-products of cattle, goats, hogs, horses and sheep. Risk assessments were conducted by EPA to assess dietary exposures from halosulfuron-methyl 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. 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. The following assumptions were made for the acute exposure assessments: A Tier 1 acute dietary exposure analysis was conducted. The assumptions of the Tier 1 analysis were tolerance level residues and 100 percent crop-treated for all commodities for which halosulfuron-methyl tolerances are established and for the section 18 subject crop (asparagus). Percent crop treated and anticipated residues were not used.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A Tier 1 chronic dietary exposure analysis was conducted. The assumptions of this Tier 1 analysis were tolerance level residues and 100 percent crop-treated for all commodities for which halosulfuron-methyl tolerances are established and for the subject section 18 crop (asparagus). Percent crop treated and anticipated residues were not used.

iii. *Cancer.* There is no evidence of carcinogenicity for halosulfuron-methyl in the mouse or rat. EPA has classified halosulfuron-methyl as a ''Not-Likely'' human carcinogen.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for halosulfuron-methyl in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of halosulfuron-methyl.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in ground water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will generally use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to halosulfuron-methyl they are further discussed in the aggregate risk sections below.

Based on the FIRST and SCI-GROW models the EECs of halosulfuron-methyl for acute exposures are estimated to be 5.39 parts per billion (ppb) for surface water and 0.049 ppb for ground water. The EECs for chronic exposures based on FIRST and SCI-GROW models are estimated to be 0.245 ppb for surface water and 0.049 ppb for ground water.

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).

Halosulfuron-methyl is currently registered for use on the following residential non-dietary sites: Residential turf. The risk assessment was conducted using the following exposure assumptions: Halosulfuron-methyl (trade name: ''Manage'') is a sulfonylurea herbicide used for control of broadleaf weeds and nutsedge. Manage may be broadcast applied at a rate of 0.031 to 0.062 lb ai/acre. For residential handlers and postapplication activities, short-term to intermediate-term exposures may occur. Chronic exposures (greater than or equal to 6 months of continuous exposure) are not expected. Adults may be dermally exposed after treatment to lawns, and children may be exposed through dermal, hand-to-mouth and incidental oral sources.

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 halosulfuron-methyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, halosulfuron-methyl 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 halosulfuron-methyl 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. 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 data base 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. *Developmental toxicity studies*. In a prenatal developmental toxicity study in rats, the NOAEL for maternal toxicity was 250 mg/kg/day and the LOAEL was 750 mg/kg/day based on increased incidence of clinical observations (primarily alopecia and urine stains) and reduced body weight gains, food consumption, and food efficiency. For developmental toxicity, the NOAEL was 250 mg/kg/day and the LOAEL was 750 mg/kg/day based on decreased mean litter size, increased number of resorptions (total and per litter), significantly decreased mean fetal body weight, and increases in fetal and litter incidences of soft tissue (primarily dilation of the lateral ventricles and other anomalies in the development of the fetal nervous system) and skeletal variations (anomalies or delays in ossification in the thoracic vertebrae, sternebrae, and ribs). EPA noted that both the fetal and litter incidences of dilated lateral ventricles of the brain were statistically significant, and appeared to be dose related, since the finding was also observed at the mid-dose in 2 fetuses of 2 litters. Due to the lack of historical control data, it was not possible to evaluate the biological significance of the low incidence of this finding at the mid-dose level. EPA recommends that the study developmental NOAEL and LOAEL as defined by the data evaluation record not be revised at this time.

In a prenatal developmental toxicity study in the rabbit, the NOAEL for maternal toxicity was 50 mg/kg/day and the LOAEL was 150 mg/kg/day based on decreased body weight gain, food consumption, and food efficiency. For developmental toxicity, the NOAEL was 50 mg/kg/day and the LOAEL was 150 mg/kg/day based on decreased mean litter size, increased number of resorptions (total and per dam) and increased postimplantation loss. EPA notes that these developmental findings, while not statistically significant, define a consistent pattern of effect. The developmental NOAEL is 50 mg/kg/day based on decreased mean litter size, increased number of resorptions (total and per dam) and increased postimplantation loss at 150 mg/kg/day (LOAEL). EPA recommends that this dose and effect be used for assessing acute dietary risks for the sub-populations, Females 13+ as well as Infants and Children. Although the endpoint is developmental toxicity occurring *in utero*, and thus may not be suitable for use in risk assessment for Infants and Children, EPA determined that it is appropriate to use for this subpopulation (infants and children) because there is evidence of alteration to the development of the fetal nervous system in the developmental study in rats (see above). Thus, EPA determined that potential effects on functional development mandate the use of this endpoint for females of child bearing age (Females 13+) as well as for infants and children. This endpoint is not applicable for adult males. A dose and endpoint was not identified for this subpopulation since there were no toxicological effects applicable to adult males and attributable to a single exposure (dose) observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits.

3. *Reproductive toxicity study*. In the 2-generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

4. *Prenatal and postnatal sensitivity*. There was no evidence of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to halosulfuron-methyl. In the prenatal developmental toxicity studies in rats and rabbits and the 2-generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

5. *Conclusion*. There is a complete toxicity data base for halosufuron-methyl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed because there was no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to halosulfuron-methyl. In the prenatal developmental toxicity studies in rats and rabbits and the 2-generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity. EPA determined that the requirement of a developmental neurotoxicity study in rats did not warrant an application of additional safety factors because: (a) The alterations in the fetal nervous system occurred in only one species (in rats and not in rabbits); (b) the fetal effects which will be investigated in the required developmental neurotoxicity study were seen only at a dose of 750 mg/kg/day which is close to the Limit-Dose (1,000 mg/kg/day); (c) there was no evidence of clinical signs of neurotoxicity, brain weight changes, or neuropathology in the subchronic or chronic studies in rats; (d) the developmental neurotoxicity study is required only as confirmatory data to understand what the effect is at a high exposure (dose) level.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to halosulfuron-methyl in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of halosulfuron-methyl on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to halosulfuron-methyl will occupy < 1.0% of the aPAD for females 13 years and older, 1.0% of the aPAD for All Infants, < 1 year old and < 1.0% of the aPAD for Children, 1–6 years old. In addition, despite the potential for acute dietary exposure to halosulfuron-methyl in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of halosulfuron-methyl in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO HALOSULFURON-METHYL

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
All infants	0.50	1.0	5.39	0.049	5,000
Females, 13–50 years	0.50	<1.0	5.39	0.049	15,000
Children, 1–6 years	0.50	<1.0	5.39	0.049	5,000

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to halosulfuron-methyl from food will utilize < 1.0% of the cPAD for the U.S. population, < 1.0% of the cPAD for All infants, < 1 year old and < 1.0% of the cPAD for Children, 1–6 years old. Based on the use pattern, chronic residential exposure to residues of halosulfuron-methyl is not expected. In addition, despite the potential for chronic dietary exposure to halosulfuron-methyl in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of halosulfuron-methyl in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3. —AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON- CANCER) EXPOSURE TO HALOSULFURON-METHYL

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.10	< 1.0	0.245	0.049	3,500
All Infants	0.10	< 1.0	0.245	0.049	990
Children, 1–6 years	0.10	< 1.0	0.245	0.049	1,000
Females, 13–50 years	0.10	< 1.0	0.245	0.049	3,000

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).

Halosulfuron-methyl is currently registered for use(s) that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for halosulfuron-methyl. EPA concludes with reasonable certainty that residues of halosulfuron-methyl in drinking water will not contribute significantly to the short-term aggregate human health risk and that the short-term aggregate exposure from halosulfuron-methyl residues in food and drinking water will not exceed the Agency's level of concern (MOE ≤ 100) for short-term aggregate exposure by any population subgroup.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 2,200 for females and 2,900 for children. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. Short-term dermal MOEs for residential handlers are all above 100 and do not exceed EPA's level of concern. Non-occupational postapplication risk was estimated for adults and children.Risk estimates for all residential exposure scenarios and time periods result in MOEs that are 100 or greater, and therefore do not exceed EPA's level of concern. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of halosulfuron-methyl in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO HALOSULFURON-METHYL

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
Females	2,200	100	0.245	0.049	14,000
Children	2,900	100	0.245	0.049	4,800

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level).

Halosulfuron-methyl is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for halosulfuron-methyl.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,700 for females, 2,000 for males, and 1,000 for children. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of halosulfuron-methyl in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 5:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE- TERM EXPOSURE TO HALOSULFURON-METHYL

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb)
Females	1,700	100	0.245	0.049	2,800
Males	2,000	100	0.245	0.049	3,300
Children	1,000	100	0.245	0.049	900

5. *Aggregate cancer risk for U.S. population.* Halosulfuron-methyl is classified as a ''not likely'' human carcinogen based on a lack of evidence of carcinogenicity in male and female mice and rats. A cancer risk assessment is not required.

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 halosulfuron-methyl residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Analytical enforcement methodology for the determination of halosulfuron-methyl in various plant commodities has been sent to the Food and Drug Administration for publication in the Pesticide Analytical Methods, Volume II (PAM II). Quantitation of residues is by gas chromotography with nitrogen specific detection (GC/TSD).

B. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits for halosulfuron-methyl in/on asparagus. Therefore, harmonization is not an issue.

VI. Conclusion

Therefore, the tolerance is established for residues of halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl) amino]carbonylaminosulfonyl-3-chloro-1-methyl-1H- pyrazole-4-carboxylate in or on asparagus at 2.0 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the 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 the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP–301197 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 February 25, 2002.

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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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) 260–4865.

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

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

of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

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

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket control number OPP–301197, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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).

VIII. Regulatory Assessment Requirements

This final rule establishes a time limited tolerance under FFDCA section 408. 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 FIFRA section 18 exemption under FFDCA section 408, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, 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: December 14, 2001.

Peter Caulkins,

Acting 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), 346(a) and 371.

2. Section 180.479 is amended by adding text to paragraph (b) to read as follows:

§ 180.479 Halosulfuron; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonylaminosulfonyl-3-chloro-1-methyl-1H-pyrazole-4-carboxylate, in or on asparagus in connection with use of the pesticide under a section 18 exemption granted by EPA. The time-limited tolerance will expire on the date specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Asparagus	2.0	12/31/03

* * * * *

[FR Doc. 01–31800 Filed 12–26–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301180; FRL–6804–1]

RIN 2070–AB78

Pymetrozine; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pymetrozine 1,2,4-triazin-3(2H)-one,4,5-dihydro-6-methyl-4-[(3-pyridinylmethylene) amino] in or on cotton seed, undelinted at 0.3 parts per million (ppm); cotton gin byproducts at 2.0 ppm; fruiting vegetables at 0.2 ppm; cucurbit vegetables at 0.1 ppm; leafy vegetables (except *Brassica*) at 0.6 ppm; head and stem *Brassica* vegetables at 0.5 ppm; leafy *Brassica* and turnip greens at 0.25 ppm; hops (dried) at 6.0 ppm; and pecans at 0.02 ppm. Syngenta Crop Protection requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective December 27, 2001. Objections and requests for hearings, identified by docket control number OPP–301180, must be received by EPA on or before February 25, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301180 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Daniel Peacock, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5407; and e-mail address: peacock.dan@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/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301180. 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.

II. Background and Statutory Findings

In the **Federal Register** of July 19, 2001 (66 FR 37677–37681 (FRL–6793–9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C.