

ester) and its desmethoxy metabolite, (methyl-N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenylcarbamate), expressed as parent compound, in or on berry, group 13 at 4.0 ppm; cotton, undelinted seed at 0.3 ppm; and cotton, gin byproducts at 30 ppm, respectively.

**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, 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) 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 6, 2000) do not apply to this rule. In addition, This 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: September 18, 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 180.582 is amending paragraph (a)(1) in the table as follows:

- i. By revising the entry for “Berry group 13”; and
- ii. By alphabetically adding “Cotton, gin byproducts” and “Cotton, undelinted seed.”

The amendments read as follows:

**§ 180.582 Pyraclostrobin; tolerances for residues.**

(a) *General.* (1) \* \* \*

Commodity	Parts per million
* * *	* *
Berry, group 13 .....	4.0
* * *	* *
Cotton, gin byproducts ...	30
Cotton, undelinted seed	0.3
* * *	* *

[FR Doc. E7-18858 Filed 9-25-07; 8:45 am]  
**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2006-0206; FRL-8147-4]

**Sulfosulfuron; Pesticide Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of sulfosulfuron in or on grass, forage, fodder, and hay group 17, forage, and grass, forage, fodder, and hay, group 17, hay. This regulation also increases tolerances for fat, meat, and meat by byproducts of cattle, goat, horse, and sheep, and milk. Monsanto Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective September 26, 2007. Objections and requests for hearings must be received on or before November 26, 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-2006-0206. 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 those engaged in the following activities:

- 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 code 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 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 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 EPA's tolerance regulations at 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, 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-2006-0206 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 as required by 40 CFR part 178 on or before November 26, 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 this copy, identified by docket ID number EPA-HQ-OPP-2006-0206, 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 Facility telephone number is (703) 305-5805.

**II. Petition for Tolerance**

In the **Federal Register** of July 14, 2006 (71 FR 40106) (FRL-8057-7), 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 6F7031) by Monsanto Company, 1300 I St., NW., Suite 450 East, Washington, DC 20005. The petition requested that 40 CFR 180.552 be amended by establishing a tolerance for residues of the herbicide sulfosulfuron, 1-(4,6-dimethoxypyrimidin-2-yl)-3-[(2-ethanesulfonyl-imidazo[1,2-a]pyridine-3-yl)sulfonyl]urea, and its metabolites converted to 2-(ethylsulfonyl)imidazol[1,2-a]pyridine and calculated at sulfosulfuron, in or on grass, forage at 13.0 parts per million (ppm); grass, hay at 14 ppm; milk at 0.02 ppm; fat of cattle, goat, horse, and sheep at 0.03 ppm; meat of cattle, goat, horse, and sheep at 0.01 ppm; and meat byproducts of cattle, goat, horse, and sheep at 0.4 ppm. That notice referenced a summary of the petition prepared by Monsanto Company, the registrant, which is available to the public 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 and Agency procedures concerning commodity names, the Agency is correcting the terminology and tolerance level for pending crops under 40 CFR 180.552 (a) as follows: Grass, forage, fodder and hay, group 17, forage at 14 ppm; grass, forage, fodder and hay, group 17, hay at 25 ppm; cattle, fat at 0.02 ppm; cattle, meat at 0.01; cattle, meat byproducts at 0.30; goat, fat at 0.02 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.30; horse, fat at 0.02 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.30; milk at 0.02; sheep, fat at 0.02 ppm; sheep, meat at 0.01 ppm; and sheep; meat byproducts at 0.30 ppm. These entries will replace current entries for cattle, fat; cattle, meat; cattle, meat byproduct; goat, fat; goat, meat; goat, meat byproducts, horse, fat; horse, meat; horse; meat byproduct; milk; sheep; fat; sheep, meat; and sheep, meat byproducts listed in paragraphs 40 CFR 180.552(a) and (b). The current entries listed in 180.552 (b) for bahiagrass, forage at 11 ppm; bahiagrass, hay at 40 ppm; bermudagrass, forage at 11 ppm; and bermudagrass, hay at 40 ppm are replaced by the entries for grass, forage, fodder and hay, group 27, forage at 14 ppm; and grass, forage, fodder and hay, group 17, hay at 25 ppm in 40 CFR 180.552 (a).

### 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. . . ." These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

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 the petitioned-for tolerance for residues of sulfofurfuron on grass, forage, fodder and hay, group 17, forage at 14 ppm; grass, forage, fodder and hay, group 17, hay at 25 ppm; cattle, fat 0.02 ppm; cattle, meat at 0.01; cattle, meat byproducts at 0.3; goat, fat at 0.02 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.3; horse, fat at 0.02 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.3; milk at 0.02; sheep, fat at 0.02 ppm; sheep, meat at 0.01 ppm; and sheep; meat byproducts at 0.3 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 adverse effects caused

by sulfofurfuron as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of May 19, 1999 (64 FR 27186 (FRL-6078-4)).

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern is derived from the highest dose at which no adverse effects are observed in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account 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. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

A summary of the toxicological endpoints for sulfofurfuron used for human risk assessment is discussed in Unit IV.A. of the final rule published in the **Federal Register** of November 16, 2005 (70 FR 69457) (FRL-7740-1)

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to sulfofurfuron, EPA considered exposure under the petitioned-for tolerances as well as all existing sulfofurfuron tolerances in (40 CFR 180.552). EPA assessed dietary

exposures from sulfofurfuron 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.

No such effects were identified in the toxicological studies for sulfofurfuron; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) 1994-1996, or 1998 Continuing Survey of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed all foods for which there are tolerances were treated and contain tolerance-level residues and Dietary Exposure Evaluation Model (DEEM) (version 7.76) default processing factors.

iii. *Cancer.* In accordance with the Agency's Proposed Guidelines for Carcinogenic Risk Assessment (April 10, 1996), the CARC classified sulfofurfuron as a likely human carcinogen. The weight-of-evidence for this classification are as follows:

- Occurrence of rare transitional cell papilloma and carcinoma of urinary bladder in female rats.

- Occurrence of rare benign mesenchymal tumors of the urinary bladder in high dose male as well as renal adenomas in female and possibly male mice.

- The relevancy of the observed tumors to human exposure. The Agency determined that a linear low-dose approach (Q 1\*) for human risk characterization and extrapolation of risk should be based on the incidence of benign mesenchymal tumors in male mice. The rat transitional tumors and mouse renal tumors were not used because of their low incidence. This extrapolation, rather than an MOE approach is supported by the lack of sufficient data to characterize the mechanism of carcinogenicity. The unit risk, Q 1\* milligram/kilogram/day (mg/kg/day)<sup>-1</sup> of sulfofurfuron based upon male mouse urinary bladder mesenchymal tumor rates is 1.03 X 10<sup>-3</sup> (mg/kg/day)<sup>-1</sup> in human equivalents. The cancer dietary analysis assumed tolerance level residues, 100% CT and DEEM (version 7.76) default processing factors.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for

sulfosulfuron 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 environmental fate characteristics of sulfosulfuron. 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) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of sulfosulfuron for acute exposures are estimated to be 10.41 parts per billion (ppb) for surface water and 2.6 ppb for ground water. The EDWCs for chronic exposures are estimated to be 1.12 ppb for surface water and 2.6 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 2.6 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).

Residential exposure is not expected for the new proposed uses. However sulfosulfuron is registered for use on turf. Residential homeowners are not expected to handle sulfosulfuron directly. However, sulfosulfuron is applied by professional commercial operators to lawn areas (such as apartment complexes, parks, schools, recreational areas and public areas) where residents would come into contact with sulfosulfuron residues. Therefore, as a part of a previous risk assessment for this herbicide, post application exposure and risk to residents (adults and children) were assessed. Post-application inhalation exposure to children is considered to be negligible. Non-dietary, incidental ingestion of residues from treated turfgrass and ingestion of contaminated soil are possible. To address the short-term residential risk to children from incidental oral exposure, the Agency used the NOAEL of 24 mg/kg/day from the combined chronic toxicity/carcinogenicity study in rats. This NOAEL is considered conservative and health protective for this assessment because it represents the lowest NOAEL in most sensitive species (the basis for

the Chronic Reference Dose (cRfD)). Agency SOPs for Residential Exposure Assessments (Draft, December 18, 1997) were used as a guideline for performing the residential post-application exposure (with amendments, 2001). Children's hand-to-mouth, object to mouth (turfgrass) and soil ingestion were assessed. As discussed above, there are no residential handler uses for sulfosulfuron. Therefore, the residential cancer assessment for adults considered post-application only. Cancer risk for residential adults was calculated based on high activity on treated lawns. A transfer coefficient (TC) of 1,000 cm<sup>2</sup>/hr was used. Several conservative assumptions are built into the assessment of residential cancer risk. These include fifty years of exposure and an estimated 20% of foliar residues being dislodgeable (DFRs) from turf, which is derived from the maximum application rate. An average of 14 days of DFRs were used for this cancer assessment, this would be considered a 10% decrease each day (from dilution by rain, and mowing or grass) of the 20% residue for at least 14 days, and then taking the mean value of this 14-day exposure. It should be noted that the current default DFR is 5% from turf. At the time of the last risk assessment, the Agency assumed 20% DFR as a default. As a result, the estimate of residential adult risk is more conservative than it would be otherwise. The Lifetime Average Daily Dose (LADD) = 6.0 X 10<sup>-5</sup> mg/kg/day for a TC of 1,000 cm<sup>2</sup>/hr (high exposure activity for 1 hour).

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 sulfosulfuron and any other substances and sulfosulfuron 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 sulfosulofuron 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 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 ("10X") 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. This additional margin of safety is commonly referred to as the FQPA safety factor. 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 FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* The developmental studies in rat and rabbit and the reproductive study in rats did not indicate increased susceptibility of rats or rabbits *in utero* and/or postnatal exposure.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

- i. The toxicity database for sulfosulfuron is complete.
- ii. There is no indication that sulfosulfuron is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that sulfosulfuron results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. Conservative ground water and surface water modeling estimates were used. Similarly conservative Residential SOPs were 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 sulfosulfuron.

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

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An endpoint was not selected for acute dietary risk assessment because there were no effects attributable to a single dose (exposure) observed in oral toxicology studies (including developmental toxicity studies in the rat and rabbit (at or up to 1,000 mg/kg/day)) and an acute neurotoxicity study in rat (at or up to 2,000 mg/kg/day). The acute oral toxicity of sulfosulfuron is also very low. Therefore, sulfosulfuron is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to sulfosulfuron from food and water will utilize <1% of the cPAD for all population subgroups including infants and children. Based the use pattern, chronic residential exposure to residues of sulfosulfuron is not expected.

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).

Sulfosulfuron 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 sulfosulfuron.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in an aggregate MOE of 1,300 for children 1-2 years old.

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).

Though residential exposure could occur no toxicological effects have been identified for intermediate-term toxicity. Therefore, the aggregate risk is the sum of the risk from food and water.

5. *Aggregate cancer risk for U.S. population.* The cancer aggregate risk

assessment considered exposure from food, water, and residential sources. EPA performs cancer assessments for the general U.S. population only. The cancer dietary analyses assumed tolerance level residues, 100% CT, and DEEM (version 7.76) default processing factors. The dietary cancer risk from drinking water and food for the U.S. population was  $3 \times 10^{-7}$ . Residential cancer risk was estimated for adults only based on dermal exposure to treated areas. The estimated cancer risk for adults on day zero, based on high-exposure activity for one hour ( $T_c=1,000 \text{ cm}^2/\text{hr}$ ) is estimated to be  $1.2 \times 10^{-7}$ . The aggregate cancer risk estimate for adults is  $3 \times 10^{-7}$ . If childhood incidental oral exposure from residential sources is included in the aggregate cancer risk assessment, the estimated cancer risk is  $4 \times 10^{-7}$ . Since the cancer risk is less than the negligible risk level of risks in the range of or below  $1 \times 10^{-6}$ , EPA does not have a concern for aggregate cancer risk from sulfosulfuron.

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 sulfosulfuron residues.

### IV. Other Considerations

#### A. Analytical Enforcement Methodology

In support of the use on wheat, the petitioner proposed two common-moisture high-performance liquid chromatography (HPLC) methods with fluorescence detection for enforcement of tolerances in wheat and livestock commodities. For grasses the company used a common moiety liquid chromatograph/mass spectrometry/mass spectrometry (LC/MS/MS) method. The validated limit of quantitation (LOQ) was 0.005 and the limit of detection (LOD) was 0.0026. The revision of the original HPLC enforcement method to use LC/MC detection resolves the previous deficiencies related to the specificity and confirmatory method. These deficiencies are no longer outstanding.

Adequate enforcement methodology LC/MS/MS 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 no established or proposed Codex or Mexican maximum residue limits (MRLs) for residues of sulfosulfuron in grasses or wheat. There are no established Canadian MRLs for residues of sulfosulfuron in grasses. A Canadian MRL has been established for residues of sulfosulfuron in wheat.

### V. Conclusion

Therefore, tolerances are established for residues of sulfosulfuron, 1-(4,6-dimethoxypyrimidin-2-yl)-3-[(2-ethanesulfonyl-imidazo[1,2-a]pyridine-3-yl)sulfonyl]urea, and its metabolites converted to 2-(ethylsulfonyl)imidazol[1,2-a]pyridine and calculated at sulfosulfuron, as discussed in Unit II.

### 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, 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) 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 FFDC. 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 6, 2000) do not apply to this rule. In addition, This 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: September 13, 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 180.552 is amended by revising the table in paragraph (a), and by removing the text and reserving paragraph (b) to read as follows:

**§ 180.552 Sulfosulfuron; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Cattle, fat .....	0.02
Cattle, meat .....	0.01
Cattle, meat byproducts .....	0.3
Goat, fat .....	0.02
Goat, meat .....	0.01
Goat, meat byproducts .....	0.3
Grass, forage, fodder and hay, group 17, forage .....	14
Grass, forage, fodder and hay, group 17, hay .....	25
Hog, fat .....	0.005
Hog, meat .....	0.005
Hog, meat byproducts .....	0.05
Horse, fat .....	0.02
Horse, meat .....	0.01
Horse, meat byproducts .....	0.3
Milk .....	0.02
Sheep, fat .....	0.02
Sheep, meat .....	0.01
Sheep, meat byproducts .....	0.3
Wheat, forage .....	4.0
Wheat, grain .....	0.02
Wheat, hay .....	0.3
Wheat, straw .....	0.1

(b) Section 18 emergency exemptions.  
[Reserved]

\* \* \* \* \*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2007-0261; FRL-8147-6]

**Methamidophos, Oxydemeton-methyl, Profenofos, and Trichlorfon; Tolerance Actions**

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

**ACTION:** Final rule.

**SUMMARY:** EPA is revoking certain tolerances for the insecticide oxydemeton-methyl. Also, EPA is

modifying certain tolerances for the insecticides oxydemeton-methyl, profenofos, and trichlorfon. In addition, EPA is establishing new tolerances for the insecticides oxydemeton-methyl and profenofos. EPA is not taking action on tolerances for methamidophos at this time. The regulatory actions finalized in this document are follow-up to the Agency’s reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and tolerance reassessment program under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(q).