

Commodity	Parts per million
Radish, tops .....	4.5
Turnip, greens .....	5.0
Vegetable, root and tuber, group 1 .....	4.0

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2006-0205; FRL-8113-8]

#### Halosulfuron-methyl; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of halosulfuron-methyl in or on the commodities alfalfa, forage at 1.0 parts per million (ppm) and alfalfa, hay at 2.0 ppm. Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The Agency is also correcting the tolerance expression for 40 CFR 180.479(a)(1) with this regulation. The tolerance expression is being corrected because the metabolites were inadvertently deleted from the most recent edition of 40 CFR 180.479.

**DATES:** This regulation is effective February 28, 2007. Objections and requests for hearings must be received on or before April 30, 2007, 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-2006-0205. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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:** Vickie Walters, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5704; e-mail address: [walters.vickie@epa.gov](mailto:walters.vickie@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. General Information**

###### *A. Does this Action Apply to Me?*

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

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System

(NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

###### *B. How Can I Access Electronic Copies of this Document?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

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

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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-2006-0205 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 April 30, 2007.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2006-0205, 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'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 telephone number is (703) 305-5805.

## II. Background and Statutory Findings

In the **Federal Register** of December 20, 2006 (71 FR 76321) (FRL-8104-4), EPA issued a notice pursuant to section 408(d)(3) of FFDC, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F2469) by Gowan Company, P. O. Box 5569, Yuma, AZ 85366. The petition requested that 40 CFR 180.479(a)(2) be amended by establishing a tolerance for residues of the herbicide halosulfuron methyl, methyl 5-[(4, 6-dimethoxy-2-pyrimidinyl)amino] carbonylamino sulfonyl-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate in or on the raw agricultural commodities alfalfa, forage at 1.0 ppm and alfalfa, hay at 2.0 ppm. The Agency also proposed that the tolerance expression for 40 CFR 180.479(a)(1) be corrected to read "Tolerances are established for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonylamino sulfonyl-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate, and its metabolites determined as 3-chloro-1-methyl-5-sulfamoylpyrazole-4-carboxylic acid, expressed as halosulfuron-methyl equivalents in or on the raw agricultural commodities listed in the table in this unit." That notice referenced a summary of the petition prepared by Gowan Company, the registrant that has been included in the public docket. There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of FFDC 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 FFDC 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 FFDC requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDC and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDC, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDC, for a tolerance for residues of halosulfuron-methyl the commodities alfalfa, forage at 1.0 ppm and alfalfa, hay at 2.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic 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 0002 (pages 16-20) in docket ID number EPA-HQ-OPP-2006-0205.

### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable

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

The linear default risk methodology (Q\*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q\* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at <http://www.epa.gov/pesticides/health/human.htm>.

A summary of the toxicological endpoints for halosulfuron-methyl used for human risk assessment can be found at <http://www.regulations.gov> in document 0002 (pages 34-35) in docket ID number EPA-HQ-OPP-2006-0205.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.479) for the residues of halosulfuron-methyl, in or on a variety of raw agricultural commodities. Tolerances have been established for halosulfuron-methyl and its metabolites determined as 3-chloro-1-methyl-5-sulfamoylpyrazole-4-carboxylic acid, expressed as halosulfuron-methyl equivalents in or on meat by products of cattle, goat, hog, horse, and sheep. Risk assessments were conducted by EPA to assess 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.

In conducting the acute dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the U.S. Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by

Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Tolerance level residues and 100 percent crop treated (PCT) for all existing and proposed uses. Percent crop treated or anticipated residues were not used.

The acute dietary exposure estimates are provided for females 13–50 years old only. The existing data showed no indication that halosulfuron-methyl could cause adverse effects in the general population based upon a single dose. Thus there is no concern for acute dietary exposure to the general population.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A chronic dietary analysis for halosulfuron-methyl was conducted using tolerance level residues and 100 PCT for all existing and proposed uses. Percent crop treated or anticipated residues were not used.

iii. *Cancer.* Halosulfuron-methyl is classified as a “not likely” human carcinogen based on a lack of evidence of carcinogenicity in male and female mice and rats following long-term dietary administration. Therefore, halosulfuron-methyl is not expected to pose a cancer risk for humans.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for halosulfuron-methyl in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of halosulfuron-methyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index>.

Based on the FQPA Index Reservoir Screening Tool (FIRST) and screening concentration in ground water (SCI-GROW) models, the estimated environmental concentrations (EECs) of halosulfuron-methyl for acute exposures are estimated to be 105 parts per billion (ppb) for surface water and 0.065 ppb for ground water. The EECs for chronic

exposures are estimated to be 105 ppb for surface water and 0.065 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID). For acute and chronic dietary risk assessment, the annual average concentration of 105 ppb was used to access 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 use on the following residential non-dietary sites: Application to commercial and residential turf and on other non-crop sites including airports, cemeteries, fallow areas, golf courses, landscaped areas, public recreation areas, residential property, roadsides, school grounds, sod or turf seed farms, sports fields, and landscaped areas with established woody ornamentals. Application may be by commercial applicator or homeowner. Residential handlers may receive short-term dermal and inhalation exposure to halosulfuron-methyl when mixing, loading, and applying the formulations. Adults and children may be exposed to halosulfuron-methyl residues through dermal contact with turf during postapplication activities. A residential exposure and risk assessment was previously conducted for these exposure scenarios. Combined margins of exposure (MOEs) for adults’ and children’s dermal exposure and toddlers’ incidental exposure from all residential activities are greater than the Agency’s LOC of 100, and therefore are not of concern. These risk assessments are fully discussed in Unit III.E.3. of a final rule published in the **Federal Register** of September 20, 2002 (67 FR 59182) (FRL–7200–8).

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to

halosulfuron-methyl and any other substances and halosulfuron-methyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that halosulfuron-methyl has a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

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

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for 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. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor (SF) value based on the use of traditional UFs and/or special FQPA SFs, as appropriate.

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

3. *Conclusion.* EPA determined that the 10X SF to protect infants and children should be removed. The FQPA factor is reduced to 1X based on the following findings.

i. The toxicity database for halosulfuron-methyl is complete. Although EPA previously required

submission of a developmental neurotoxicity, that requirement has been waived based on a review of the entire database including recently submitted acute and subchronic neurotoxicity studies. This review showed that there was no evidence of clinical signs of neurotoxicity, brain weights changes, or neuropathology in the subchronic (including the neurotoxicity study) or chronic studies in rats, mice, or dogs. The acute neurotoxicity study showed some minor, transient functional observational battery (FOB) effects on day 0 (none statistically significant) at the limit dose with no effects persisting past day 0. There were not effects on brain weights or neuropathology. The observed FOB effects are not considered attributable to a direct neurotoxic response as they are minor, transient and occurred at the limit dose.

ii. There is no evidence of increased susceptibility of young rats in the reproduction study with halosulfuron-methyl. Although there is qualitative evidence of increased susceptibility in the prenatal developmental studies in rats and rabbits, the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of halosulfuron-methyl. The degree of concern for pre and/or postnatal toxicity is low.

iii. 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. Conservative ground water and surface water modeling estimates were used in the risk assessments. Agency Residential standard operational procedures (SOPs) are used to assess post-application exposure to children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by halosulfuron-methyl.

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

1. *Acute risk.* The acute aggregate risk assessment is provided for females 13–50 years old only. The existing data showed no indication that halosulfuron-methyl could cause adverse effects in the general population based upon a single dose. Thus there is no concern for acute dietary exposure to the general population. Using the exposure assumptions discussed in this Unit III.C. for acute exposure, the acute dietary exposure from food and water to halosulfuron-methyl will occupy 1.0% of the acute Population Adjusted Dose (aPAD) for females 13 years and older.

EPA does not expect the acute aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk.* Using the exposure assumptions described in Unit III.C. for chronic exposure, EPA has concluded that exposure to halosulfuron-methyl from food and water will utilize 3.0% of the chronic Population Adjusted Dose (cPAD) for the U.S. population, 8.0 of the cPAD for all infants (<1 year old), and 4.0% of the cPAD for children 1–2 years old and children 3–5 years old. Based the use pattern, chronic residential exposure to residues of halosulfuron-methyl is not expected. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

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

Halosulfuron-methyl is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for halosulfuron-methyl.

A short-term risk assessment is required for adults because there is a residential handler exposure scenario. In addition, a short-term risk assessment is required for infants and children because there is a residential post-application exposure scenario for infants and children.

Using the exposure assumptions described in Unit III.C. for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs ranging from 2,400 to 4,400. The MOE for the U.S. population is 4,300. The most highly exposed subgroup was all infants (less than 1 year old with an MOE of 2,400. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food and residential uses. EPA does not expect short-term aggregate exposure to exceed the Agency's LOC.

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

Halosulfuron-methyl is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for halosulfuron methyl.

An intermediate-term risk assessment is required for adults because there is a residential handler exposure scenario. In addition, an intermediate-term risk assessment is required for infants and

children because there is a residential post-application exposure scenario for infants and children.

As an additional protective measure, residential handler exposures were included in the intermediate-term aggregate risk assessment, although residential exposure over the intermediate-term (more than 30 days) is unlikely.

Using the exposure assumptions described is Unit III.E. for intermediate-term exposures; EPA has concluded that food and residential exposures aggregated result in aggregate MOEs ranged from 480 to 560. The MOEs for the U.S. population is 480. The most highly exposed children's subgroup was all infants (less than 1 year old) with a MOE of 560. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food and residential uses. EPA does not expect intermediate-term aggregate exposure to exceed the Agency's LOC.

5. *Aggregate cancer risk for U.S. population.* Halosulfuron-methyl is classified as "not likely to be carcinogenic to humans" based on the lack of evidence for carcinogenicity in mice and rats following long-term dietary administration. Therefore halosulfuron-methyl is not expected to pose a cancer risk for humans.

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

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

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

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

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

There are currently no established Codex, Canadian, or Mexican maximum residue levels (MRLs) for halosulfuron-methyl in or on alfalfa, forage or alfalfa, hay. International harmonization is therefore not an issue.

#### **V. Conclusion**

Therefore, the tolerance is established for residues of halosulfuron methyl, methyl 5-[(4, 6-dimethoxy-2-pyrimidinyl)amino]

carbonylamino-sulfonyl-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate in or on the raw agricultural commodities alfalfa, forage at 1.0 ppm and alfalfa, hay at 2.0 ppm (40 CFR 180.479(a)(2)). The Agency is also correcting the tolerance expression for 40 CFR 180.479(a)(1) to read “Tolerances are established for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonylamino-sulfonyl-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate, and its metabolites determined as 3-chloro-1-methyl-5-sulfamoylpyrazole-4-carboxylic acid, expressed as halosulfuron-methyl equivalent, in or on the raw agricultural commodities listed in the table in this unit.”

**VI. Statutory and Executive Order Reviews**

This final rule establishes a tolerance 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCa. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

**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: February 14, 2007.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

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

**PART 180—[AMENDED]**

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

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

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

**§180.479 Halosulfuron-methyl; tolerances for residues.**

(a) *General.* (1) Tolerances are established for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonylamino-sulfonyl-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate, and its metabolites determined as 3-chloro-1-methyl-5-sulfamoylpyrazole-4-carboxylic acid, expressed as halosulfuron-methyl equivalent in or on the raw agricultural commodities listed in the table in this unit.

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(2) \* \* \*

Commodity	Parts per million
Alfalfa, forage .....	1.0
Alfalfa, hay .....	2.0
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[FR Doc. E7-3205 Filed 2-27-07; 8:45 am]

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