EPA. The tolerances are specified in the following table, and will expire and are revoked on the dates specified.

Commodity	Parts per million	Expiration/revocation date
Alfalfa, forage	6.0	6/30/2004
Alfalfa, hay	6.0	6/30/2004

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0243; FRL–7200–8]

Halosulfuron-methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonyaminosulfonyl-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate in or on asparagus; vegetables, fruiting (except cucurbits), group; bean, dry, seed and bean, snap, succulent. Gowan Company and Interregional Research Project Number 4 (IR–4) 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 September 20, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0243, must be received on or before November 19, 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 ID number OPP–2002–0243 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins and Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–5687 and (703) 308–9368, respectively; e-mail address: *tompkins.jim@epa.gov* and *jamerson.hoyt@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 codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing 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_00/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 ID number OPP–2002–0243. 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 June 3, 2002 (67 FR 38276) (FRL–7179–2), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170), announcing the filing of a pesticide petition (PP 1E6322) by Interregional Research Project Number 4(IR–4), 681 U.S. Highway 1 South, North Brunswick, New Jersey 08902–3390. In addition to the **Federal Register** of August 31, 2001 (66 FR 45993) (FRL–6796–1), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) 21 U.S.C. 346a, as amended by the FQPA announcing the filing of pesticide petitions 0F6169 and 1F6229) by Gowan Company, P.O. Box 5569; Yuma, AZ 85366. These notices included a summary of the petitions prepared by Gowan Company, the registrant. There were no comments received in response to these notices of filing.

The petitions requested that 40 CFR 180.479(a) be amended by establishing tolerances for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonyaminosulfonyl-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate, in or on vegetables, fruiting (except cucurbits), group at 0.05 part per million (ppm) (PP 0F6169), asparagus at 0.8 ppm (1F6229); and dry bean and succulent snap bean at 0.05 ppm (1E6322). The tolerance in or on asparagus at 0.8 ppm established by the current action will replace the time limited tolerance for asparagus established under § 180.479(b) in the **Federal Register** of December 27, 2001 (66 FR 66778) (FRL–6816–1).

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....''

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), 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 a tolerance for residues of halosulfuron-methyl on asparagus at 0.8 ppm; bean, dry, seed at 0.05 ppm; bean, snap, succulent at 0.05 ppm and vegetables, fruiting (except cucurbits), group at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by halosulfuron-methyl are discussed in Unit II.A. of the final rule on halosulfuron-methyl pesticide tolerances in the **Federal Register** of September 29, 2000 (65 FR 58424) (FRL–6746–2).

B. Toxicological Endpoints

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

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 factor 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 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 TOXICOLOGICAL DOSE AND ENDPOINTS FOR HALOSULFURON-METHYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose (mg/kg/day) UF/MOE	Hazard Based Special FQPA Safety Factor	Endpoint for Risk Assessment
Dietary Risk Assessments			
Acute Dietary (females 13–50 years of age)	NOAEL = 50	1x	Developmental Toxicity - Rabbit

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

Exposure Scenario	Dose (mg/kg/day) UF/MOE	Hazard Based Special FQPA Safety Factor	Endpoint for Risk Assessment
	UF = 300[a] Acute RfD = 0.17 mg/kg/day		LOAEL = 150 mg/kg/day based on decreased mean litter size, increased number of resorptions (total and per dam) and increased postimplantation loss (developmental toxicity)
Acute Dietary general population including infants and children	NOAEL = N/A UF = N/A Acute RfD = N/A	N/A	No appropriate dose/endpoint selected.
Chronic Dietary all populations	NOAEL = 10 UF = 300[a] Chronic RfD = 0.03 mg/kg/day	1x	Chronic Toxicity - Dog LOAEL = 40 mg/kg/day based on decreased body weight gains in females
Incidental Oral Short-Term (1–30 Days) Residential Only	NOAEL = 50 UF = 300[a] MOE = 300	1x	Developmental Toxicity-Rabbit LOAEL = 150 mg/kg/day based on decreased body weight gain, food consumption, and food efficiency. (maternal toxicity)
Incidental Oral Intermediate-Term (1–6 Months) Residential Only	NOAEL = 10 UF = 300[a] MOE = 300	1x	13 Week Subchronic Toxicity - Dog LOAEL = 40 mg/kg/day based on decreased body weight gain and food efficiency in females
Non-Dietary Risk Assessments			
Dermal Short-Term (1–30 days) Residential	Dermal NOAEL = 100 MOE = 300	 1x	21-Day Dermal Toxicity Study - Rat LOAEL = 1000 mg/kg/day based on decreased body weight gain in males
Dermal[b] Intermediate-Term (1–6 Months) Residential	Oral NOAEL = 10 MOE = 300	 1x	13 Week Subchronic Toxicity – Dog LOAEL = 40 mg/kg/day based on decreased body weight gain and food efficiency in females.
Dermal[b] Long-Term (>6 Months) Residential	Oral NOAEL= 10 MOE = 300	 1x	Chronic Toxicity - Dog LOAEL = 40 mg/kg/day based on decreased body weight gains in females
Inhalation[c] Short-Term (1–30 days) Residential	Oral NOAEL = 50 MOE = 300	 1x	Developmental Toxicity-Rabbit LOAEL = 150 mg/kg/day based on decreased body weight gain, food consumption, and food efficiency. (Maternal toxicity)
Inhalation[c] Intermediate-Term (1–6 Months) Residential	Oral NOAEL = 10 MOE = 300	 1x	13 Week Subchronic Toxicity - Dog LOAEL = 40 mg/kg/day based on decreased body weight gain and food efficiency in females
Inhalation[c] Long-Term (>6 Months) Residential	Oral NOAEL = 10 MOE = 300	 1x	Chronic Toxicity - Dog LOAEL = 40 mg/kg/day based on decreased body weight gains in females
Cancer	Classification: ''not likely to be carcinogenic to humans'' by the oral route, based on no evidence of carcinogenicity from studies in rats and mice		

*[a] = UFDB = 300 (10x for inter-species extrapolation and 10 x for intra- species variability, 3x for lack of DNT).
[b] = A 75% dermal absorption factor was used for route to route extrapolation.
[c] = Absorption via inhalation route is presumed to be equivalent to oral absorption.

C. 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. Additionally, tolerances for residues of halosulfuron-methyl and its metabolites determined as 3-chloro-1-methyl-5-sulfamoylpyrazole-4-carboxylic acid (CSA, expressed as parent equivalents) are established at 0.1 ppm 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: 100% of the crops with halosulfuron-methyl tolerances (both established and proposed) are treated and that all commodities contain tolerance level residues when consumed.

The acute dietary exposure estimates are provided for females 13–50 years old only. No appropriate endpoint attributable to a single exposure was identified for the general U.S. population including infants, children and adult males. This assessment concludes that the acute dietary exposure estimates are below the Agency's level of concern (<100% aPAD) at the 95th exposure percentile for females 13–50 (<1% of the aPAD). The results are presented in the following Table 2.

TABLE 2.—ACUTE DIETARY EXPOSURE ESTIMATES AT THE 95TH PERCENTILE OF EXPOSURE

Population Subgroup	Exposure (mg/kg/day)	% aPAD
Females 13–50 years old	0.00068	<1

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: 100% of the crops treated with halosulfuron-methyl tolerances (both established and proposed) are treated and that all commodities contain tolerance level residues when consumed.

The tier 1 chronic dietary exposure assessment was conducted for all supported halosulfuron-methyl food uses. The chronic dietary exposure estimates are presented for the general U.S. population including infants, children and adult males in the following Table 3. This assessment concludes that the chronic dietary exposure estimates are below the Agency's level of concern (<100% cPAD) for the general U.S. population (<1% of the cPAD). The most highly exposed population subgroup is all infants <1 year old at 2.4% of the cPAD.

TABLE 3.—RESULTS OF CHRONIC DIETARY EXPOSURE ANALYSIS

Population Subgroup	Exposure (mg/kg/day)	% cPAD
U.S. Population (total)	0.00028	<1
All Infants (<1 year)	0.00071	2.4
Children 1–6 years	0.00052	1.7
Children 7–12 years	0.00039	1.3
Females 13–50	0.00023	<1
Males 13–19	0.00027	<1
Males 20+ years	0.00023	<1
Seniors 55+	0.00024	<1

iii. *Cancer.* 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 is not expected.

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 SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will 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 Unit III.E.

Based on the FIRST and SCI-GROW models the estimated environmental concentrations (EECs) of halosulfuron-methyl for acute exposures are estimated to be 105 parts per billion (ppb) for surface water and 0.065 ppb for ground water. The EECs for chronic exposures are estimated to be 105 ppb for surface water and 0.065 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: Application to commercial and residential turf and on other non-crop sites including airports, cemeteries, fallow areas, golf courses, landscaped areas, public recreation areas, residential property, road sides, school grounds, sod or turf seed farms, sports fields, landscaped areas with established woody ornamentals and other similar use sites. Application may be by commercial applicator or homeowner. The risk assessment was conducted using the following residential exposure assumptions: No chemical-specific exposure data for handler activities were submitted to the Agency in support of the registered lawn uses. The Agency's Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments, and Recommended Revisions (Policy Number 11, revised Feb. 22, 2001), were used as the basis for the residential handler exposure calculations. The handler exposure data used in this assessment are from the Outdoor Residential Exposure Task Force (ORETF). The task force recently submitted proprietary data to the Agency on hose-end sprayers, push-type granular spreaders, and handgun sprayers. The ORETF data were used in this assessment in place of PHED data for the garden hose-end sprayer scenario. The ORETF data were designed to replace the present PHED data with higher-confidence, higher quality data that contain more replicates than the PHED data for those scenarios.

Table 4 shows the assumptions and exposure calculations for this scenario. For short-term exposure and risk for residential lawn applicators (''handlers''), the resulting dermal MOE is 21,000 and the inhalation MOE is 7,000,000. The Total MOE of 20,000 for residential handlers is well above the target MOE of 300, and therefore, does not trigger the Agency's level of concern.

TABLE 4.—SHORT-TERM HANDLER EXPOSURE AND RISK ESTIMATES FOR RESIDENTIAL LAWN APPLICATORS

PHED Scenario Selected from Draft SOP for Residential Exposure Assessments	Exposure Route	Application Rate (lb ai/A)	Acres Treated (acres/day)	ORETF Unit Exposure (mg/lb ai)	Absorption Factor	Daily Dose[1] (mg/kg/day)	Short-Term MOE[2]	Total MOE[3]
Garden Hose End Sprayer/Liquid Open Pour (Mix, Load, and Apply)	Dermal	0.062	0.5	11	1.0	0.0043	21,000	20,000
	Inhalation	0.062	0.5	0.016	1.0	0.0000071	7,000,000	20,000

[1] Daily Dose =[Application Rate (lb ai/A) x Acres Treated (A/day) x Unit Exposure (mg/lb ai handled) x Absorption Factor]/Body Weight (70 kg)
[2] MOE = NOAEL/Daily Dose; where dermal NOAEL = 100 mg/kg/day, and inhalation NOAEL = 10
[3] Total MOE = 1 / [(1/dermal MOE) + (1/inhalation MOE)]

The following postapplication exposure scenarios resulting from lawn treatment were assessed: (1) Toddlers' incidental ingestion of pesticide residues on lawns from hand-to-mouth transfer, (2) object-to-mouth transfer from mouthing of pesticide-treated turfgrass, (3) incidental ingestion of soil from pesticide-treated residential areas, and (4) children's and adult's postapplication dermal exposure. Postapplication exposures from various activities following lawn treatment are considered to be the most common and significant in residential settings. The exposure via incidental ingestion of other plant material may occur but is considered negligible.

The exposure estimates are based on some upper-percentile (i.e., maximum application rate, initial amount of transferrable residue and duration of exposure) and some central tendency (i.e., surface area, hand-to-mouth activity, and body weight) assumptions and are considered to be representative of high-end exposures. The uncertainties associated with this assessment stem from the use of an assumed amount of pesticide available from turf, and assumptions regarding transfer of chemical residues and hand-to mouth activity. The estimated exposures are believed to be reasonable high-end estimates based on observations from chemical-specific field studies and professional judgement.

The exposure and risk estimates for the residential exposure scenarios are assessed for the day of application (day ''0'') because it is assumed that toddlers could contact the lawn immediately after application. Both short-term and intermediate-term oral and dermal exposure are expected, but inhalation exposure is expected to be negligible. Risk from short-term and intermediate-term incidental ingestion by toddlers is assessed by comparing these exposures to the NOAELs of 50 mg/kg/day and 10 mg/kg/day, respectively. Dermal postapplication risk was assessed by comparing the exposures to the NOAELs of 100 mg/kg/day and 10 mg/kg/day, respectively. The results of the exposure calculations are presented in the following Tables 5 through 8.

TABLE 5.—POSTAPPLICATION DERMAL EXPOSURE AND RISK FROM TREATED LAWNS

Subgroup Exposed	Application Rate (lb ai/A)	Dislodgeable Foliar Residue[1] (ug/cm^2)	Short- / Intermediate-Term Dermal Transfer Coefficient (cm^2/hr)	Body Wt (kg)	Daily Dose[2] (mg/kg/day)		Dermal MOE[3]	
					Short-term	Intermediate-term	Short-term	Intermediate-term
Adults	0.062	0.035	14,500/7,300	70	0.014	0.0054	7,000	1,800
Children	0.062	0.035	5,200/2,600	15	0.024	0.0090	4,200	1,100

[1] Dislodgeable Foliar Residue$^{\text{Postapplication day zero}}$ (ug/cm^2) = Application rate (lb ai/A) x Fraction of ai Retained on the Foliage (0.05) x [(1- Fraction of Residue That Dissipates Daily (0.1)]$^{\text{Postapplication day}}$ x 4.54E+8 µg/Lb x 2.47E-8 A/cm^2 (11.2)
[2] Daily Dose = [Dislodgeable Foliar Residue x Absorption Factor (1 for short-term, 0.75 for intermediate-term) x 0.001 mg/ug x Dermal Transfer Coefficient x Exposure Time (2 hrs/day)]/Body weight

[3] Dermal MOE = Dermal NOAEL/Daily Dose; where short-term NOAEL = 100 mg/kg/day, and intermediate-term NOAEL = 10 mg/kg/day

TABLE 6.—POSTAPPLICATION ORAL HAND-TO-MOUTH EXPOSURE AND RISK FOR CHILDREN FROM TREATED LAWNS

Appl. Rate (lb ai/A)	Fraction of ai Retained on the Foliage	Saliva Extraction Factor	Dislodgeable Foliar Residue[1] (ug/cm^2)	Hand Surface Area (cm^2/event)	Short-term/ Intermediate-term Freq. (events/hr)	Body Weight (kg)	Daily Dose[2] (mg/kg/day)		Oral MOE[3]	
							Short-term	Intermediate-term	Short-term	Intermediate-term
0.062	0.05	50%	0.035	20	20/9.5	15	0.00093	0.00044	54,000	23,000

[1] Dislodgeable Foliar Residue$^{Postapplication\ day}$ (ug/cm^2)=Application rate (lb ai/A) x Fraction of ai Retained on the Foliage x (1- Fraction of Residue That Dissipates Daily, 0.10)$^{Postapplication\ day}$ x 4.54E+8 µg/lb x 24.7E-9 A/cm^2 (11.2138)
[2] Daily Dose = (Dislodgeable Foliar Residue (ug/cm^2) x Hand Surface Area (cm^2/event) x Extraction factor x Frequency (events/hr) x 0.001 mg/ug x Exposure time (2 hrs/day))]/[Body Weight (kg)]
[3] Oral MOE = Oral NOAEL/Daily Dose; where Short-term NOAEL = 50 mg/kg/day, and Intermediate-term NOAEL = 10 mg/kg/day

TABLE 7.—POSTAPPLICATION ORAL OBJECT-TO-MOUTH (TURFGRASS) EXPOSURE AND RISK FOR CHILDREN FROM TREATED LAWNS

Application Rate (lb ai/A)	Fraction of ai Retained on the Foliage	Grass Residue[1] ug/cm^2)	Ingestion Rate (cm^2/day)	Body Weight (kg)	Daily Dose[2] (mg/kg/day)	Oral MOE[3]	
						Short-term	Intermediate-term
0.062	0.20	0.031	25	15	0.00023	220,000	43,000

[1] Grass residue$^{Postapplication\ day}$ (ug/cm^2) = Application rate (lb ai/A) x Fraction of ai Retained on the Foliage x (1- Fraction of Residue That Dissipates Daily)$^{Postapplication\ day}$ x 4.54E+8 µg/lb x 24.7E-9 A/cm^2
[2] Daily Dose = [Grass reside (ug/cm^2) x Ingestion rate (cm^2/day) x 0.001 mg/ug] / [Body Weight (kg)]]
[3] Oral MOE = Oral NOAEL/Daily Dose; where Short-term NOAEL = 50 mg/kg/day, and Intermediate-term NOAEL = 10 mg/kg/day

TABLE 8.—POSTAPPLICATION INCIDENTAL SOIL INGESTION EXPOSURE AND RISK FOR CHILDREN FROM TREATED LAWNS

Appl. Rate (lb ai/A)	Fraction of ai Retained in the Soil	Soil Residue[1] (ug/g)	Ingestion Rate (mg/day)	Body Weight (kg)	Daily Dose[2] (mg/kg/day)	Oral MOE[3]	
						Short-term	Intermediate-term
0.062	1	0.47	100	15	3.1E-06	16,000,000	3,200,000

[1] Soil residue $^{Postapplication\ day}$ (ug/cm^2) = Application rate (lb ai/A) x Fraction of ai Retained on the Foliage x (1- Fraction of Residue That Dissipates Daily) $^{Postapplication\ day}$ x 4.54E+8 µg/lb x 24.7E-9 A/cm^2 x 0.67 cm^3/g soil
[2] Daily Dose = [Soil reside (ug/g) x Ingestion rate (mg/day) x 0.000001 g/ug] / [Body Weight (kg)]]
[3] Oral MOE = Oral NOAEL/Daily Dose; where Short-term NOAEL = 50 mg/kg/day, and Intermediate-term NOAEL = 10 mg/kg/day

Both short-term and intermediate-term MOEs for each scenario are above the target MOE of 300, and are not of concern.

When a common effect (i.e., decreased body weight gain) is observed in those studies selected for the endpoints for all routes of exposure; MOEs are to be combined where appropriate. Aggregate residential risk was assessed for adults and children (Tables 9 and 10). For children, short-term and intermediate-term aggregate risk was assessed based on postapplication dermal and oral exposure. For adults, short-term aggregate residential risk was assessed based on exposure through application (handler) and postapplication dermal exposure. Intermediate aggregate risk for adults was not assessed because the application of halosulfuron-methyl is not expected to occur for more than 30 days. The Total MOEs resulting from the combined MOEs for both adults and children, are also above the target MOE of 300, and are not of concern.

TABLE 9.—ADULT'S AGGREGATE EXPOSURE AND RISK ESTIMATES FROM RESIDENTIAL LAWNS

Adult's Scenario	Exposure Route	Rate (lb ai/acre)	Acres Treated (acres/day)	PHED Unit Exposure (mg/lb ai)	Short-term Daily Dose (mg/kg/day)	Short-term MOE	Total Short-term MOE
1. Mix/load and broadcast application of liquid formulation (garden hose-end sprayer)	dermal	0.062	0.5	30	0.0043	21,000	5,200
	inhalation	0.062	0.5	0.016	0.0000071	7,000,000	5,200
2. Postapplication exposure	dermal	0.062	N/A	N/A	0.014	7,000	5,200

TABLE 10.—CHILDREN'S AGGREGATE EXPOSURE AND RISK ESTIMATES FROM RESIDENTIAL LAWNS

TTR/GR/SR_0 (ug/cm^2 or g)[1]	Children's ScenariosExposure Route	Short-Term $PDR^{0\ norm}$ (mg/kg/day)	Intermediate $PDR^{0\ norm}$ (mg/kg/day)	Short-Term MOE	Intermediate-Term MOE	Total Short-Term MOE	Total Intermedite-term MOE
(1) Dermal contact	0.035	0.024	0.0090	4,200	1,100	3,800	1,000
(2) Hand-to-mouth	0.035	0.00093	0.00044	54,000	23,000	3,800	1,000
(3) Mouth grass	0.14	0.00023	0.00023	220,000	43,000	3,800	1,000
(4) Soil ingestion	0.047	3.1E-6	3.1E-6	16,000,000	3,2000,000	3,800	1,000

[1] TTR=turf transferable residue on the ''0''; GR=gras residue on the day ''0''; SR_0=soil residue on the day ''0.''
[2] PDR $_{0\text{-norm}}$ = potential doe rate on day ''0.''

Halosulfuron-methyl may be used on turf at recreational use sites, and, therefore may result in postapplication exposure to adults and children involved in recreational activities. Exposures to adults and children from the use of halosulfuron-methyl at recreational use sites are assumed to be the same as those assessed for residential use sites, and therefore, a separate recreational exposure assessment was not included. Refer to section 4.4 of this risk assessment for details on assumptions, input variables and risk estimates for residential use sites. Residential turf exposure assessment results in what are considered upper bound risk estimates. Therefore, it is not expected that the upper bound residential exposure scenario would occur on the same day as an upper bound recreational exposure scenario. Exposure from these two exposure scenarios are not aggregated. Rather, the residential risk estimate should serve as an upper bound for both residential and recreational exposure.

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

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 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 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.* There is no evidence of increased susceptibility of young rats in the reproduction study with halosulfuron-methyl. Although there is qualitative evidence of increased susceptibility in the prenatal developmental studies in rats and rabbits, the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment of halosulfuron-methyl.

3. *Conclusion.* There is a complete toxicity data base for halosulfuron-methyl except for a developmental neurotoxicity study and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that, based on reliable data, an additional database uncertainty factor of 3X is necessary to protect the safety of infants and children in assessing halosulfuron-methyl exposures and risks. This factor is necessary to address a data deficiency for the developmental neurotoxicity study. The additional uncertainty factor of 3X is incorporated into the numerical expression for the acute and chronic RfD and PAD (aPAD and cPAD) and applied to all dietary and residential (non-dietary) exposure scenarios. For residential assessments, an MOE of 300 (10X for interspecies extrapolation, 10X for intraspecies variation, and the additional database uncertainty factor of 3X) is required.

No Special FQPA Safety Factor is necessary to protect the safety of infants and children in assessing halosulfuron-methyl exposure and risks because:

i. There is no evidence of increased susceptibility of young rats in the reproduction study with halosulfuron-methyl. Although there is qualitative evidence of increased susceptibility in the prenatal developmental studies in rats and rabbits, the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment of halosulfuron-methyl.

ii. There are no residual uncertainties identified in the exposure databases. The dietary (food and drinking water) exposure assessments will not underestimate the exposure (postapplication exposure to children as well as incidental oral exposure to toddlers) and risks posed by halosulfuron-methyl.

Recently, EPA has received objections to a tolerance it established for residues of halosulfuron-methyl in or on the melon subgroup (66 FR 66786, December 26, 2001) and an emergency exemption for asparagus (66 FR 66778, December 27, 2001). The objections were filed by the Natural Resources Defense Council (NRDC) and raised several issues regarding aggregate exposure estimates and the additional safety factor for the protection of infants and children. NRDC's objections raise complex legal, scientific, policy, and factual matters and EPA has initiated a public comment period on them in the **Federal Register** of June 19, 2002 (67 FR 41628) (FRL–7167–7), which ends on September 17, 2002. Although that proceeding remains ongoing, prior to

acting on this current tolerance action, EPA reviewed the halosulfuron-specific objections raised by NRDC and has addressed them below.

In reference to NRDC's statements that the Agency erred by not retaining the additional 10X children's safety factor in light of the data gap for developmental neurotoxicity study, the Agency re-reviewed its determination that a different safety factor, 3X, would be safe for infants and children. Taking into account the lack of the developmental neurotoxicity study, EPA concluded that an additional traditional Database Uncertainty Factor of 3X is needed for all dietary and residential (non-dietary) exposure scenarios until the data are received and evaluated. An uncertainty factor of 3X (as opposed to a higher value) was viewed to be adequate because the doses selected for dietary and non-dietary risk assessments would address the concerns for the alterations of the fetal nervous system seen in the developmental toxicity study in rats and provide a large margin of safety in regard to any uncertainty arising from the lack of a developmental neurotoxicity study. The NOAEL of 50 mg/kg/day (used for acute dietary, short-term incidental oral and inhalation risk assessments) and the NOAEL of 10 mg/kg/day (used for chronic dietary and intermediate-term incidental oral, dermal and inhalation risk assessments) are 5X and 25X lower, respectively, than the NOAEL of 250 mg/kg/day in the rat developmental study where alterations of the fetal nervous system were seen at 750 mg/kg/day (LOAEL). It was these alterations of the fetal nervous system seen at 750 mg/kg/day in the rat developmental study that caused EPA to require submission of a developmental neurotoxicity study. Thus, in combination with the 3X database uncertainty factor, the doses selected for risk assessment provide a 15X (acute) and 75X (chronic) margin of safety with regard to observed developmental neurotoxic effects. Consequently, based on the available data, use of a 3X factor instead of a 10X factor will provide an adequate margin of safety for the protection of infants and children.

NRDC also claimed that there were several other data gaps necessitating retention of the additional 10X safety factor for the protection of infants and children. NRDC claimed that no cancer risk assessment or short-term or intermediate-term residential risk assessments had been conducted. NRDC's allegations in this regard are contradicted by the **Federal Register** notice establishing the halosulfuron-methyl tolerances. EPA did assess the cancer risk posed by halosulfuron-methyl and concluded that ''no cancer risk is expected from exposure to halosulfuron-methyl.'' (66 FR 66333, 66338, December 26, 2001). This conclusion was based on EPA's qualitative conclusion that halosulfuron-methyl is not likely to be a human carcinogen. *Id.* Having concluded that, as a qualitative matter, halosulfuron-methyl is not likely to be a human carcinogen EPA did not perform a quantitative cancer risk assessment, as such risk assessment would not be scientifically justified. EPA's statement earlier in the **Federal Register** notice regarding not conducting a cancer risk assessment referred to the fact that a quantitative assessment was unnecessary. *Id.* at 66336. Short-term and intermediate-term risk residential risk assessments were performed and considered by the Agency. *Id.* at 66337-66338.

E. 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 + residential 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 USEPA Office of Water are used to calculate DWLOCs 21/70 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, the Office of Pesticide Programs (OPP) concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in Unit III.C., Exposure Assessment, for acute exposure, the acute dietary exposure from food to halosulfuron-methyl will occupy <1% of the aPAD for females 13 years and older. The acute dietary exposure estimates are provided for females 13–50 years old only. No appropriate endpoint attributable to a single exposure was identified for the general U.S. population including infants, children, and adult males. In addition, there is potential for acute dietary exposure to halosulfuron-methyl in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 11:

TABLE 11.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO HALOSULFURON-METHYL

Population Subgroup	aPAD (mg/kg)	Food Exposure (mg/kg/day)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females 13–50 years old	0.17	0.00068	105	0.065	5100

2. *Chronic risk*. Using the exposure assumptions described in Unit III.C., Exposure Assessment, for chronic exposure, EPA has concluded that exposure to halosulfuron-methyl from food will utilize <1% of the cPAD for the U.S. population, 2.4% of the cPAD for all infants <1 year old and 1.7% of the cPAD for children 1–6 years . Based the use pattern, chronic residential exposure to residues of halosulfuron-methyl is not expected. In addition, there is potential for chronic dietary exposure to halosulfuron-methyl in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 12:

TABLE 12.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO HALOSULFURON-METHYL

Population Subgroup	cPAD mg/kg/day	Food Exposure (mg/kg/day)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.03	0.00028	105	0.065	1,000
All infants (<1 year old)	0.03	0.00071	105	0.065	300
Females 13–50 years old	0.03	0.00023	105	0.065	900
Males 13–19 years old	0.03	0.00027	105	0.065	1,000

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 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.

Using the exposure assumptions described in Unit III.C., Exposure Assessment, for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 5200 for adults from exposure to residential lawns including MOEs of 21,000 for dermal, 7,000,000 for inhalation and 7,000 for postkapplication dermal; 3800 for children from exposure to residential lawns including MOEs of 4,200 for dermal contact, 54,000 for hand-to-mouth, 220,000 for mouthing grass, and 16,000,000 for soil ingestion. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of halosulfuron-methyl in ground 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 13:

TABLE 13.—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)
U.S. population	5300	300	105	0.065	5500
Females 13–50 years old	4700	300	105	0.065	4700
All infants (<1 year old)	3600	300	105	0.065	1500
Males 13–19 years old	5400	300	105	0.065	5500

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

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 Unit III.C., Exposure Assessment, for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,000 for children from residential lawns including MOEs of 1100 for dermal contact, 23,000 for hand-to-mouth, 43,000 for mouthing grass, and 3,200,000 for soil ingestion. 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 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 14:

TABLE 14.—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)
All infants (<1 year)	960	300	105	0.065	230

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. Accordingly, exposure to halosulfuron-methyl is not expected to pose a cancer risk to humans.

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.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate analytical enforcement method is available to enforce the proposed tolerance for residues of halosulfuron-methyl in or on asparagus; vegetables, fruiting (except cucurbits), group; bean, dry, seed and bean, snap succulent. The method used to validate residues of halosulfuron-methyl is the ''Analytical Method for the Determination of MON 12000 in Raw Agricultural Commodities and Processed Fractions,'' RES–109–97–4, which has been approved by the Agency for enforcement of tolerances for halosulfuron-methyl *per se* in plant commodities and has been sent to FDA for publication in PAM II. The method limit of quantification (LOQ) was 0.05 ppm.

An adequate analytical method is available to enforce the established tolerances for secondary residues in livestock commodities. The Agency-approved analytical method for livestock commodities is Monsanto method RES–046–93. The method quantifies halosulfuron-methyl and the 3-chlorosulfonamide acid metabolite expressed as parent equivalents. The limit of quantitation is 0.01 ppm.

Adequate enforcement methodology (example: gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Paul Golden, Analytical Chemistry Lab. Office of Pesticide Programs, Environmental Protection Agency, Environmental Science Center, 701 Maples Road, Fort Mead, MD 20755–5350; telephone number: (410) 305–2960; e-mail address: *golden.paul@epa.gov*.

B. International Residue Limits

No Codex, Canadian, or Mexican maximum residue levels (MRL) have been established for residues of halosulfuron-methyl in/on asparagus, bean, dry, seed, and bean, snap, succulent, tomatoes, and bell or non-bell peppers. International harmonization is therefore not an issue.

V. Conclusion

Therefore, the tolerances are established for residues of halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonylaminosulfonyl-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate, in or on asparagus at 0.8 ppm; vegetables, fruiting (except cucurbits), group at 0.05 ppm; bean, dry, seed at 0.05 ppm and bean, snap, succulent at 0.05 ppm. Paragraph (b) of § 180.479 is removed and reserved since the tolerance established in this document for asparagus at 0.8 ppm replaces the tolerance for asparagus and the tolerance for tomato is removed because the vegetables, fruiting (except cucurbits), group at 0.05 ppm includes tomatoes.

VI. 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 ID number OPP–2002–0243 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 November 19, 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 (1900C), 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. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy, Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

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

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

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 VI.A., you should also send a copy of your request to the PIRIB for its

inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP–2002–0243, 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).

VII. Regulatory Assessment Requirements

This final 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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.

VIII. 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: September 12, 2002.

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 as follows:

i. By revising the section heading and alphabetically adding the following

commodities to the table in paragraph (a)(2).

ii. The text of paragraph (b) is removed and reserved.

§ 180.479 Halosulfuron-methyl; tolerances for residues.

(a) *General.* * * *

(2) * * *

Commodity	Parts per million
* * * * *	
Asparagus	0.8
Bean, dry, seed	0.05
Bean, snap, succulent	0.05
* * * * *	
Vegetables, fruiting (except cucurbits), group	0.05

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

* * * * *

[FR Doc. 02–23995 Filed 9–19–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0219; FRL–7198–5]

Methoxyfenozide; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of methoxyfenozide and the combined residues of methoxyfenozide and its glucuronide metabolite on various agricultural food commodities. This regulation also establishes tolerances for indirect or inadvertent residues for methoxyfenozide and establishes tolerances for indirect or inadvertent combined residues for methoxyfenozide and its metabolites on various food commodities, and increases the already established tolerances for residues of methoxyfenozide and increases the already established tolerances for the combined residues of methoxyfenozide and its glucuronide metabolite on various food commodities. Rohm and Haas Company and the Interregional Research Project Number 4 (IR–4), Technology Center of New Jersey, the State University of New Jersey requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The chemical was subsequently purchased by Dow Agrosciences from Rohm and Haas Company. The specific food commodities affected by the establishment or increase of these tolerances are set forth in the preamble to this document.

DATES: This regulation is effective September 20, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0219, must be received on or before November 19, 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 ID number OPP–2002–0219 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joseph M. Tavano, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–6411; e-mail address: *tavano.joseph@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_00/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 ID number OPP–2002–0219. 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 Registers** of January 10, 2000, 65 FR 1370–1381; FRL–6394–6; March 19, 2001, 66 FR 15432–15459; FRL–6766–7; May 23, 2001, 66 FR 28482–28487; FRL–6782–5 and August 24, 2001, 66 FR 44629–44634; FRL–6796–2; and August 14, 2002, 67 FR 52996–53001; FRL–7191–9. EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170), announcing the filing of a pesticide petitions (PP 9F6033; 9F6062; 0F6201; 0F6213; 1F 6259; 1F6287; 2E6382 and