

- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, these rules do not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

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 action 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 the rule in the Federal Register. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 4, 2010. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are

encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of today's Federal Register, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements.

Dated: July 6, 2010.

**Keith Takata,**

*Acting Regional Administrator, Region IX.*

■ Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

#### PART 52—[AMENDED]

■ 1. The authority citation for Part 52 continues to read as follows:

**Authority:** 42 U.S.C. 7401 *et seq.*

#### Subpart F—California

■ 2. Section 52.220, is amended by adding paragraphs (c)(379) (i)(A)(3) and (4) to read as follows:

##### § 52.220 Identification of plan.

\* \* \* \* \*

(c) \* \* \*

(379) \* \* \*

(i) \* \* \*

(A) \* \* \*

(3) Rule 1111, "Reduction of NO<sub>x</sub> Emissions from Natural Gas-Fired, Fan-Type Central Furnaces," amended on November 6, 2009.

(4) Rule 1147, "NO<sub>x</sub> Reductions from Miscellaneous Sources," adopted on December 5, 2008.

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[FR Doc. 2010-19057 Filed 8-3-10; 8:45 am]

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA-HQ-OPP-2009-0797; FRL-8835-8]

#### Halosulfuron-methyl; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of halosulfuron-methyl in or on multiple commodities which are identified and discussed later in this document. Additionally, this regulation removes the existing tolerance on bean, snap, succulent at 0.05 parts per million (ppm) in that it is superseded by this action establishing a tolerance at 0.05 ppm on pea and bean, succulent shelled, subgroup 6B. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective August 4, 2010. Objections and requests for hearings must be received on or before October 4, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2009-0797. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., 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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7610; e-mail address: [jackson.sidney@epa.gov](mailto:jackson.sidney@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 those engaged in the following activities:

- 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 to provide 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 Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.gpoaccess.gov/ecfr>.

#### *C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-0797 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before October 4, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2009-0797, by one of the following methods:

• *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

• *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of Wednesday, January 6, 2010 (75 FR 864) (FRL-8801-5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E7577) by IR-4 Project Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08549. The petition requested that 40 CFR 180.479 be amended by establishing tolerances for residues of the herbicide halosulfuron-methyl, methyl 3-chloro-5-[[[4,6-dimethoxy-2-pyrimidinyl]amino]carbonyl]amino]sulfonyl]-1-methyl-1 H-pyrazole-4-carboxylate, and its metabolites and degradates (compliance with the tolerance level specified is to be determined by measuring only those halosulfuron-methyl residues convertible to 3-chloro-1-methyl-5-sulfamoylpyrazole-4-carboxylic acid, expressed as the stoichiometric equivalent of halosulfuron-methyl) in or on pea and bean, succulent shelled, subgroup 6B; pea and bean, dried shelled, except soybean, subgroup 6C; vegetables, tuberous and corm, subgroup 1C; bushberry, subgroup 13-07B; apple; rhubarb; and okra at 0.05 ppm. That notice referenced a summary of the petition prepared by Gowan Company, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is not taking action at this time on the petitioned-for tolerance for pea and bean, dried shelled, except soybean, subgroup 6C due to insufficient field trial data to support this use. Additionally, the Agency is revoking the existing tolerance on bean, snap,

succulent at 0.05 ppm in order to eliminate redundancy with the 0.05 ppm tolerance on pea and bean, succulent shelled, subgroup 6B established by this action. EPA is also revising the tolerance expressions for halosulfuron-methyl for new uses in this regulation and for existing plant and livestock commodities to clarify the chemical moieties that are covered by the tolerances and specify how compliance with the tolerances is to be measured. The reasons for these changes are explained in Unit IV.D.

## **III. Aggregate Risk Assessment and Determination of Safety**

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...."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in 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 and to make a determination on aggregate exposure for halosulfuron-methyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with halosulfuron-methyl follows.

### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their 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.

Halosulfuron-methyl has low acute toxicity by oral, dermal, and inhalation routes of exposure. It is not a dermal sensitizer nor is it an eye or skin irritant. The toxicity mode of action in mammals is undetermined. However, available data show that the dog is the most sensitive animal species. In the dog, decreased body weight was seen in the chronic oral toxicity study and decreased body weight gain was observed in females in the subchronic oral toxicity study. In the rat and mouse, there was a decrease in body weight gains at high dose levels in short-term and long-term oral and dermal studies. Both acute and subchronic neurotoxicity studies showed no neurotoxic effects. There was no quantitative evidence for increased susceptibility following pre- and/or post-natal exposure. However, there was qualitative evidence for increased susceptibility. In the rat developmental toxicity study, increases in resorptions, soft tissue (dilation of the lateral ventricles) and skeletal variations, and decreases in body weights were seen in the fetuses compared to clinical signs and decreases in body weights and food consumption in the maternal animals. In the rabbit study, increases in resorptions and post-implantation losses and a decrease in mean litter size were seen in the presence of decreases in body weight and food consumption in maternal animals. Thus, in both species, the developmental effect was

considered to be qualitatively more severe than maternal effects.

Halosulfuron-methyl is classified as “not likely to be carcinogenic to humans” based on a lack of evidence for carcinogenicity in mice and rats following long-term dietary administration. Halosulfuron-methyl is negative for mutagenicity in a battery of genotoxicity studies. There is no evidence of immunotoxicity in the available studies for halosulfuron-methyl. Acute and subchronic neurotoxicity studies showed no evidence of neurotoxicity.

Specific information on the studies received and the nature of the adverse effects caused by halosulfuron-methyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document: “Halosulfuron-Methyl: Human Health Risk Assessment for IR-4 Proposed Uses on Crop Group 6B Succulent Shelled Pea and Bean Subgroup, Crop Group 1C Tuberous and Corm Vegetables Subgroup, Crop Group 6C Dried Shelled Pea and Bean (Except Soybean), Subgroup 13-07B Bushberry, Okra, Apples, and Rhubarb, dated April 5, 2010,” p. 13 in docket ID number EPA-HQ-OPP-2009-0797-0005.

#### *B. Toxicological Points of Departure/ Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies

toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level – generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) – and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for halosulfuron-methyl used for human risk assessment is shown in the Table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/FQPA Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13–49 years of age)	NOAEL = 50 milligrams/kilograms/day (mg/kg/day) UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Acute RfD = 0.5 mg/kg/day aPAD = 0.5 mg/kg/day	Developmental Toxicity - Rabbit LOAEL = 150 mg/kg/day based on decreased mean litter size, increased number of resorptions and increased post-implantations loss.
Acute dietary (General population including infants and children)	N/A	N/A	No adverse effect attributable to a single dose was identified and no dose/endpoint was selected.
Chronic dietary (All populations)	NOAEL = 10 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.1 mg/kg/day cPAD = 0.1 mg/kg/day	Chronic Toxicity - Dog LOAEL = 40 mg/kg/day based on decreased body weight gains in females.
Incidental oral short-term (1 to 30 days)	NOAEL = 50 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Residential LOC for MOE = 100.	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 to 6 months)	NOAEL = 10 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Residential LOC for MOE = 100	13 week Subchronic toxicity - Dog LOAEL = 40 mg/kg/day based on decreased body weight gains and food efficiency along with hematological and clinical chemistry changes.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/Scenario	Point of Departure and Uncertainty/FQPA Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Dermal short-term (1 to 30 days)	Dermal study NOAEL = 100mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Residential LOC for MOE = 100	21-Day Dermal Toxicity Study - Rat LOAEL = 1,000 mg/kg/day based on decreased body weight gain in males.
Dermal intermediate-term (1 to 6 months)	Dermal study NOAEL= 10 mg/kg/day (dermal absorption rate = 75%) UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Residential LOC for MOE = 100	13 Week Subchronic Toxicity - Dog LOAEL = 40 mg/kg/day based on decreased body weight gains and food efficiency along with hematological and clinical chemistry changes.
Inhalation short-term (1 to 30 days)	Inhalation study NOAEL = 50 mg/kg/day (inhalation absorption rate = 100%) UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Residential LOC for MOE = 100	Developmental Toxicity - Rabbit LOAEL = 150 mg/kg/day based on decreased body weight gain, food consumption, and food efficiency (maternal toxicity).
Inhalation Intermediate-term (1 to 6 months)	Inhalation (or oral) study NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%) UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Residential LOC for MOE = 100	13 week Subchronic Toxicity - Dog LOAEL = 40 mg/kg/day based on based on decreased body weight gains and food efficiency along with hematological and clinical chemistry changes.
Cancer (Oral, dermal, inhalation)	Classification: ≥not likely to be carcinogenic to humans≥ by the oral route, based on no evidence of carcinogenicity from studies in rats and mice.		

A 75% dermal absorption factor should be used in route-to-route extrapolation for the intermediate term dermal exposure risk. Absorption via the inhalation route is presumed to be equivalent to oral absorption. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UFA = extrapolation from animal to human (inter-species). UFH = potential variation in sensitivity among members of the human population (intra-species). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to halosulfuron-methyl, EPA considered exposure under the petitioned-for tolerances as well as all existing halosulfuron-methyl tolerances in 40 CFR 180.479. EPA assessed dietary exposures from halosulfuron-methyl in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and 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 1-day or single exposure.

Such effects were identified for halosulfuron-methyl including decreased mean litter size, increased number of resorptions (total and per dam) and increased post-implantation loss (developmental toxicity) were identified for the population subgroup females 13 to 49 years old (the only population subgroup with a toxicological endpoint attributable to a single dose of halosulfuron-methyl). In

estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT) for all existing and recommended new uses of halosulfuron-methyl.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed tolerance-level residues and 100 PCT for all existing and recommended new uses of halosulfuron-methyl

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that halosulfuron-methyl does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information* EPA did not use anticipated residue and/or PCT information in the dietary assessment for halosulfuron-methyl. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for halosulfuron-methyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of halosulfuron-methyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST), Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations

(EDWCs) of halosulfuron-methyl are Tier I EDWCs based on a maximum annual application rate of 0.125 lb active ingredient (ai)/acre(A) for rice.

Acute exposures and chronic exposures for non-cancer assessments are estimated to be 59.2 parts per billion (ppb) based on FIRST model for surface water and 0.065 ppb based on SCI-GROW model results for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute and chronic dietary risk assessment, the water concentration value of 59.2 ppb was used to assess the contribution to drinking 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 the following uses that could result in residential exposures: Ornamentals, and commercial and residential turfgrass. EPA assessed residential exposure using the following assumptions: Residential handlers may receive short-term dermal and inhalation exposures to halosulfuron-methyl when mixing, loading and applying halosulfuron-methyl products. Adults and children may be exposed to halosulfuron-methyl residues through dermal contact with turf during postapplication activities. In addition, toddlers may receive short- and intermediate-term oral exposure from incidental ingestion during postapplication activities.

Halosulfuron-methyl exposure data for handler activities were not submitted to EPA in support of registered lawn uses. EPA's Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments, and Recommended Revisions were used as the basis for the residential handler exposure calculations. The handler exposure data used in this assessment are from the Outdoor Residential Exposure Task Force (ORETF).

For residential exposure from lawn use, the Agency evaluated the combined exposure and risk estimates to adults from halosulfuron-methyl under scenarios including:

- i. Mix/load and broadcast application of liquid formulation (garden hose-end sprayer) for both dermal and inhalation routes, and
- ii. Post-application exposure by dermal route.

For residential postapplication exposure, the following scenarios

resulting from lawn treatment were assessed:

- a. Adult and children 3 to <6 years old post-application dermal exposure,
- b. Child 3 to <6 years old incidental ingestion of pesticide residues on lawns from hand-to-mouth transfer,
- c. Toddlers' object-to-mouth transfer from mouthing of pesticide-treated turf grass, and
- d. Children 3 to <6 years old incidental ingestion of soil from pesticide-treated residential areas. Post-application exposures from various activities following lawn treatment are considered to be the most common and significant in residential settings.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

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."

EPA has not found halosulfuron-methyl to share a common mechanism of toxicity with 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 assumed that halosulfuron-methyl does not have 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 EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable

data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicity database for halosulfuron-methyl includes rat and rabbit developmental toxicity studies and a 2-generation reproduction toxicity study in rats. As discussed in Unit III.A., there was no quantitative evidence for increased susceptibility following pre-natal and/or post-natal exposure. However, there was qualitative evidence for increased susceptibility of fetuses in the rat and rabbit developmental studies. In the rat study, increases in resorptions, soft tissue (dilation of the lateral ventricles) and skeletal variations, and decreases in body weights were seen in the fetuses compared to clinical signs and decreases in body weights and food consumption in the maternal animals. In the rabbit study, increases in resorptions and post-implantation losses and decrease in mean litter size was seen in the presence of decreases in body weight and food consumption in maternal animals. Thus, in both species, the developmental effect was considered to be qualitatively more severe than maternal effects (i.e., qualitative evidence for susceptibility). In both studies, there are clear NOAELs/LOAELs for developmental and maternal toxicities, developmental effects were seen in the presence of maternal toxicity, and the effects were only seen at the high dose. Additionally, in rats, developmental effects were seen at a dose which is approaching the limit-dose. The degree of concern is low and there are no residual uncertainties for prenatal toxicity in both rats and rabbits.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for halosulfuron-methyl is complete except for an immunotoxicity study as required by the latest amendment to 40 CFR part 158. After analysis of the database, an additional factor (UF<sub>DB</sub>) for database uncertainty is not needed to account for the lack of this study because the available data do not suggest that this chemical affects the immune system.

ii. There is no indication that halosulfuron-methyl is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although there is qualitative evidence of increased susceptibility in the prenatal developmental studies in

rats and rabbits, as discussed in this unit, there are no residual uncertainties after establishing toxicity endpoints and the degree of concern for pre-and/or post-natal toxicity is low.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues, and conservative (protective) assumptions in the ground water and surface water modeling were used to assess exposure to halosulfuron-methyl in drinking water. Similarly conservative assumptions were also used to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by halosulfuron-methyl.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

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 less than 1% of the aPAD for the population subgroup of concern, females 13-49 years old, the only population group where there are acute toxicology concerns.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to halosulfuron-methyl from food and water will utilize 5% of the cPAD for all infants less than 1 year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of halosulfuron-methyl is not expected.

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

determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to halosulfuron-methyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in short-term aggregate MOEs ranging from 2,800 to 4,800. The MOE for the U.S. population is 4,700. The most highly exposed subgroup is all infants (< 1 year old), with a MOE of 2,800. Because these estimates of short-term aggregate risk for halosulfuron-methyl are above a MOE of 100, these MOEs are not of concern to EPA.

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

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs ranging from 500 to 680. The MOE for the U.S. population is 500. The most highly exposed children's subgroup was all infants (< 1 year old), with a MOE of 680. These estimates of aggregate risk do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, halosulfuron-methyl is not expected to pose a cancer risk to humans.

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

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

An adequate analytical method is available for the enforcement of tolerances for residues of halosulfuron-methyl in plants. Monsanto Analytical Method RES-109-97-4 (gas chromatography, using thermionic-specific detection, TSD, nitrogen specific) has been validated by EPA.

The method's limit of quantitation (LOQ) determined across a variety of tested crops is 0.05 ppm. 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](mailto:residuemethods@epa.gov).

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are no Codex, Canadian or Mexican maximum residue limits (MRLs) established for residues of halosulfuron-methyl in crop or livestock commodities.

##### *C. Revisions to Petitioned-For Tolerances*

EPA is not taking action on the petitioned-for tolerance for pea and bean, dried shelled (except soybean) due to inadequate data available to support these uses. Generally, EPA recommends that five field trials be submitted for peas but none have been submitted with this petition.

EPA is revising the tolerance expressions for halosulfuron-methyl for new uses in this regulation and for existing plant and livestock commodities to clarify the chemical moieties that are covered by the tolerances and specify how compliance with the tolerances is to be measured.

The revised tolerance expression for livestock commodities makes clear that the tolerances cover residues of halosulfuron-methyl and its metabolites and degradates and that compliance with the tolerance levels will be determined by measuring only those halosulfuron-methyl residues containing the 3-chlorosulfonamide (3CSA) moiety, expressed as the stoichiometric equivalent of halosulfuron-methyl.

EPA believes that it is reasonable to make these changes in the tolerance expressions final without prior proposal and opportunity for comment, because public comment is not necessary, in that the changes have no substantive effect on the tolerance, but rather are merely intended to clarify the tolerance expression compliance component(s) measurement.

## V. Conclusion

Therefore, tolerances are established for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonylaminosulfonyl]-3-chloro-1-methyl-1H-pyrazole-4-carboxylate, including its metabolites and degradates, in or on pea and bean, succulent shelled, subgroup 6B; vegetable, tuberous and corm, subgroup 1C; bushberry, subgroup 13-07B; apple; rhubarb; and okra at 0.05 ppm. Compliance with the tolerance level specified below is to be determined by measuring only halosulfuron-methyl.

## VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

## VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: July 26, 2010.

**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 as follows:

- i. Revise the introductory text in paragraphs (a)(1) and (a)(2);
- ii. In paragraph (a)(2), in the table, revise the commodity Bean, snap, succulent to read Pea and bean, succulent shelled, subgroup 6; and
- iii. Alphabetically add the following commodities to the table in paragraph (a)(2) 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-1H-pyrazole-4-carboxylate, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only those halosulfuron-methyl residues containing the 3-chlorosulfonamide (3-CSA) moiety, expressed as the stoichiometric equivalent of halosulfuron-methyl, in or on the commodity.

\* \* \* \* \*

(2) Tolerances are established for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonylaminosulfonyl]-3-chloro-1-methyl-1H-pyrazole-4-carboxylate, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only halosulfuron-methyl.

Commodity	Parts per million
* * *	* *
Apple .....	0.05
* * *	* *
Bushberry, subgroup 13-07B .....	0.05
* * *	* *
Okra .....	0.05



Commodity	Parts per million
* * *	*
Pea and bean, succulent shelled, subgroup 6B ..	0.05
* * *	*
Rhubarb .....	0.05
* * *	*
Vegetable, tuberous and corm, subgroup 1C ....	0.05
* * *	*

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## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 97

[WP Docket No. 10-72, WP Docket No. 10-54; FCC 10-124]

### Amendment of the Commission's Rules Regarding Amateur Radio Service Communications During Government Disaster Drills

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** In this document, the Federal Communications Commission (Commission) amends its rules to permit amateur radio operators to transmit messages, under certain limited circumstances, during either government-sponsored or non-government sponsored emergency and disaster preparedness drills, regardless of whether the operators are employees of entities participating in the drill.

**DATES:** Effective September 3, 2010.

**FOR FURTHER INFORMATION CONTACT:** Thomas Beers, Policy Division, Public Safety and Homeland Security Bureau, (202) 418-1170, or TTY (202) 418-7233.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's *Report and Order (R&O)* in WP Docket No. 10-72; WP Docket No. 10-54; FCC 10-124, adopted July 14, 2010, and released July 14, 2010. The complete text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center, Room CY-A257, 445 12th Street, SW., Washington, DC 20554. This document may also be obtained from the Commission's duplicating contractor, Best Copy and Printing, Inc., in person at 445 12th Street, SW., Room CY-B402, Washington, DC 20554, via telephone at (202) 488-5300, via facsimile at (202) 488-5563, or via

e-mail at [FCC@BCPIWEB.COM](mailto:FCC@BCPIWEB.COM). Alternative formats (computer diskette, large print, audio cassette, and Braille) are available to persons with disabilities by sending an e-mail to [FCC504@fcc.gov](mailto:FCC504@fcc.gov) or calling the Consumer and Governmental Affairs Bureau at (202) 418-0530, TTY (202) 418-0432. This document is also available on the Commission's Web site at <http://www.fcc.gov>.

### Summary of the Report and Order

1. Current rules provide for amateur radio use during emergencies. At the same time, the rules prohibit communications in which the station licensee or control operator has a pecuniary interest, including communications on behalf of an employer. While there are some exceptions to this prohibition, there is none that would permit amateur station control operators who are employees of public safety agencies and other entities, such as hospitals, to participate in drills, tests and exercises in preparation for such emergency situations and transmit messages on behalf of their employers during such drills and tests. Accordingly, the Commission amends its rules to provide that, under certain limited conditions, amateur radio operators may transmit messages during emergency and disaster preparedness drills and exercises, limited to the duration of such drills and exercises, regardless of whether the operators are employees of entities participating in the drills or exercises.

2. One of the fundamental principles underlying the amateur radio service is the "[r]ecognition and enhancement of the value of the amateur service to the public as a voluntary noncommercial communication service, particularly with respect to providing emergency communications." Further, the rules state that "[n]o provision of these rules prevents the use by an amateur station of any means of radio communication at its disposal to provide essential communication needs in connection with the immediate safety of human life and immediate protection of property when normal communication systems are not available." Indeed, amateur radio operators provide essential communications links and facilitate relief actions in disaster situations. While land mobile radio services are the primary means of conducting emergency communications, amateur radio plays a unique and critical role when these primary facilities are damaged, overloaded, or destroyed. For example, during Hurricane Katrina, amateur radio operators volunteered to support many agencies, such as the

Federal Emergency Management Agency, the National Weather Service, and the American Red Cross. Amateur radio stations provided urgently needed wireless communications in many locations where there were no other means of communicating and also provided other technical aid to the communities affected by Hurricane Katrina.

3. Since amateur radio is often an essential element of emergency preparedness and response, many state and local governments, public safety agencies, and hospitals incorporate amateur radio operators and the communication capabilities of the amateur service into their emergency planning. In this regard, some entities, such as hospitals, emergency operations centers, and police, fire, and emergency medical service stations, have emphasized the participation of their employees who are amateur station operators in emergency and disaster drills and tests. For example, a representative of the New Orleans Urban Area Security Initiative recently emphasized the importance of conducting emergency drills and the need for amateur participation.

4. The Commission's rules expressly permit operation of amateur stations for public service communications during emergencies, and on a voluntary basis during drills and exercises in preparation for such emergencies. Given, however, that the Amateur Radio Service is primarily designated for "amateurs, that is, duly authorized persons interested in radio technique solely with a personal aim and without pecuniary interest," the rules expressly prohibit amateur stations from transmitting communications "in which the station licensee or control operator has a pecuniary interest, including communications on behalf of an employer." Accordingly, public safety and public health entities seeking to have employees operate amateur stations during government-sponsored emergency preparedness and disaster drills presently must request a waiver. In this connection, Commission staff has granted several waivers on a case-by-case basis.

5. On February 17, 2010, the American Hospital Association (AHA) filed a request for a blanket waiver of Section 97.113(a)(3) of the Commission's rules to permit hospitals seeking accreditation to use amateur radio operators who are hospital employees to transmit communications on behalf of the hospital as part of emergency preparedness drills. On March 3, 2010, the Wireless Telecommunications and Public Safety