the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 12, 2002. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

40 CFR Part 60

Administrative practice and procedure, Air pollution control, Aluminum, Ammonium sulfate plants, Beverages, Carbon monoxide, Cement industry, Coal, Copper, Dry cleaners, Electric power plants, Fertilizers, Fluoride, Gasoline, Glass and glass products, Graphic arts industry, Household appliances, Insulation, Intergovernmental relations, Iron, Lead, Lime, Metallic and nonmetallic mineral processing plants, Metals, Motor vehicles, Natural gas, Nitric acid plants, Nitrogen dioxide, Paper and paper products industry, Particulate matter, Paving and roofing materials, Petroleum, Phosphate, Plastics materials and synthetics, Reporting and recordkeeping requirements, Sewage disposal, Steel, Sulfur oxides, Tires, Urethane, Vinyl, Waste treatment and disposal, Zinc.

Dated: August 27, 2002.

Jack W. McGraw,

Acting Regional Administrator, Region 8.

40 CFR part 52, of chapter I, title 40 is amended as follows:

PART 52—[AMENDED]

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

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

Subpart QQ—South Dakota

2. A new § 52.2185 is added to read as follows:

§ 52.2185 Change to approved plan.

South Dakota Air Pollution Control Program Chapter 74:36:07, New Source Performance Standards, is removed from the approved plan, except for sections 74:36:07:08, 74:36:07:11 and 74:36:07:29–30. On April 2, 2002, we issued a letter delegating responsibility for all sources located, or to be located, in the State of South Dakota subject to the specified NSPS in 40 CFR part 60. See the table in 40 CFR 60.4 for the delegation status of NSPS to the State of South Dakota.

PART 60—[AMENDED]

1. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401, 7411, 7414, 7416, and 7601 as amended by the Clean Air Act Amendments of 1990, Pub. L. 101–549, 104 Stat. 2399 (November 15, 1990; 402, 409, 415 of the Clean Air Act as amended, 104 Stat. 2399, unless otherwise noted).

Subpart A—General Provisions

2. Section 60.4 is amended by revising the column heading for ''SD'' in the table entitled ''Delegation Status of New Source Performance Standards [(NSPS) for Region VIII]'' in paragraph (c) to read as follows:

§ 60.4 Address.

* * * * *

(c) * * *

DELEGATION STATUS OF NEW SOURCE PERFORMANCE STANDARDS

[(NSPS) for Region VIII]

Subpart	CO	MT	ND	SD	UT [1]	WY
* *	*	*	*	*	*	*

* Indicates approval of State regulation.

[1] Indicates approval of State Regulation as part of the State Implementation Plan (SIP).

[FR Doc. 02–22976 Filed 9–10–02; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0141 FRL–7187–2]

Iodosulfuron-Methyl-Sodium; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerances 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 corn, field, grain; corn, field, forage; and corn, field, stover. Aventis CropScience USA LP requested this tolerance under the Federal Food, Drug,

and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 11, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0141 must be received on or before November 12, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0141 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–6224; e-mail address: *Miller.Joanne@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

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

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

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

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

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

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–0141. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of January 24, 2001 (66 FR 7644) (FRL–6758–9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170), announcing the filing of a pesticide petition (PP F6160) by Aventis CropScience USA LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. This notice included a summary of the petition prepared by Aventis CropScience, the registrant. There were no comments received in response to the notice of filing.

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 corn, field, grain at 0.03 part per million (ppm); corn, field, forage at 0.05 ppm; and corn, field, stover at 0.05 ppm.

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of iodosulfuron-methyl-sodium on corn, field, grain at 0.03 ppm; corn, field, stover at 0.05 ppm; and corn, field, forage at 0.05 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. The nature of the toxic effects caused by iodosulfuron-methyl-sodium are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study type	Results
870.3100	90-Day oral toxicity rodents-rat	NOAEL = 67 mg/kg/day in males, 74 mg/kg/day in females. LOAEL = 347 mg/kg/day in males, 388 mg/kg/day in females based on reduced body weight and overall body weight gains in both sexes
870.3100	90-Day oral toxicity rodents-mouse	NOAEL = 119 mg/kg/day in males, Not observed in females LOAEL = 332 mg/kg/day in males, 139 mg/kg/day in females based on hepatotoxicity
870.3150	90-Day oral toxicity nonrodents-dog	NOAEL = 8.1 mg/kg/day in males, 8.4 mg/kg/day infemales. LOAEL = 49 mg/kg/day in males, 51 mg/kg/day in females based on changes in hematology, microscopic pathology of the bone marrow and spleen (females), clinical chemistry (males)
870.3700	Prenatal developmental in rodents-rat	Maternal: NOAEL = 315 mg/kg/day LOAEL = 1,000 mg/kg/day based on increased salivation Developmental: NOAEL = 315 mg/kg/day LOAEL =1,000 mg/kg/day based on delayed ossification
870.3700	Prenatal developmental in nonrodents-rabbit	Maternal: NOAEL = 400 mg/kg/day (HDT) LOAEL = Not observed Developmental: NOAEL = 400 mg/kg/day (HDT) LOAEL = Not observed
870.3800	Reproduction and fertility effects-rat	Parental/Systemic NOAEL = 346 mg/kg/day in males, 390 mg/kg/day in females (HDT). LOAEL = not established. Reproductive NOAEL = 346 mg/kg/day in males, 390 mg/kg/day in females (HDT). LOAEL = not established. Offspring NOAEL = 34.2 mg/kg/day in males, 39.7 mg/kg/day in females. LOAEL = 346 mg/kg/day in males, 390 mg/kg/day in females (HDT) based on pup mortality.
870.4100	Chronic toxicity-dogs	NOAEL = 41.8 mg/kg/day in males, 7.25 mg/kg/day in females LOAEL = Not Established in males, 43.7 mg/kg/day in females based on gross and histopathologic changes observed in the hematopoietic system.
870.4300	Chronic/carcinogenicity-rats	NOAEL = 29.7 mg/kg/day in males, 39.1 mg/kg/day in females. LOAEL = 331 mg/kg/day in males and 452 mg/kg/day in females based on reduced body weight and body weight gains in males and on reduced body weight, body weight gains and food efficiency in females. No evidence of carcinogenicity.
870.4300	Carcinogenicity-mice	NOAEL = 54.2 mg/kg/day in males, 57.6 mg/kg/day in females. LOAEL = 279 mg/kg/day in males, 277 mg/kg/day in females based on increased liver weights and histopathological changes in the liver. No evidence of carcinogenicity at doses tested.
870.5100	Gene mutation	Non-mutagenic when tested up to 5000 ug/plate, in presence and absence of metabolic activation, in S. typhimurium strains TA98, TA100, TA1535 and TA1537 and E.coli strain WP2uvra.
870.5300	Gene mutation	Negative for induction of forward mutation at the HPRT locus in Chinese hamster V79 lung fibroblasts, in the presence or absence of S9-activation at doses up to limit of solubility (2649 Fg/mL).
870.5375	Chromosome aberration	Did not induce structural chromosome aberration in Chinese hamster lung (V79) cell cultures in the presence and absence of activation up to cytotoxic concentrations.
870.5385	Chromosomal aberration	Non-mutagenic in NMRI mouse bone marrow micronucleus chromosomal aberrations assay up to the limit dose (2,000 mg/kg).

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study type	Results
870.5550	Other genotoxicity	No evidence that unscheduled DNA synthesis was induced by iodosulfuron-methyl, as determined by radioactive tracer procedures nuclear silver grain counts. Iodosulfuron-methyl was tested up to cytotoxic concentrations ($3,000 μg/mL). UDS activity was assessed at 0.01 to 1,000 μg/mL.
870.7485	Metabolism and pharmacokinetics-rat	Total recovery of the administered dose was 95.9-102.4% for all treatment groups. No radioactivity was detected in exhaled air or organic volatiles. Elimination of radioactivity occurred primarily in the urine, mostly within 24 hours of dosing, and was essentially complete within 3 days of dosing. Overall urinary excretion accounted for 78.5% and 85.8% of the dose for males and females, respectively, and fecal elimination accounted for 19.2% and 10.1% of the dose, respectively. By 3 days post-dose, ≤0.5% of the dose remained in the blood and tissues of both sexes of rats from the low- and high-dose groups. Rats excreted the majority of the dose as unchanged parent via the urine (48.7-86.3% dose) or feces (1.1-11.1% dose). Minor routes of metabolism for iodosulfuron-methyl included hydrolysis of the methylester to form 4-iodo-2-[3-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)ureidosulfonyl] benzoic acid (AE F145740; 0.9-4.5% dose); *O*-demethylation of the triazine ring to form methyl 2-[3-(4-hydroxy-6-methyl-1,3,5-triazin-2-yl)ureidosulfonyl]-4-iodobenzoate (AE F148741; 1.5-8.2% dose); or hydroxylation of the methyl group on the triazine ring to form methyl 2-[3-(4-hydroxymethyl-6-methoxy-1,3,5-triazin-2-yl)ureidosulfonyl]-4-iodobenzoate (AE F168532; 0.3-6.6% dose). Each of these minor metabolites was present in both the urine and feces. The remaining metabolites each accounted for <3% of the dose.
870.7485	Metabolism and pharmacokinetics-dog	Within 72 hours of oral dosing, 90-94% of the dosed radioactivity was recovered in the excrement and cage wash of both dose groups. Renal excretion accounted for 64-74% of the dose and elimination in the feces accounted for 14-17% of the radioactive dose. Most of the dose was excreted within 24 hours. Quantitative RP-HPLC analyses isolated up to 6 distinct radioactive components in urine and feces. The major isolated fraction was the parent: urine (54-61% dose) and feces (8-11%). In the rat, the major isolated fraction was also the parent, while the major metabolite was AE F145741. The metabolites identified in the dog were consistent with those identified in the rats.
870.7600	Dermal penetration-rat	For both the low- and high-dose groups, dermal penetration of radioactivity was low (< 2% dose) at exposure intervals up to 8 hours. Absorption increased slightly with duration of exposure in the low-dose group, increasing from 0.019% of the dose (0.043 Fg/cm^2) at 3 hours to 0.69% of the dose (0.159 Fg/cm^2) at 8 hours. However, a similar trend was not observed in the high-dose group, as the maximum absorption was observed at the 5-hour exposure (1.60% dose, 6.02 Fg/cm^2).

B. Toxicological Endpoints

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 lowest dose at which adverse effects of concern are identified 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (*e.g.,* risk is expressed as 1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for iodosulfuron-methyl-sodium used

for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR IODOSULFURON-METHYL-SODIUM FOR USE IN HUMAN RISK ASSESSMENT

Exposure scenario	Dose used in risk assessment, UF	FQPA SF and level of concern for risk assessment	Study and toxicological effects
Acute dietary for general population	NOAEL= 315 mg/kg/day UF = 100 aRfD = 3.15 mg/kg/day	FQPA SF = 10x aPAD = 0.31 mg/kg/day	Developmental Toxicity in Rats Based on increased salivation seen in dams on day one and throughout the dosing period at the high dose of 1,000 mg/kg/day (LOAEL, Maternal)
Chronic dietary all populations	NOAEL = 7.3 mg/kg/day UF = 100 cRfD = 0.073 mg/kg/day	FQPA SF= 10 cPAD = 0.007 mg/kg/day	Chronic Oral Toxicity diet - dog Based on gross and histopathologic changes observed in the hematopoietic system seen at 1,200 ppm (LOAEL 43.7 mg/kg/day)
Incidental oral short-term (1-30 days)	Oral NOAEL = 49 mg/kg/day	FQPA SF= 10 LOC for MOE = 1,000 (residential)	Subchronic Oral Toxicity diet - dog Based on alterations in hematological parameters and changes in clinical chemistry seen at 4 week observation period at a dose level of 301 mg/kg/day (HDT)
Incidental oral, intermediate-term (30 days-6 months)	Oral NOAEL= 8.1 mg/kg/day	FQPA SF= 10 LOC for MOE = 1,000 (residential)	Subchronic Oral Toxicity diet - dog Based on changes in hematology (males and females), microscopic pathology of the bone marrow (males and females) and spleen (females), and clinical chemistry (males) seen at termination at a dose level of 49 mg/kg/day (LOAEL)
Dermal short-term (1-30 days)	Oral NOAEL= 49 mg/kg/day dermal absorption factor 2%	LOC for MOE = 1,000 (residential) LOC for MOE = 100 (occupational)	Subchronic Oral Toxicity diet - dog. Based on alterations in hematological parameters and changes in clinical chemistry seen at 4 week observation period at a dose level of 301 mg/kg/day (HDT)
Dermal, intermediate-term (30 days-6 months)	Oral NOAEL= 8.1 mg/kg/day dermal absorption factor 2%	LOC for MOE = 1,000 (residential) LOC for MOE = 100 (occupational)	Subchronic Oral Toxicity diet - dog Based on changes in hematology (males and females), microscopic pathology of the bone marrow (males and females) and spleen (females), and clinical chemistry (males) seen at termination at a dose level of 49 mg/kg/day (LOAEL)
Dermal, long-term (6 months-life time)	Oral NOAEL= 7.3 mg/kg/day dermal absorption factor 2%	LOC for MOE = 1,000 (residential) LOC for MOE = 100 (occupational)	Chronic Oral Toxicity diet - dog Based on gross and histopathologic changes observed in the hematopoietic system seen at 1,200 ppm (LOAEL 43.7 mg/kg/day)
Inhalation, short-term (1-30 days)	Oral NOAEL= 49 mg/kg/day inhalation absorption factor 100%	LOC for MOE = 1,000 (residential) LOC for MOE = 100 (occupational)	Subchronic Oral Toxicity diet - dog Based on alterations in hematological parameters and changes in clinical chemistry seen at 4 week observation period at a dose level of 301 mg/kg/day (HDT)
Inhalation, intermediate-term (30 days-6 months)	Oral NOAEL= 8.1 mg/kg/day inhalation absorption factor 100%	LOC for MOE = 1,000 (residential) LOC for MOE = 100 (occupational)	Subchronic Oral Toxicity diet - dog Based on changes in hematology (males and females), microscopic pathology of the bone marrow (males and females) and spleen (females), and clinical chemistry (males) seen at termination at a dose level of 49 mg/kg/day (LOAEL)
Inhalation, Long-term (6 months-life time)	Oral NOAEL= 7.3 mg/kg/day inhalation absorption factor 100%	LOC for MOE = 1,000 (residential) LOC for MOE = 100 (occupational)	Chronic Oral Toxicity diet - dog Based on gross and histopathologic changes ST observed in the hematopoietic system seen at 1,200 ppm (LOAEL 43.7 mg/kg/day)

The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* This is the first request for an iodosulfuron-methyl-sodium registration to establish tolerances for the residues of iodosulfuron-methyl-sodium, in or on a variety of raw agricultural commodities. Metsulfuron-methyl (registered active ingredient; PC code 122010) has been identified as a residue of concern in drinking water as a result of iodosulfuron-methyl-sodium application (metsulfuron-methyl was not identified as a residue of concern in cereal grains or livestock). Since metsulfuron-methyl had not undergone a full review by the EPA at the time the iodosulfuron-methyl-sodium risk assessment was completed, it was assumed that the doses and endpoints identified for iodosulfuron-methyl-sodium were applicable to metsulfuron-methyl. This assumption was considered appropriate based on structural activity relationship (both are sulfonylureas), and the fact that metsulfuron-methyl is a predominant metabolite of iodosulfuron-methyl-sodium in soil in drinking water. Recently, metsulfuron-methyl has undergone a full review by EPA. In all instances, excluding short-term inhalation and incidental oral, the metsulfuron-methyl endpoints were greater than those identified for iodosulfuron-methyl-sodium. No acute dietary endpoint was selected for metsulfuron-methyl. Since metsulfuron-methyl was considered toxicologically equivalent to iodosulfuron-methyl-sodium for risk assessment purposes, the dietary and residential analyses included all registered and proposed uses for iodosulfuron-methyl-sodium and metsulfuron-methyl. Additionally, the iodosulfuron-methyl-sodium risk assessment incorporated a 10X FQPA safety factor (metsulfuron-methyl has a 1X FQPA safety factor). Therefore, this assessment is considered highly conservative. The nature of metsulfuron-methyl residues in/on cereal grains (residues of concern - metsulfuron-methyl and its 4 hydroxy metabolite) and ruminants (residues of concern - metsulfuron-methyl) have been determined and tolerances have been established in/on barley, grass, sugarcane, wheat, sorghum, milk and in the fat, meat, meat byproducts, and kidney of cattle, goats, hogs, horses, and sheep ranging from 0.05 - 20 ppm (40 CFR 180.428). Based on data from the ruminant and poultry metabolism studies, in which a cow and hens were dosed at 179x and 333x the MTDB, respectively, there is no reasonable expectation that finite residues of iodosulfuron-methyl-sodium will occur in livestock commodities (40 CFR 180.6(a)(3)). Therefore, livestock feeding studies and tolerances for livestock commodities were not performed. If the use of iodosulfuron-methyl-sodium is expanded in the future to include other livestock feed items, the need for feeding studies will be reevaluated. Risk assessments were conducted by EPA to assess dietary exposures from iodosulfuron-methyl-sodium in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: The acute analysis was performed for the general U.S. population and all population subgroups using existing and recommended tolerance level residues, 100% crop treated information, and DEEM™ default processing factors for all iodosulfuron-methyl-sodium and metsulfuron-methyl registered and proposed commodities.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic analysis was performed for the general U.S. population and all population subgroups using existing and recommended tolerance level residues, 100% crop treated information, and DEEM™ default processing factors for all iodosulfuron-methyl-sodium and metsulfuron-methyl registered and proposed commodities.

iii. *Cancer.* The mouse carcinogenicity study was negative as was the carcinogenicity study conducted in 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. The maximum dose, however, was not achieved for the mouse cancer study for iodosulfuron-methyl-sodium; thus, EPA has requested a new carcinogenicity study in mice as confirmatory data.

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

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentrations in Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from

residential uses. Since DWLOCs address total aggregate exposure to iodosulfuron-methyl-sodium and metsulfuron-methyl, they are further discussed in the aggregate risk sections see section E.

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of iodosulfuron-methyl-sodium and metsulfuron-methyl for acute exposures are estimated to be 1.43 parts per billion (ppb) for surface water and 0.105 ppb for ground water. The EECs for chronic exposures are estimated to be 0.338 ppb for surface water and 0.105 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Iodosulfuron-methyl-sodium is not registered for use on any sites that would result in residential exposure. However, metsulfuron-methyl is currently registered for use on the following residential non-dietary site(s): Golf courses and residential turfgrass. Based on the use pattern, potential residential exposure scenarios include:

- Golfer post-application exposure (adult and adolescent)
- Non-dietary ingestion (toddler hand-to-mouth, object-to-mouth, soil ingestion)
- Dermal post-application exposure to turfgrass (adult and toddler)

All MOEs calculated for residential post-application exposures do not exceed the HED's levels of concern for the respective exposure scenarios (MOEs<1,000).

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

EPA does not have, at this time, available data to determine whether iodosulfuron-methyl-sodium and metsulfuron-methyl have a common mechanism of toxicity with other substances or how to include these pesticides in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, iodosulfuron-methyl-sodium and metsulfuron-methyl do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that iodosulfuron-methyl-sodium and metsulfuron-methyl 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 the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. There is evidence for both quantitative and qualitative increased susceptibility in the multi-generation rat reproduction study. While no parental toxicity was seen at the HDT (346 mg/kg/day), off-spring toxicity was manifested as reduced pup viability (death on Day 0 in F_2, LOAEL 346 mg/kg/day; NOAEL 34 mg/kg/day). Similarly, there is evidence for qualitative increase in susceptibility in the rat developmental toxicity study where delayed ossification was observed in the fetuses of dams that exhibited minimal maternal toxicity (salivation; maternal and developmental LOAEL 1,000 mg/kg/day and NOAEL 315 mg/kg/day). Maternal and developmental LOAELs were not established in the non-rodent (rabbit) developmental toxicity study (HDT 400 mg/kg/day; study is classified as unacceptable/not upgradable due to inadequate dosing). Therefore, susceptibility of the offspring could not be addressed in this species.

3. *Conclusion*. There is a complete toxicity data base for iodosulfuron-methyl-sodium. EPA concluded that the FQPA safety factor be retained at 10x for iodosulfuron-methyl-sodium for the following weight-of-evidence considerations: There is qualitative evidence of increased susceptibility following *in utero* exposure to iodosulfuron-methyl-sodium in the rat developmental toxicity study; there is quantitative and qualitative evidence of increased susceptibility following prenatal/postnatal exposure to iodosulfuron-methyl-sodium in the 2–generation reproduction study in rats; susceptibility could not be assessed in the non-rodent (rabbit) developmental study since the doses tested in this study were considered to be inadequate (this study is classified as unacceptable); there is a data gap for an acute neurotoxicity study conducted in adult rats required to confirm and characterize the signs of neurotoxicity observed in the 90-day dog study and the rat developmental toxicity study; and the requirement for a developmental neurotoxicity study (DNT) with iodosulfuron-methyl-sodium is ''reserved'' pending the results of the acute neurotoxicity study.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (*i.e.,* the PAD) is available for exposure through drinking water [*e.g.,* allowable chronic water exposure (mg/kg/day) = cPAD − (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

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

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when

considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to iodosulfuron-methyl-sodium and metsulfuron-methyl will occupy 1% of the aPAD for the U.S. population, <1% of the aPAD for females 13 years and older, 1% of the aPAD for all infants and 1% of the aPAD for children (1-6 years old). In addition, there is potential for acute dietary exposure to iodosulfuron-methyl-sodium and metsulfuron-methyl in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO IODOSULFURON-METHYL-SODIUM AND METSULFURON-METHYL

Population subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Acute DWLOC (ppb)
U.S. population—all seasons	0.315	1	1.42	0.105	11,000
All Infants (<1 year old)	0.315	1	1.42	0.105	3,100
Children (1-6 years old)	0.315	1	1.42	0.105	3,100
Children (7-12 years old)	0.315	1	1.42	0.105	3,100
Females (13-50 years old)	0.315	<1	1.42	0.105	9,400
Males (13-19 years old)	0.315	1	1.42	0.105	11,000
Males (20+ years old)	0.315	<1	1.42	0.105	11,000
Seniors (55+ years old)	0.315	<1	1.42	0.105	11,000

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to iodosulfuron-methyl-sodium and metsulfuron-methyl from food will utilize 10% of the cPAD for the U.S. population, 12% of the cPAD for all infants and 29% of the cPAD for children (1-6 years old). There are no residential uses for iodosulfuron-methyl-sodium and metsulfuron-methyl that result in chronic residential exposure. Based on the use pattern, chronic residential exposure to residues of iodosulfuron-methyl-sodium and metsulfuron are not expected. In addition, there is potential for chronic dietary exposure to iodosulfuron-methyl-sodium and metsulfuron-methyl in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO IODOSULFURON-METHYL-SODIUM AND METSULFURON-METHYL

Population subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.0073	10	0.338	0.105	230
All Infants (<1 year old)	0.0073	12	0.338	0.105	65
Children (1-6 years old)	0.0073	29	0.338	0.105	52
Children (7-12 years old)	0.0073	17	0.338	0.105	61
Females (13-50 years old)	0.0073	7	0.338	0.105	200
Males (13-19 years old)	0.0073	11	0.338	0.105	240
Males (20+ years old)	0.0073	7	0.338	0.105	240
Seniors (55+ years old)	0.0073	6	0.338	0.105	240

3. *Short-term risk.* Iodosulfuron-methyl-sodium is not registered for use on any sites that would result in residential exposure. However, for the purposes of this assessment, iodosulfuron-methyl-sodium and metsulfuron-methyl are being considered toxicologically equivalent. Metsulfuron-methyl is currently

registered for use that could result in short-term residential exposure. Since a common toxicological effect was identified when assessing short-term oral and dermal exposures (alterations in hematology and clinical chemistry parameters), the aggregate short-term assessment considered exposure from food (chronic dietary), water, and residential uses (oral and dermal). The short-term oral and dermal endpoints were based on the same study, and therefore can be aggregated.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 5.6e+05 for all U.S. populations, 2.5e+05 for all infants (<1 year old), 1.5e+05 for children (1-6 years old), 2.1e+05 for children (7-12 years old), 7.7e+05 for females (13-50 years old), 5.1e+05 for males (13-19 years old), 7.4e+05 for males (20+ years old), and 8.4e+05 for seniors (55+ years old). These aggregate MOEs do not exceed the Agency's level of concern. In addition, short-term DWLOCs were calculated and compared to the EECs for average exposure of iodosulfuron-methyl-sodium and metsulfuron-methyl in ground and surface water. DWLOCs were then calculated using the following default body weights and drinking water consumption figures: 70 kg/2L (adult male), 60 kg/2L (adult female) and 10 kg/1L (infant/child). After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 5:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO IODOSULFURON-METHYL-SODIUM AND METSULFURON-METHYL

Population subgroup	Aggregate MOE (Food + residential)	Aggregate level of concern (LOC)	Surface water EEC (ppb)	Ground water EEC (ppb)	Short-term DWLOC (ppb)
U.S. population—all	5.6e+05	1,000	0.338	0.105	1.7e+03
All infants (<1 year old)	2.5e+05	1,000	0.338	0.105	4.7e+02
Children (1-6 years old)	1.5e+05	1,000	0.338	0.105	4.6e+02
Children (7-12 years old)	2.1e+05	1,000	0.338	0.105	4.7e+02
Females (13-50 years old)	7.7e+05	1,000	0.338	0.105	1.5e+03
Males (13-19 years old)	5.1e+05	1,000	0.338	0.105	1.7e+03
Males (20+ years old)	7.4e+05	1,000	0.338	0.105	1.7e+03
Seniors (55+ years old)	8.4e+05	1,000	0.338	0.105	1.7e+03

4. *Intermediate-term risk.* Iodosulfuron-methyl-sodium is not registered for use on any sites that would result in residential exposure. However, for the purposes of this assessment, iodosulfuron-methyl-sodium and metsulfuron-methyl are being considered toxicologically equivalent. Metsulfuron-methyl is currently registered for use that could result in intermediate-term residential exposure. Therefore, the aggregate intermediate-term assessment considered exposure from food (chronic dietary), water, and residential uses.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1.1e+04 for all U.S. populations, 9.6e+03 and all infants (<1 year old), 3.9e+03 for children (1-6 years old), 6.6e+03 for children (7-12 years old), 1.7e+04 for females (13-50 years old), 1.0e+04 for males (13-19 years old), 1.7e+04 for males (20+ years old), and 2.0e+04 for seniors (55+ years old). These aggregate MOEs do not exceed the Agency's level of concern for food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of iodosulfuron-methyl-sodium and metsulfuron-methyl in ground and surface water. DWLOCs were then calculated using the following default body weights and drinking water consumption figures: 70kg/2L (adult male), 60kg/2L (adult female) and 10kg/1L (infant/child). After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 6:

TABLE 6.—AGGREGATE AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO IODOSULFURON-METHYL-SODIUM AND METSULFURON-METHYL

Population subgroup	Aggregate MOE (Food + residential)	Aggregate level of concern (LOC)	Surface water EEC (ppb)	Ground water EEC (ppb)	Intermediate-term DWLOC (ppb)
U.S. population—all	1.1e+04	1,000	0.338	0.105	2.6e+02
All infants (<1 year old)	9.6e+03	1,000	0.338	0.105	7.3e+01

TABLE 6.—AGGREGATE AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO IODOSULFURON-METHYL-SODIUM AND METSULFURON-METHYL—Continued

Population subgroup	Aggregate MOE (Food + residential)	Aggregate level of concern (LOC)	Surface water EEC (ppb)	Ground water EEC (ppb)	Intermediate-term DWLOC (ppb)
Children (1-6 years old)	3.9e+03	1,000	0.338	0.105	6.0e+01
Children (7-12 years old)	6.6e+03	1,000	0.338	0.105	6.9e+01
Females (13-50 years old)	1.7e+04	1,000	0.338	0.105	2.3e+02
Males (13-19 years old)	1.0e+04	1000	0.338	0.105	2.6e+02
Males (20+ years old)	1.7e+04	1,000	0.338	0.105	2.7e+02
Seniors (55+ years old)	2.0e+04	1,000	0.338	0.105	2.7e+02

5. *Aggregate cancer risk for U.S. population*. Given the available data, it is likely that iodosulfuron-methyl-sodium does not pose a cancer risk to humans. To date, cancer studies have proven negative and metsulfuron-methyl is classified as Group E (not likely human carcinogen) by Agency. Other registered sulfonyl urea compounds have also been found to be non-carcinogenic. There is some uncertainty here, however, due to the failure to test at a high enough dose in the mouse study. Nonetheless, given the following considerations, even assuming that the requested cancer study showed that iodosulfuron-methyl-sodium has some carcinogenic potential, EPA concludes that the cancer risk from exposure to iodosulfuron-methyl-sodium is negligible. First, cancer testing at relatively high doses has already had negative results, so the new study, at worst, could show iodosulfuron-methyl-sodium to be a relatively weak carcinogen. Second, human exposure to iodosulfuron-methyl-sodium is expected to be basically non-existent. Field corn will be the only registered use, and field corn is only consumed by animals not humans. Studies have shown that there is no reasonable expectation that finite residues of iodosulfuron-methyl-sodium will occur in livestock commodities as a result of livestock consuming iodosulfuron-methyl-sodium -treated corn. Finally, there are no residential uses for iodosulfuron-methyl-sodium.

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 iodosulfuron-methyl-sodium and metsulfuron-methyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The analytical methods used to analyze the storage stability, field trial, and processing samples were adequately validated and are appropriate for data gathering purposes. The proposed tolerance enforcement method has been adequately validated by an independent laboratory and was forwarded to the Analytical Chemistry Laboratory (ACL) for petition method validation (PMV). The ACL concludes that this method using HPLC/MS, in general, meets the requirements for a residue analytical method for tolerance enforcement as defined in the Residue Chemistry Test Guidelines, 860.1340. The petitioner submitted data which indicated that iodosulfuron-methyl-sodium and metsulfuron-methyl are not adequately recovered when using FDA multiresidue method protocols. This information has been forwarded to the FDA.

B. International Residue Limits

There is neither a Codex proposal, nor Canadian or Mexican limits, for residues of iodosulfuron-methyl-sodium in/on field corn. Harmonization is not an issue for this petition.

C. Conditions

EPA is able to successfully validate the proposed field corn enforcement method and concludes that the toxicological, residue chemistry, and occupational/residential databases are sufficient for a conditional field corn registration. The following data are being required to confirm the results of the studies already reviewed by the Agency and/or to complete the database requirements prior to approval of an unconditional registration of iodosulfuron-methyl-sodium:

i. Acute Neurotoxicity Study—to confirm the clinical signs of neurotoxicity.

ii. 28-Day Inhalation Toxicity Study - for further characterization of inhalation hazard for risk assessment; the protocol for the existing 90-day inhalation toxicity study (OPPTS 870.3465) should be followed with the exposure (treatment) ending after 28 days, instead of 90 days.

iii. 21-Day Dermal Toxicity Study

iv. Developmental Toxicity Study in Rabbits

v. Carcinogenicity Study in Mice

V. Conclusion

Therefore, the tolerance is 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 corn, field, grain at 0.03 ppm; corn, field, forage at 0.05 ppm; and corn, field, stover at 0.05 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409.

However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need To Do To File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–2002–0141 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 November 12, 2002.

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

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

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

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

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

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP–2002–0141 to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) 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). [1]This rule, however, has been repealed. 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 FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the

development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: September 3, 2002.

James Jones,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.580 is added to read as follows:

§ 180.580 Iodosulfuron-Methyl-Sodium; tolerances for residues.

(a) *General.* Tolerances are established 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 the following commodities:

Commodity	Parts per million
Corn, field, forage	0.05
Corn, field, grain	0.03
Corn, field, stover	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

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DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

49 CFR Parts 1200, 1201, 1241, 1242, 1243, and 1244

[STB Ex Parte No. 636]

Accounts, Records, and Reports—Technical Amendments

AGENCY: Surface Transportation Board, DOT.

ACTION: Final rules.

SUMMARY: The Surface Transportation Board (Board) amends regulations concerning accounts, records, and reports (Subchapter C) to reflect current agency organizational components, account titles and accounting references. In addition, General Instruction 1–18, Distribution of expenses for material, tools, fuel, lubricants, purchased services and general, which was inadvertently omitted in recent publications of the accounting regulations, is added.

EFFECTIVE DATE: These rules are effective September 30, 2002.

FOR FURTHER INFORMATION CONTACT: Paul Aguiar, (202) 565–1527. [Federal Information Relay Service (FIRS) for the hearing impaired: 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: Because these changes merely update obsolete references in the regulations or otherwise make revisions that are not substantive, we find good cause to dispense with notice and comment. 5 U.S.C. 553(b)(3) (A) and (B). These changes will be incorporated into the next edition of the Code of Federal Regulations.

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

Pursuant to 5 U.S.C. 605(b), we conclude that our action will not have a significant economic effect on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

List of Subjects

49 CFR Part 1200

Common carriers, Uniform System of Accounts.

49 CFR 1201

Railroads, Uniform System of Accounts.

49 CFR 1241

Railroads, Reporting and recordkeeping requirements.

49 CFR 1242

Railroads, Taxes.

49 CFR 1243

Railroads, Reporting and recordkeeping requirements.

49 CFR 1244

Freight, Railroads, Reporting and recordkeeping requirements.

Decided: August 28, 2002.

By the Board, Chairman Morgan and Vice Chairman Burkes.

Vernon A. Williams,

Secretary.

For the reasons set forth in the preamble, title 49, chapter X, parts 1200, 1201, 1241, 1242, 1243, and 1244 of the