

Commodity	Parts per million
Sheep, fat	0.1
Sheep, kidney	1.0
Sheep, mbyp (except kidney)	0.1
Sheep, meat	0.1

(b) Section 18 emergency exemptions.
[Reserved]

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[FR Doc. 01-31493 Filed 12-21-01; 8:45 am]
BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301200; FRL-6816-8]

RIN 2070-AB78

Halosulfuron-methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of halosulfuron-methyl in or on the melon subgroup. IR-4 requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective December 26, 2001. Objections and requests for hearings, identified by docket control number OPP-301200, 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-301200 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-3194; and e-mail address: brothers.shaja@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:

Cat-egories	NAICS	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/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301200. 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 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 Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (PP) for tolerance by the Interregional Research Project Number 4 (IR-4), 681 U.S. Highway 1 South, North Brunswick, NJ 08902-3390. This notice included a summary of the petition prepared by Gowan Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.479 be amended by establishing a tolerance for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl) aminocarbonylamino] sulfonyl-3-chloro-1-methyl-1H-pyrazole-4-carboxylate, in or on the melon subgroup-crop group 9A (includes citron melon, muskmelon, and watermelon) at 0.1 part per million (ppm).

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 (62 FR 62961, November 26, 1997) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of halosulfuron-methyl on the melon subgroup at 0.1 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 published in the **Federal Register** for 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 intra species 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 x 10⁶ 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 13–50 years of age	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 and increases in resorptions and post implantation loss.
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 decrease in body weight gain and alterations in hematology and clinical chemistry parameters.
Short-Term Dermal (1 to 7 days) (Residential)	dermal (or 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 and increases in resorptions and post implantation loss.

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Intermediate-Term Dermal (1 week to several months) to Long - Term (several months to lifetime) (Residential)	dermal (or oral) study NOAEL = 10 mg/kg/day (dermal absorption rate = 75%)	LOC for MOE = 100 (Residential)	Chronic Toxicity-Dog; LOAEL 40 mg/kg/day decrease in body weight gain and alterations in hematology and clinical chemistry parameters.

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.479) for residues of halosulfuron-methyl, in or on the following raw agricultural commodities: squash/cucumber (crop subgroup 9-B); tree nuts (crop group 14), pistachio nutmeat; almond hulls; sugar cane; corn (sweet, kernel+cob with husks removed; field grain, fodder and forage; and pop grain and fodder); rice (grain and straw); and cotton (gin by-products and undelinted seed) at the range of 0.05 to 0.8 ppm. 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 including 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: The Acute DEEM® analysis was performed assuming tolerance level residues and 100% crop treated (CT) for commodities for which halosulfuron-methyl is registered and 0.1 ppm (the recommended tolerance) and 100% CT for the melon subgroup (crop group 9–A). No reduction factors of any kind were used in the analysis. This analysis is considered highly conservative.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model

(DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic DEEM® analysis was performed assuming tolerance level residues and 100% crop treated (CT) for commodities for which halosulfuron-methyl is registered and a proposed tolerance 0.1 ppm and 100% CT for the melon subgroup (crop group 9–A). No reduction factors of any kind were used in the analysis. This analysis is considered highly conservative.

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. Accordingly, a cancer risk assessment was not conducted.

2. *Dietary exposure from drinking water.* The available data on halosulfuron-methyl (parent) shows that the compound is mobile in soil and is persistent at phytotoxically significant levels for months to years at some sites. Halosulfuron-methyl has the potential to leach to groundwater, and also presents concerns for transport to surface water by runoff.

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 Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1

model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. 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 GENEEC model the acute and chronic estimated environmental concentrations (EECs) of halosulfuron-methyl for surface water are estimated to be 8.3 µg/L and 1.7 µg/L, respectively. Based on the SCI-GROW model the estimated EECs of

halosulfuron-methyl for groundwater is estimated to be 0.065 µg/L.

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: 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. The risk assessment was conducted as follows: For short-term exposure and risk for residential lawn applicators (handlers), the resulting dermal exposure for female handlers is 0.000043 mg/kg/day resulting in an MOE of 1,200,000. This MOE does not exceed EPA's level of concern for residential handlers. Chronic- and intermediate-term handler assessments were not conducted because lawn application of halosulfuron-methyl is not expected to be made continuously over the duration of the chronic- or intermediate-term exposure scenarios.

For residential postapplication exposure and risk calculations for adults, short- and intermediate-term exposures result in MOEs that range from 1,800 to 5,200. These MOEs do not exceed EPA's level of concern for adults.

For children's residential postapplication exposure and risk calculations, dermal exposure was combined with incidental oral hand-to-mouth and object-to-mouth exposures (because all exposures are compared to the same endpoint) to represent a worst-case scenario. The short-term risk estimate results in an MOE of 2,900 and the intermediate-term risk results in an MOE of 1,100. These risks do not exceed EPA's level of concern.

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).

D. Safety Factor for Infants and Children

1. *In general.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* 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 two-generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

3. *Conclusion.* There is a complete toxicity database for halosulfuron-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 *in utero* and/or postnatal exposure to halosulfuron methyl, and although a developmental neurotoxicity study was required, an additional safety factor was not warranted.

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 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, 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 this unit for acute exposure, the acute dietary exposure from food to halosulfuron-methyl will occupy <1% of the aPAD for females (13 years and older), infants, and children (1–6 years old). 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 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	0.5	0.00070	8.3	0.065	5,000
Children (1–6 years)	0.5	0.00097	8.3	0.065	5,000
Females (13–50 years)	0.5	0.00058	8.3	0.065	15,000

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% of the cPAD for the U.S. population, infants (<1 year old), children (1–6 years old), and

females (13–50 years old). Based on 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 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	0.00020	1.7	0.065	3,500
All infants (<1 year)	0.10	0.00059	1.7	0.065	1,000
Children (1–6 years)	0.10	0.00035	1.7	0.065	1,000
Females (13–50 years)	0.10	0.00016	1.7	0.065	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 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 this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated

result in aggregate MOEs of 4,500 for females 13–50 years and older, and 2,800 for infants (<1 year old). A short-term risk assessment is required for adults because there is a residential exposure scenario (handler and postapplication). In addition, a short-term risk assessment is required for infants and children because there are residential post-application dermal and oral exposure scenarios. The risk calculations for adult females is expected to result in a higher risk than adult males because a lower body weight is used (60 kg), therefore adult

females will represent the U.S. population. 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 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)
U.S. Population	4,500	100	1.7	0.065	17,000
Infants (<1 year old)	2,800	100	1.7	0.065	4,800
Females (13–50 years old)	4,500	100	1.7	0.065	15,000

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 this unit for intermediate-term exposures, EPA has concluded that

food and residential exposures aggregated result in aggregate MOEs of 1,700 females 13–50 years old, and 1,100 for infants (<1 year old). An intermediate-term risk assessment is required for adults because there is a residential exposure scenario (handler and postapplication). In addition, an intermediate-term risk assessment is required for infants and children because there are residential post-application dermal and oral exposure scenarios. The risk calculations for adult females is expected to result in a higher risk than adult males because a lower body weight is used (60 kg), therefore

adult females will represent the U.S. population. 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 5:

TABLE 5.— AGGREGATE 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)
U.S. Population	1,700	100	1.7	0.065	3,300
Infants (<1 year old)	1,100	100	1.7	0.065	910
Females (13–50 years old)	1,700	100	1.7	0.065	2,800

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, and thus no cancer risk is expected from exposure to halosulfuron methyl.

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

EPA now requires measurement of parent halosulfuron only using the revised enforcement method, Analytical Method for the Determination of MON 12000 in Raw Agricultural Commodities and Processed Fractions. The method was accepted by EPA as an enforcement method and sent to FDA to be included in PAM II.

The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no established Codex, Canadian, or Mexican maximum residue

limits (MRLs) or tolerances for residues of halosulfuron-methyl in/on the melon subgroup.

V. Conclusion

Therefore, the tolerance is established for residues of halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl) amino] carbonylamino sulfonyl-3-chloro-1-methyl-1H-pyrazole-4-carboxylate, in or on melon subgroup at 0.1 ppm.

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 control number OPP–301200 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 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 control number OPP-301200, 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 FFDC 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 FFDC 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 FFDC 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: December 13, 2001.

Peter Caulkins,

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 alphabetically adding the following commodity to the table in paragraph (a)(2) to read as follows:

§ 180.479 Halosulfuron-methyl; tolerances for residues.

- (a) * * *
- (2) * * *

Commodity	Parts per million
* * *	* *
Melon Subgroup	0.1
* * *	* *

* * * * *

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL-7120-8]

Kentucky: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: Kentucky has applied to EPA for Final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA has determined that these changes satisfy all requirements needed to qualify for Final authorization, and is authorizing the State's changes through this immediate final action. EPA is publishing this rule to authorize the changes without a prior proposal because we believe this action is not controversial and do not expect comments that oppose it. Unless we get written comments which oppose this authorization during the comment period, the decision to authorize Kentucky's changes to their hazardous waste program will take effect as provided below. If we get comments that oppose this action, we will publish a document in the **Federal Register** withdrawing this rule before it takes effect and a separate document in the proposed rules section of this **Federal Register** will serve as a proposal to authorize the changes.

DATES: This Final authorization will become effective on February 25, 2002 unless EPA receives adverse written comment by January 25, 2002. If EPA receives such comment, it will publish a timely withdrawal of this immediate final rule in the **Federal Register** and inform the public that this authorization will not take effect.

ADDRESSES: Send written comments to Narindar Kumar, Chief, RCRA Programs Branch, Waste Management Division, U.S. Environmental Protection Agency, The Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, GA, 30303-3104; (404) 562-8440. You can view and copy Kentucky's application from 8 a.m. to 4:30 p.m. at the following addresses: Kentucky Department for Environmental Protection, Division of Waste Management, Fort Boone Plaza, Building 2, 18 Reilly Road, Frankfort, Kentucky 40601, (502) 564-6716; U.S. EPA, Region 4, Library, 61 Forsyth Street, SW., Atlanta, Georgia 30303-3104; (404) 562-8190.

FOR FURTHER INFORMATION CONTACT: Narindar Kumar, Chief RCRA Programs

Branch, Waste Management Division, U.S. Environmental Protection Agency, The Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, GA, 30303-3104; (404) 562-8440.

SUPPLEMENTARY INFORMATION:

A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, States must change their programs and ask EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

B. What Decisions Have We Made in This Rule?

We conclude that Kentucky's application for the Omnibus Provision meets all of the statutory and regulatory requirements established by RCRA. Therefore, we grant Kentucky Final authorization to operate its hazardous waste program with the Omnibus Provision changes described in the authorization application. Kentucky has responsibility for permitting Treatment, Storage, and Disposal Facilities (TSDFs) within its borders (except in Indian Country) and for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations of the Hazardous and Solid Waste Amendments of 1984 (HSWA). New Federal requirements and prohibitions imposed by Federal regulations that EPA promulgates under the authority of HSWA take effect in authorized States before they are authorized for the requirements. Thus, EPA will implement those requirements and prohibitions in Kentucky, including issuing permits, until the State is granted authorization to do so.

C. What Is the Effect of Today's Authorization Decision?

The effect of this decision is that a facility in Kentucky subject to RCRA will now have to comply with the authorized State requirements instead of the equivalent Federal requirements in order to comply with RCRA. Kentucky has enforcement responsibilities under its state hazardous waste program for