

Commodity	Parts per million	Expiration/Revocation Date
Vegetable, leafy, except brassica, group	0.1	9/27/03
Vegetable, root and tuber, group	0.1	9/27/03

(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-2002-0113; FRL-7183-2]

Halosulfuron; 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 in or on tomato. 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 tomato. This regulation establishes a maximum permissible level for residues of halosulfuron in this food commodity. The tolerance will expire and is revoked on June 30, 2005.

DATES: This regulation is effective July 10, 2002. Objections and requests for hearings, identified by docket ID number OPP-2002-0113, must be received on or before September 9, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP-2002-0113 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-6463; e-mail address: Madden.Barbara@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml/00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0113. The official record consists

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

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the herbicide halosulfuron, methyl 5-[[4,6-dimethoxy-2-pyrimidinyl]amino]carbonylamino-sulfonyl-3-chloro-1-methyl-1H-pyrazole-4-carboxylate, in or on tomato at 0.05 part per million (ppm). This tolerance will expire and is revoked on June 30, 2005. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

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

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

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

Recently, EPA has received objections to a tolerance it established for halosulfuron on a different food commodity. The objections were filed by the Natural Resources Defense Council (NRDC) and raised several issues regarding aggregate exposure estimates and the additional safety factor for the protection of infants and children. Although these objections concern separate rulemaking proceedings under the FFDCA, EPA has considered whether it is appropriate to establish the emergency exemption tolerance for halosulfuron in or on tomato while the objections are still pending.

Factors taken into account by EPA included how close the Agency is to concluding the proceedings on the objections, the nature of the current action, whether NRDC's objections raised frivolous issues, and the extent to which the issues raised by NRDC had already been considered by EPA. Although NRDC's objections are not frivolous, the other factors all support establishing this tolerance at this time. First, the objections proceeding is not near to conclusion. NRDC's objections raise complex legal, scientific, policy, and factual matters and EPA has just initiated a 60 day public comment period on them. [67 FR 41628-41635,

June 19, 2002] Second, the nature of the current actions are extremely time-sensitive as they address emergency situations. Third, the issues raised by NRDC are not new matters but questions that have been the subject of considerable study by EPA and comment by stakeholders. Accordingly, EPA is proceeding with establishing the tolerances for halosulfuron in or on tomato.

III. Emergency Exemption for Halosulfuron on Tomato and FFDCA Tolerances

Yellow (*Cyperus esculentus*) and purple nutsedge (*Cyperus rotundus*) are very difficult to control warm season, perennial weeds that reproduce by seeds and nutlets. They have high reproductive potential and can be very competitive with tomatoes during crop establishment. In addition to crop competition nutsedge plants can penetrate the plastic mulch used in tomato culture destroying the plastic and allowing entrance of other pest species.

Halosulfuron will allow preemergence or post emergence applications to control emerged nutsedge plants before they can flower or form nutlets to propagate themselves. It can be used in the plant rows or between the plant rows. The alternative chemicals consist of methyl bromide whose production is being phased out, metam sodium, pebulate, and napropamide. The last three chemicals can only be applied preplant incorporated or preemergence and do not provide season long control of nutsedge. Cultivation and hand weeding only help to further distribute the plants and nutlets. Deep plowing can provide suppression the first time it is used but subsequent plowing operations bring the old tubers back up to germinate. The states of Florida and Georgia claim that yield losses of tomatoes due to purple and yellow nutsedge infestations can be as high as 20 to 30% compared to the next best alternative.

EPA has authorized under FIFRA section 18 the use of halosulfuron on tomato for control of purple and yellow nutsedge in Florida and Georgia. After having reviewed the submission, 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 in or on tomato. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and

with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6). Although this tolerance will expire and is revoked on June 30, 2005, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on tomato 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 meets EPA's registration requirements for use on tomato 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 by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Florida and Georgia to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for halosulfuron, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of halosulfuron and to make a determination on aggregate exposure,

consistent with section 408(b)(2), for a time-limited tolerance for residues of halosulfuron in or on tomato at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

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). A summary of the toxicological dose and endpoints for halosulfuron-methyl for use in this human risk assessment is discussed in Unit III.B. of the final rule on halosulfuron-methyl pesticide tolerances published in the **Federal Register** of December 26, 2001 (66 FR 66333) (FRL-6816-8).

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.479) for the residues of halosulfuron, in or on a variety of raw agricultural commodities. The established tolerances include tree nuts (crop group 14); pistachio nutmeat; almond hulls; sugarcane; corn (sweet, kernel+cob with husks removed, field grain, fodder, forage, pop); rice (grain, straw); and cotton (gin by-products and undelinted seed). 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. Risk assessments were conducted by EPA to assess dietary exposures from halosulfuron 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: Tolerance level residues and 100 percent crop-treated for all commodities.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Tolerance level residues and 100 percent crop-treated for all commodities.

iii. *Cancer.* Halosulfuron is classified as a "Not Likely" human carcinogen. Therefore, risk assessments to assess cancer risk were not completed.

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 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.

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 ground water. 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 percent of the Reference dose (%RfD) or percent of population adjusted dose (%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 they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the EECs of halosulfuron for acute exposures are estimated to be 8.3 parts per billion (ppb) for surface water and 0.065 ppb for ground water. The EECs for chronic exposures are estimated to be 1.7 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 is currently registered for use on the following residential non-dietary sites: Residential turfgrass and landscaped areas.

Short- and intermediate-term exposure may occur for residential handlers and for postapplication activities. Exposure for adults is expected for handler and postapplication exposure. Residential post-application dermal and oral exposure is expected for infants and children. Adults may be exposed through skin contact with treated surfaces (dermal exposure), while children may be exposed through skin contact as well as orally, through hand-to-mouth exposure and through object-to-mouth exposure (putting grass in their mouth). Exposure estimates for adult handlers' and children's postapplication exposure to halosulfuron-methyl are based on the Agency's Draft Standard Operating Procedures for Residential Exposure Assessments (12/18/1997) and its interim revisions, and data from the review of Outdoor Residential Exposure

Task Force Chemical Handler Exposure Studies. Chronic exposures for the residential uses are not expected based on the use pattern.

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 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 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 has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Safety Factor for Infants and Children

1. *In general.* FFDC 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. *Conclusion.* There is a complete toxicity database for halosulfuron and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency has determined that the 10X FQPA Safety factor for enhanced sensitivity to infants and children can

be reduced to 1X. The decision is based upon the following reasons: There was no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to halosulfuron-methyl. In the prenatal developmental toxicity studies in rats and rabbits and the 2-generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

The Agency determined that the requirement of a developmental neurotoxicity study in rats did not warrant an application of additional safety factors because: (1) The alterations observed in the fetal nervous system occurred in only one species (in rats and not in rabbits); (2) the fetal effects which will be investigated in the required developmental neurotoxicity study were seen only at a dose of 750 mg/kg/day which is close to the Limit-Dose (1,000 mg/kg/day); (3) there was no evidence of clinical signs of neurotoxicity, brain weight changes, or neuropathology in the subchronic or chronic studies in rats; (4) the developmental neurotoxicity study is required only as confirmatory data to understand what the effect is at a high exposure (dose) level; (5) exposure assessments do not indicate a concern for potential risk to infants and children based on the results of the field trial studies and the very low application rate (~ 0.06 lbs. active ingredient per acre). Detectable residues are not expected in foods. Consequently, there is no concern that the level of 750 mg/kg/day would be approached.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the population adjusted dose (PAD)) is available for exposure through drinking water [e.g.,

allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

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

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

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to halosulfuron will occupy 1% or less of the aPAD for all population subgroups in DEEM® including females 13 years and older, infants and children. In addition, despite the potential for acute dietary exposure to halosulfuron in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of halosulfuron in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

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

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females 13 years and older	0.5	<1%	8.3	0.065	15,000
All infants (< 1 year old)	0.5	1%	8.3	0.065	5,000
Children	0.5	<1%	8.3	0.065	5,000

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to halosulfuron from food will utilize less than 1% of the chronic population adjusted dose (cPAD) for all population subgroups in DEEM® including the U.S. population, infants

and children. There are no residential uses for halosulfuron that result in chronic residential exposure to halosulfuron. Based on the use pattern, chronic residential exposure to residues of halosulfuron is not expected. In addition, despite the potential for chronic dietary exposure to

halosulfuron in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of halosulfuron in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

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

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.1	<1%	1.7	0.065	3,500
All infants (<1 year old)	0.1	<1%	1.7	0.065	1,000
Children	0.1	<1%	1.7	0.065	1,000

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

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 adults for both handler and postapplication exposures and 2,800 for infants and children for dermal and incidental oral exposures. 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 in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 4:

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

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	2,800	100	1.7	0.065	4,800
Children	2,800	100	1.7	0.065	4,800

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

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,700 for adults and 1,100 for infants and children. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food

and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of halosulfuron in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 5:

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

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Inter-mediate-Term DWLOC (ppb)
U.S. Population	1,700	100	1.7	0.065	3,300
Infants	1,100	100	1.7	0.065	910
Children	1,100	100	1.7	0.065	910

5. *Aggregate cancer risk for U.S. population.* Halosulfuron is classified as a “Not Likely” human carcinogen. Therefore, risk assessments to assess cancer risk were not completed.

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 residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. 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 is neither a Codex proposal, nor Canadian or Mexican maximum residue limits, for residues of halosulfuron in or on tomatoes, therefore harmonization is not an issue.

C. Conditions

A maximum of 0.094 pounds halosulfuron may be applied per acre per season. A total of 2 applications per season may be made. The preharvest interval (PHI) is 30 days.

VI. Conclusion

Therefore, the tolerance is established for residues of halosulfuron, methyl 5-[(4,6- dimethoxy-2-pyrimidinyl)amino] carbonylamino-sulfonyl-3-chloro-1-methyl-1H-pyrazole-4-carboxylate, in or on tomato at 0.05 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCFA, 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 FFDCFA 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 FFDCFA 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-2002-0113 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 September 9, 2002.

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

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania

Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

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

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

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

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket control number OPP-2002-0113, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental

Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VIII. Regulatory Assessment Requirements

This final rule establishes a time limited tolerance under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045,

entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under FFDCA section 408, such as the [tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive order to include regulations that have "substantial direct effects on one or more Indian tribes, on the

relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: June 24, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346(a) and 374.

2. In § 180.479, paragraph (b) is amended by revising the text and by alphabetically adding an entry for "Tomato" to the table to read as follows:

§ 180.479 Halosulfuron; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of halosulfuron, methyl 5-[[[4,6-dimethoxy-2-pyrimidinyl]amino] carbonylamino]sulfonyl-3-chloro-1-

methyl-1H-pyrazole-4-carboxylate, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA in or on the following commodities:

Commodity	Parts per million	Expiration/revocation date
* * * * *	* * *	* * *
Tomato	0.05	6/30/05
* * * * *		

[FR Doc. 02-17266 Filed 7-9-02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2002-0117; FRL-7184-2]

Mesotrione; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of mesotrione, 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in or on sweet corn and sweet corn forage and stover. 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 corn. This regulation establishes maximum permissible levels for residues of mesotrione in these food commodities. The tolerances will expire and are revoked on June 30, 2004.

DATES: This regulation is effective July 10, 2002. Objections and requests for hearings, identified by docket control number OPP-2002-0117, must be received on or before September 9, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP-2002-0117 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,

Washington, DC 20460; telephone number: (703) 308-9366; e-mail address: Pemberton.libby@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register"—Environmental Documents. You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0117. The official record consists of the documents specifically referenced in this action, and other information

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

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for residues of the herbicide mesotrione, 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in or on sweet corn, sweet corn forage, and sweet corn stover at 0.01, 0.50, and 2.0 part per million (ppm), respectively. These tolerances will expire and are revoked on June 30, 2004. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

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

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide