Commodity	Parts per million
Vegetable, leafy except Brassica group 4, except spinach	4.0

(2) Tolerances are established for combined residues of flonicamid [*N*-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide], and its metabolites TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.02
Cattle, meat	0.05
Cattle, meat by-products	0.08
Egg	0.03
Goat, fat	0.02
Goat, meat	0.05
Goat, meat byproducts	0.08
Horse, fat	0.02
Horse, meat	0.05
Horse, meat by-products	0.08
Milk	0.02
Poultry, fat	0.02
Poultry, meat	0.02
Poultry, meat by-products	0.02
Sheep, fat	0.02
Sheep, meat	0.05
Sheep, meat by products	0.08

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

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

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

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0165; FRL–7719–8]

Halosulfuron-methyl; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of halosulfuron-methyl in or on sweet potatoes. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on sweet potatoes. This regulation establishes a maximum permissible level for residues of halosulfuron-methyl in this food commodity. The tolerance will expire and is revoked on December 31, 2008.

DATES: This regulation is effective August 31, 2005. Objections and requests for hearings must be received on or before October 31, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under docket identification (ID) number OPP–2005–0165. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket/*. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; e-mail address: *ertman.andrew@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the herbicide halosulfuron-methyl, in or on sweet potatoes at 1.0 parts per million (ppm). This tolerance will expire and is revoked on December 31, 2008. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations (CFR).

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

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.''

Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

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

Several sweet potato growing States requested the use of halosulfuron-methyl due to resistance to pesticides registered for the control of the weed purple nutsedge in sweet potato fields. EPA has authorized under section 18 of FIFRA the use of halosulfuron-methyl on sweet potatoes for control of purple nutsedge in Louisiana, Mississippi, and North Carolina. After having reviewed the submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of halosulfuron-methyl in or on sweet potatoes. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of FFDCA would be consistent with the safety standard and with section 18 of FIFRA. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of FFDCA. Although this tolerance will expire and is revoked on December 31, 2008, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on sweet potatoes after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

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

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

Consistent with section 408(b)(2)(D) of FFDCA , EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of halosulfuron-methyl and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a time-limited tolerance for residues of halosulfuron-methyl in or on sweet potatoes at 1.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences. For halosulfuron-methyl, the Agency identified the need for a developmental neurotoxicity (DNT) study. In the absence of a DNT study, EPA concluded that an additional database UF of 3X is needed for all dietary and residential (non-dietary) exposure scenarios until the data are received and evaluated. An UF of 3X (as opposed to a higher value) was viewed to be adequate because 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). Consequently, based on the available data it is unlikely the results of the DNT would impact the overall risk assessment.

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 (SF).

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100.

To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x10^{-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 Table 1 of this unit:

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

Exposure scenario	Dose milligram/kilogram/day (mg/kg/day) UF/MOE	Hazard based special FQPA SF	Endpoint for risk assessment
Dietary risk assessments			
Acute dietary Females 13–50 years of age	NOAEL = 50 UF = 300[a] Acute RfD = 0.17 mg/kg/day	1x	Developmental toxicity—rabbit LOAEL = 150 mg/kg/day based on decreased mean litter size, increased number of resorptions (total and per dam) and increased post-implantation loss. (developmental toxicity).
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 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 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)	Dermal NOAEL = 100		21–Day dermal toxicity study—rat LOAEL = 1,000 mg/kg/day based on decreased body weight gain in males.
Residential	MOE = 300		
Dermal[b] Intermediate-term (1–6 months)	Oral NOAEL = 10		13 Week subchronic toxicity—dog LOAEL = 40 mg/kg/day based on decreased body weight gain and food efficiency in females.
Residential	MOE = 300	1x	
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] 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.

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

Exposure scenario	Dose milligram/kilogram/day (mg/kg/day) UF/MOE	Hazard based special FQPA SF	Endpoint for risk assessment
Cancer	Classification: ''not likely to be carcinogenic to humans'' by the oral route, based on no evidence from studies in rats and mice.		

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

B. Exposure Assessment

1. *Dietary exposure from food, feed uses, and drinking water*. Tolerances have been previously established (40 CFR 180.479) for the residues of halosulfuron-methyl, in or on a variety of raw agricultural commodities. The established tolerances include almond hulls; corn (sweet, kernel+cob with husks removed, field grain, fodder, forage, pop); cotton (gin by-products and undelinted seed); pistachio nutmeat; sugarcane; rice (grain, straw); and tree nuts (crop group 14). Additionally, tolerances are established (40 CFR 180.479 (a)(1)) for residues of halosulfuron-methyl and its metabolites determined as 3-chloro-1-methyl-5-sulfamoylpyrazole-4-carboxylic acid (also referred to as CSA, expressed as parent equivalents) at 0.1 ppm in or on meat by-products of cattle, goats, hogs, horses, and sheep.

In conducting the acute and chronic dietary risk assessments, EPA used the Dietary Exposure Evaluation Model (DEEM™) software. Modeled estimates of drinking water concentrations were directly entered into the exposure model to assess the contribution from drinking water. 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 DEEM™ analysis evaluated the individual food consumption as reported by respondents in the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: Tolerance level residues and 100 percent crop treated (PCT) for all commodities for which halosulfuron-methyl tolerances are established and for the crop. Aggregate acute food and water exposure was determined by including modeled estimates of drinking water concentrations in the dietary model. The Agency used the acute water concentration (105 parts per billion (ppb)) derived from surface water modeling results, which was significantly higher than the modeled ground water concentration, and therefore protective of potential exposures via ground water sources of drinking water.

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 1994–1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: tolerance level residues and 100 PCT for all commodities for which halosulfuron-methyl tolerances are established and for sweet potatoes. Aggregate chronic food and water exposure was determined by including modeled estimates of drinking water concentrations in the dietary model. The Agency used the chronic water concentration (105 ppb) derived from surface water modeling results, which was significantly higher than the modeled ground water concentration, and therefore protective of potential exposures via ground water sources of drinking water.

iii. *Cancer*. Halosulfuron-methyl is classified as a ''Not Likely'' human carcinogen. Therefore, risk assessments to assess cancer risk were not conducted.

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

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

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water.

Based on the FIRST and SCI-GROW models the estimated environmental concentrations (EECs) of halosulfuron-methyl for acute exposures are estimated to be 105 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: Residential turfgrass and landscaped areas.

The short-term aggregate risk assessment estimates risks likely to

result from 1– to 30–day exposure to halosulfuron-methyl residues. A short-term risk assessment is required for adults because there are both residential handler and post-application exposure scenarios. In addition, a short-term risk assessment is required for infants and children because there is a residential post-application exposure scenario. Since the same effect was identified as the endpoint across all routes of exposure (decreased body-weight gain), MOEs are combined to result in an aggregate MOE (using the ''1/MOE Approach''). The Agency's level of concern for short-term exposure is an MOE of 300 or lower. Results from the short-term risk assessment indicate that all short-term aggregate MOEs are 3,100 or higher. Therefore, estimated aggregate (food + water + residential) exposure to halosulfuron-methyl are not of concern for short-term aggregate exposure.

The intermediate-term aggregate risk assessment estimates risks likely to result from 1 to 6 months of exposure to halosulfuron-methyl residues from food, drinking water, and residential pesticide uses. An intermediate-term risk assessment is not required for adults because residential handler scenarios are not expected to occur for longer than a short-term time frame. However, an intermediate-term risk assessment is required for infants and children because there is a residential post-application oral exposure scenario. Since the same effect was identified as the endpoint across all routes of exposure (decreased body weight gain), MOEs are combined to result in an aggregate MOE (using the ''1/MOE Approach''). High-end estimates of residential exposure are used in the intermediate-term assessment, while average values are used for food and drinking water exposure. The Agency's level of concern for intermediate-term exposure is an MOE of 300 or lower. Results from the intermediate-term risk assessment indicate that the intermediate-term aggregate MOE is 819 for the most highly exposed child subgroup. Therefore, estimated aggregate (food + water + residential) exposure to halosulfuron-methyl are not of concern for intermediate-term aggregate exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to halosulfuron-methyl and any other substances and 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 policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

C. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-natal and post-natal 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 MOE analysis or through using UFs in calculating a dose level that poses no appreciable risk to humans.

2. *Conclusion*. The Agency concludes that no special FQPA SF 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 is regulating at the NOAEL of 50 mg/kg/day for acute dietary, short-term incidental oral and inhalation risk assessments and the NOAEL of 10 mg/kg/day for chronic dietary and intermediate-term incidental oral, dermal, and inhalation risk assessments. These endpoints 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).

ii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments may be refined using anticipated residues calculated from field trial data with any PCT information. Conservative ground and surface water modeling estimates have been used. The Agency's residential standard operating procedures (SOPs) are used to assess post-application exposure to children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by halosulfuron-methyl.

However, a 3X additional database UF will be used to address the data deficiency for the developmental neurotoxicity study. The 3X safety factor should be applied to all dietary and residential non-dietary exposure scenarios. No FQPA SF is appropriate for halosulfuron-methyl.

D. Aggregate Risks and Determination of Safety

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against EECs. The DWLOC values are not regulatory standards for drinking water, but 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 EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2 L/60 kg (adult female), and 1 L/10 kg (child). 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 ground water 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. When new uses are added OPP reassesses the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

More recently the Agency has used another approach to estimate aggregate exposure through food, residential, and drinking water pathways. In this approach, modeled surface and ground water EECs are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic estimate of exposure because actual body weights and water consumption from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in developing drinking water modeling inputs. This risk assessment for halosulfuron-methyl was conducted using this approach.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to halosulfuron-methyl will occupy 14% for females 13–50 years of age, the population subgroup of concern. EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 2 of this unit:

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

Population subgroup	aPAD (mg/kg)	% aPAD (Food and Water)
Females 13 years and older	0.17	14%

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to halosulfuron-methyl from food and water will utilize 2% or less of the cPAD for all population subgroups in DEEM™ including the U.S. population, infants and children. There are no residential uses for halosulfuron-methyl that result in chronic residential exposure to halosulfuron-methyl. Based on the use pattern, chronic residential exposure to residues of halosulfuron-methyl is not expected. EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3 of this unit:

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

Population subgroup	cPAD mg/kg/day	% cPAD (Food and Water)
U.S. population	0.03	1%
All Infants (< 1 year)	0.03	1%
Children 1–2 years old	0.03	2%
Children 3–5 years old	0.03	2%
Children 6–12 years old	0.03	1%
All other population subgroups	0.03	<1%

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Halosulfuron-methyl is currently registered for use(s) that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for halosulfuron-methyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water and residential exposures aggregated result in aggregate MOEs of 5,800 for the general U.S. population and 3,200 for children 3–5 years old for dermal, incidental oral, and inhalation exposures. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 4 of this unit:

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

Population subgroup	Aggregate MOE (Food + Water + Residential)	Aggregate Level of Concern (LOC)
U.S. population	5,800	300
Children 3–5 years	3,200	300
Adults 20–50 years	5,900	300
Females 13–49 years	5,800	300

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Halosulfuron-methyl is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for halosulfuron-methyl.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food, water and residential exposures aggregated result in an aggregate MOE of 819 for infants and children (the population subgroup of concern). This aggregate MOE does not exceed the Agency's level of concern for aggregate exposure to food, water and residential uses. EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 5 of this unit:

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

Population subgroup	Aggregate MOE (Food + Water + Residential)	Aggregate Level of Concern (LOC)
Children 3–5 years	819	300

5. *Aggregate cancer risk for U.S. population*. Halosulfuron-methyl is classified as a ''Not Likely'' human carcinogen. Therefore, risk assessments to assess cancer risk were not conducted.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to halosulfuron-methyl residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There is neither a Codex proposal, nor Canadian or Mexican maximum residue limits, for residues of halosulfuron-methyl in or on sweet potatoes. Therefore, harmonization is not an issue.

VI. Conclusion

Therefore, the tolerance is established for residues of halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonylaminosulfonyl-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate, in or on sweet potato at 1.0 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0165 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 October 31, 2005.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by the docket ID number OPP–2005–0165, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Statutory and Executive Order Reviews

This final rule establishes a time-limited tolerance under section 408 of FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of FFDCA, 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 section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 19, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.479 is amended by revising the introductory text of paragraph (a)(1) and by adding text to paragraph (b) to read as follows:

§ 180.479 Halosulfuron-methyl; tolerances for residues.

(a) * * * (1) Tolerances are established for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl) amino]carbonylaminosulfonyl-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate, in or on the raw agricultural commodities listed in the table in this unit.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited 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 connection with use of the pesticide under FIFRA section 18 emergency exemptions granted by EPA in or on the following commodity:

Commodity	Parts per million	Expiration/ revocation date
Sweet potato	1.0	12/31/08

* * * * *

[FR Doc. 05–17204 Filed 8–30–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0230; FRL–7729–5]

Lactic Acid, 2-Ethylhexyl Ester; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes four exemptions from the requirement of a tolerance for residues of lactic acid, 2-ethylhexyl ester or ethylhexyl lactate when used as an inert ingredient (solvent) in or on growing crops, when applied to raw agricultural commodities after harvest, or to animals. Purac America, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of lactic acid, 2-ethylhexyl ester.

DATES: This regulation is effective August 31, 2005. Objections and requests for hearings must be received on or before October 31, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit XI. of the**SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2003–0230. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6304; e-mail address: *boyle.kathryn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Documents and Other Related Information?

In addition to using EDOCKET at *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at*http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at*http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of July 11, 2003 (68 FR 41349) (FRL–7316–1), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 0F6179) by Purac America, Inc., 111 Barclay Boulevard, Lincolnshire, IL 60069. The petition requested that 40 CFR 180.950 be amended by establishing an exemption from the requirement of a tolerance for residues of the (S) isomer of lactic acid, 2-ethylhexyl ester, also known as lactic acid, 2-ethylhexyl ester, (2S)- or 2-ethylhexyl lactate (CAS Reg. No. 186817–80–1) when used as a solvent, an inert ingredient, in pesticide products. That notice included a summary of the petition prepared by the petitioner. There were no comments received in response to the notice of filing.

PURAC's petition requested only the establishment of a tolerance exemption for the (S) isomer of lactic acid, 2-ethylhexyl ester. However, according to information on the PURAC website, there is also a general CAS Reg. No. for lactic acid, 2-ethylhexyl ester (CAS Reg. No. 6283–86–9). In the simplest terms an isomer can be defined as a substance which has the same molecular formula as another, but the individual elements of the molecule—the links from one element to another within the molecule—are arranged differently. A stereochemical isomer differs in the 3-D spatial arrangement of the elements. In certain cases, this is sometimes referred to as ''mirror images.'' An example of such a mirror image arrangement is a person's right and left hand. A person holding his hands out, both palms up, cannot make the presentation of four fingers and the thumb of the right hand match the orientation of the left hand. They can be viewed as if there is a mirror between the two. The chemical and physical properties of two isomeric chemicals are essentially the same. There can be some differences in the biological properties of the two isomers. The Agency has determined that both of the names are appropriate for this chemical and is therefore establishing tolerance exemptions using the (S) isomer and the general nomenclature of lactic acid, 2-ethylhexyl ester.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in