

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180****[EPA-HQ-OPP-2009-0275; FRL-8412-6]****Iodosulfuron-methyl-sodium; Pesticide Tolerances****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of iodosulfuron-methyl-sodium in or on wheat, forage; wheat, grain; wheat, hay; and wheat, straw. Bayer Cropscience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective May 20, 2009. Objections and requests for hearings must be received on or before July 20, 2009, 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-2009-0275. 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:** Hope Johnson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5410; e-mail address: [johnson.hope@epa.gov](mailto:johnson.hope@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 Access Electronic Copies of this Document?*

In addition to accessing electronically available documents 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 e-CFR cite at <http://www.gpoaccess.gov/ecfr>.

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

Under section 408(g) of FFDCA, 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-2009-0275 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 July 20, 2009.

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-2009-0275, 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. Petition for Tolerance**

In the **Federal Register** of July 9, 2008 (73 FR 39289) (FRL-8371-2), 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 1F6299) by Bayer Cropscience, 2 Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.580 be amended by establishing tolerances for residues of the herbicide iodosulfuron-methyl-sodium, methyl 4-iodo-2-[3-(4-methoxy-6-methyl-1,3,5-triazin-2-yl) ureidosulfonyl] benzoate, sodium salt, in or on wheat, grain at 0.02 parts per million (ppm); wheat, forage at 0.06 ppm; wheat, straw at 0.05 ppm; and wheat, hay at 0.05 ppm. That notice referenced a summary of the petition prepared by Bayer Cropscience, 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, EPA has concluded that 40 CFR 180.580 can be amended by establishing tolerances for residues of the herbicide iodosulfuron-methyl sodium, methyl 4-iodo-2-[3-(4-methoxy-6-methyl-1,3,5-triazin-2-yl) ureidosulfonyl] benzoate, sodium salt, in or on wheat, grain at 0.02 ppm; wheat, straw at 0.05 ppm; wheat, hay at 0.05 ppm; and wheat, forage at 0.10 ppm

instead of the petitioned for 0.06 ppm for wheat, forage. The reason for this change is explained in Unit IV.C.

### 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 the petitioned-for tolerances for residues of iodosulfuron-methyl-sodium on wheat, forage at 0.06 ppm; wheat, grain at 0.02 ppm; wheat, hay at 0.05 ppm; and wheat, straw at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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 iodosulfuron-methyl-sodium 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 *Iodosulfuron-Methyl-Sodium; Human-Health Risk Assessment for Proposed*

*Section 3 New Use on Wheat*, page 37 in docket ID number EPA-HQ-OPP-2009-0275.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) 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 (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD 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 dietary risks by comparing aggregate food and water 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 POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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>.

Iodosulfuron-methyl-sodium was assessed in a complete battery of subchronic (mice and rats), chronic (mice, rats, and dogs), carcinogenicity (mice and rats), developmental (rat and rabbit) and reproductive (rat) toxicity studies. In general high doses typically in the range of greater than 300 mg/kg/day were required to cause systemic toxicity characterized as decreases in body weight, body weight gain, hepatotoxicity in mice and/or dogs and gross and histopathological changes in

the hematopoietic system in dogs. Developmental toxicity was seen only at the limit dose in the rats, no developmental toxicity was seen in the rabbit, and no reproductive toxicity was seen in the rat.

Hematopoietic-related toxicity was only seen in female dogs in both the subchronic and chronic toxicity studies. The hematopoietic system involved in the production of blood includes primarily the bone marrow, spleen, and lymph nodes. In both the subchronic and chronic studies, microscopic pathology of the bone marrow and spleen were seen at approximately (50 m/kg/day; LOAEL). The NOAEL was 8 mg/kg/day.

The toxicity profile of iodosulfuron-methyl-sodium indicates that the dog to be the most sensitive species with the effects on the hematopoietic system being the most sensitive endpoint. The NOAEL (approximately 8 mg/kg/day) based on the most sensitive endpoint is used for assessing risk to intermediate (oral, dermal and inhalation routes) and chronic (oral, dermal and inhalation routes) durations resulting from exposure to iodosulfuron-methyl-sodium.

A summary of the toxicological endpoints for iodosulfuron-methyl-sodium used for human risk assessment can be found at <http://www.regulations.gov> in document *Iodosulfuron-Methyl-Sodium; Human-Health Risk Assessment for Proposed Section 3 New Use on Wheat*, page 13 in docket ID number EPA-HQ-OPP-2009-0275.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to iodosulfuron-methyl-sodium, EPA considered exposure under the petitioned-for tolerances as well as all existing iodosulfuron-methyl-sodium tolerances in (40 CFR 180.580). EPA assessed dietary exposures from iodosulfuron-methyl-sodium 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 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 used tolerance level residues and 100% crop treated

information to complete the acute dietary exposure assessment. Drinking water values were incorporated directly into the assessment.

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 used tolerance level residues and 100% crop treated information to complete the chronic dietary exposure assessment. Drinking water values were incorporated directly into the assessment.

iii. *Cancer.* The Agency determined that iodosulfuron-methyl-sodium was “not likely to be a human carcinogen” with regards to its potential as a human carcinogen. This decision was based on the lack of evidence for carcinogenicity in mice and rats. Iodosulfuron-methyl-sodium was negative for mutagenicity in various assays. Furthermore, registered sulfonyl urea compounds (structurally similar compounds) have been found to be non-carcinogenic. Based on this weight-of-evidence, an exposure assessment to evaluate cancer risk for iodosulfuron-methyl-sodium was not necessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue or PCT information in the dietary assessment for iodosulfuron-methyl-sodium. 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 iodosulfuron-methyl-sodium in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of iodosulfuron-methyl-sodium. 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 iodosulfuron-methyl-sodium for acute exposures are estimated to be 0.60 parts per billion (ppb) for surface water and 0.00004 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 0.067 ppb for surface water and 0.00004 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 0.60 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 0.067 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).

Iodosulfuron-methyl-sodium is currently registered for the following uses that could result in residential exposures: Ornamental turf. EPA assessed residential exposure using the following assumptions: As the ornamental turf use is labeled “intended for professional use,” and therefore is not available for direct residential use, a residential handler assessment was not conducted. All applications for the turf use are to be performed by professional (commercial) applicators. The ornamental turf product is intended for use on ornamental turfgrass on golf courses, sports fields, commercial lawns, cemeteries, parks, campsites, recreational areas, home lawns, roadsides, school grounds and sodfarms. Based on this use pattern, short and intermediate term risk was assessed.

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 iodosulfuron-methyl-sodium to share a common mechanism of toxicity with any other substances, and iodosulfuron-methyl-sodium does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that iodosulfuron-methyl-sodium 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.* There is qualitative evidence of increased susceptibility based on the rat developmental study where delayed ossification was observed in the fetuses of dams that exhibited minimal maternal toxicity (salivation). Similarly, there is qualitative and quantitative evidence of increased susceptibility based on the multi-generation rat reproduction study where no parental systemic effects were observed at the highest dose tested (HDT) and offspring toxicity was observed at a lower dose. Susceptibility was not observed in the developmental toxicity study in the rabbit.

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 iodosulfuron-methyl-sodium is complete, except for the requirements for an immunotoxicity, acute, and subchronic neurotoxicity studies. The existing data are sufficient for endpoint selection for exposure/risk assessment scenarios and for evaluation of the requirements under FQPA. EPA has determined that an additional uncertainty factor is not required to account for potential neurotoxicity or immunotoxicity. The reasons for this determination are described as follows:

a. The toxicity database for iodosulfuron-methyl-sodium is complete, except for immunotoxicity testing. EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Since this requirement went into effect well after the tolerance petition was submitted, these studies are not yet available for iodosulfuron-methyl-sodium.

In the absence of specific immunotoxicity studies, EPA has evaluated the available iodosulfuron-methyl-sodium toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. In the case of iodosulfuron-methyl-sodium, the available data do not indicate a concern for potential immunotoxicity. No treatment-related changes were seen in hematology parameters, organ weights (thymus, spleen), gross necropsy (enlarged lymph nodes) or histopathology (spleen, thymus, lymph nodes) when tested up to and including the limit dose (1000 mg/kg/day) in mice or rats. Marginal effects, manifested as histopathological changes in the bone marrow and spleen, were seen in female dogs. Minimal to moderate hyperplasia of the hematopoietic cells was seen in the one female. No treatment-related changes were seen in male dogs. The subcapsular congestion in the spleen is a common finding and is probably related to the means of euthanasia since barbiturates can cause the splenic musculature to relax and often leads to blood filled spleens. Therefore, the lesions of the spleen are not evidence of immunotoxicity. In the absence of corroborative changes in any hematology parameters, weights of thymus, spleen and lymph nodes, or histopathological changes in the thymus and lymph nodes in the dogs, the changes observed are considered hematopoietic, not immunotoxic. Therefore an additional uncertainty factor is not needed to account for potential immunotoxicity.

b. Acute and subchronic neurotoxicity testing is also required as a result of changes made to pesticide data requirements in December 2007. Although acute and subchronic neurotoxicity testing has not yet been submitted, iodosulfuron-methyl-sodium does not belong to a class chemical that would be expected to be neurotoxic. There is no evidence of neurotoxicity in the data base in any species at any dose level. In the 90-day dietary studies with mice and rats, there were no signs indicative of neurotoxicity when tested at the limit dose (1000 mg/kg/day). In both species, the LOAEL was based on decreases in body weight and/or body weight gain. These findings indicate that the prospective neurotoxicity studies will have to be tested at the Limit Dose and even with the enhanced evaluation of neurotoxic parameters; these studies will not yield a lower dose for risk assessment. Therefore, a

database uncertainty factor is not required.

ii. While there is qualitative evidence of increased susceptibility based on the rat developmental study, the developmental toxicity manifested as delayed ossification (which are variations not malformations) were seen only at the limit dose in the presence of maternal toxicity, and with a clear NOAEL for the effect of concern. Susceptibility was not observed in the developmental toxicity study in the rabbit. Additionally no parental systemic effects were observed at the limit dose and offspring toxicity was observed at a lower dose (34.2 mg/kg/day; manifested as decreased pup viability on post-natal day (PND) 0 and 4) in the multi-generation rat reproduction study. In spite of the lack of parental toxicity, there was a well characterized NOAEL/LOAEL for offspring toxicity; the developmental NOAEL is used for the acute dietary risk assessment; and the NOAEL (7.3 mg/kg/day) used for the chronic dietary risk assessment is approximately 47-fold lower than the offspring NOAEL (346 mg/kg/day). Therefore, there is low concern for increased susceptibility for iodosulfuron-methyl-sodium and no additional uncertainty factor is needed.

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. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to iodosulfuron-methyl-sodium in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by iodosulfuron-methyl-sodium.

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

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the

product of all applicable UFs is not exceeded.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to iodosulfuron-methyl-sodium will occupy <1.0 % of the aPAD for (all infants (<1 year old)) the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to iodosulfuron-methyl-sodium from food and water will utilize 3.1% of the cPAD for (children 3–5 years 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 iodosulfuron-methyl-sodium 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).

Iodosulfuron-methyl-sodium 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 exposure through food and water with short-term residential exposures to iodosulfuron-methyl-sodium.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs of 110,000 for children 3–5 years old and 420,000 for adults 20–49 years old.

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).

Iodosulfuron-methyl-sodium is currently registered for use that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure to iodosulfuron-methyl-sodium through food and water with intermediate-term exposures for iodosulfuron-methyl-sodium.

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 aggregated result in aggregate MOEs of 21,000 for children 3–5 years old, and 84,000 for adults 20–49 years old.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence for carcinogenicity in mice and rats, iodosulfuron-methyl-sodium is not expected to pose a cancer risk.

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 iodosulfuron-methyl-sodium residues.

**IV. Other Considerations**

*A. Analytical Enforcement Methodology*

Adequate enforcement methodology (liquid chromatography using mass spectrometric detection (LC/MS/MS) and by high performance liquid chromatography with ultra violet detection (HPLC/UV)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: *residuemethods@epa.gov*.

*B. International Residue Limits*

There are no Codex MRLs for residues of iodosulfuron-methyl-sodium, and no Mexican MRLs have been established. Canadian MRLs have been established for certain residues of iodosulfuron-methyl-sodium; however, no MRLs have been established for wheat commodities at this time.

*C. Revisions to Petitioned-For Tolerances*

Review of available field trial data indicate that the proposed tolerance for wheat, forage (0.06 ppm) is too low; a tolerance of 0.10 ppm is appropriate based on the maximum residue limit (MRL) observed in/on forage.

**V. Conclusion**

Therefore, tolerances are established for residues of iodosulfuron-methyl-sodium, methyl 4-iodo-2-[3-(4-methoxy-6-methyl-1,3,5 triazin-2-yl)ureidosulfonyl] benzoate, sodium salt, in or on wheat, forage at 0.10 ppm; wheat, grain at 0.02 parts per million (ppm); wheat, hay at 0.05 ppm; and wheat, straw at 0.05 ppm.

**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: May 11, 2009.

**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 180.580 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

**§ 180.580 Iodosulfuron-methyl-sodium; tolerances for residues.**

(a) \* \* \*

| Commodity           | Parts per million |
|---------------------|-------------------|
| * * * * *           |                   |
| Wheat, forage ..... | 0.10              |
| Wheat, grain .....  | 0.02              |
| Wheat, hay .....    | 0.05              |

| Commodity          | Parts per million |
|--------------------|-------------------|
| Wheat, straw ..... | 0.05              |

\* \* \* \* \*

[FR Doc. E9-11633 Filed 5-19-09; 8:45 am]  
BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 271

[EPA-R06-RCRA-2008-0757; FRL-8905-4]

### Louisiana: Final Authorization of State Hazardous Waste Management Program Revision

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

**ACTION:** Immediate final rule.

**SUMMARY:** Louisiana has applied to the EPA for final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The EPA has determined that these changes satisfy all requirements needed to qualify for final authorization, and is authorizing the State's changes through this immediate final action. The EPA is publishing this rule to authorize the changes without a prior proposal because we believe this action is not controversial and do not expect comments that oppose it. Unless we receive written comments which oppose this authorization during the comment period, the decision to authorize Louisiana's changes to its hazardous waste program will take effect. If we receive comments that oppose this action, we will publish a document in the **Federal Register** withdrawing this rule before it takes effect, and a separate document in the proposed rules section of this **Federal Register** will serve as a proposal to authorize the changes.

**DATES:** This final authorization will become effective on July 20, 2009 unless the EPA receives adverse written comment by June 19, 2009. If the EPA receives such comment, it will publish a timely withdrawal of this immediate final rule in the **Federal Register** and inform the public that this authorization will not take effect.

**ADDRESSES:** Submit your comments by one of the following methods:

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

2. *E-mail:* [patterson.alima@epa.gov](mailto:patterson.alima@epa.gov).

3. *Mail:* Alima Patterson, Region 6, Regional Authorization Coordinator, State/Tribal Oversight Section (6PD-O), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733.

4. *Hand Delivery or Courier:* Deliver your comments to Alima Patterson, Region 6, Regional Authorization Coordinator, State/Tribal Oversight Section (6PD-O), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733.

*Instructions:* Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://regulations.gov), or e-mail. The Federal [regulations.gov](http://regulations.gov) Web site is an "anonymous access" system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to the EPA without going through [regulations.gov](http://regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. You can view and copy Louisiana's application and associated publicly available materials from 8:30 a.m. to 4 p.m. Monday through Friday at the following locations: Louisiana Department of Environmental Quality, 602 N. Fifth Street, Baton Rouge, Louisiana 70884-2178, phone number (225) 219-3559 and EPA, Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733, phone number (214) 665-8533. Interested persons wanting to examine these documents should make an appointment with the office at least two weeks in advance.

**FOR FURTHER INFORMATION CONTACT:** Alima Patterson, Region 6, Regional Authorization Coordinator, State/Tribal Oversight Section (6PD-O), Multimedia Planning and Permitting Division, EPA

Region 1445 Ross Avenue, Dallas, Texas 75202-2733, (214) 665-8533 and e-mail address [patterson.alima@epa.gov](mailto:patterson.alima@epa.gov).

#### SUPPLEMENTARY INFORMATION:

#### A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from the EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, States must change their programs and ask the EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur.

Most commonly, States must change their programs because of changes to the EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 268, 270, 273, and 279.

#### B. What Decisions Have We Made in This Rule?

We conclude that Louisiana's application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, we grant Louisiana final authorization to operate its hazardous waste program with the changes described in the authorization application. Louisiana has responsibility for permitting treatment, storage, and disposal facilities within its borders (except in Indian Country) and for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations of the Hazardous and Solid Waste Amendments of 1984 (HSWA). New Federal requirements and prohibitions imposed by Federal regulations that the EPA promulgates under the authority of HSWA take effect in authorized States before they are authorized for the requirements. Thus, the EPA will implement those requirements and prohibitions in Louisiana including issuing permits, until the State is granted authorization to do so.

#### C. What Is the Effect of Today's Authorization Decision?

The effect of this decision is that a facility in Louisiana subject to RCRA will now have to comply with the