

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.

**XII. 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: July 26, 2002

**Janet L. Andersen,**

*Director, Biopesticides and Pollution Prevention 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), 346(a) and 371.

2. Section 180.1143 is revised to read as follows:

**§ 180.1143 Methyl anthranilate; exemption from the requirement of a tolerance.**

Residues of methyl anthranilate, a biochemical pesticide, are exempt from the requirement of a tolerance in or on all food commodities, when used in accordance with good agricultural practices.

[FR Doc. 02-19808 Filed 8-6-02; 8:45 am]

**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-2002-0160; FRL-7189-2]

**Metsulfuron Methyl; Pesticide Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for combined residues of metsulfuron methyl and its metabolite methyl 2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]-4-hydroxybenzoate in or on sorghum, grain, grain at 0.1 part per million (ppm); sorghum, grain, forage and sorghum, grain, stover at 0.2 ppm. E.I. DuPont de Nemours & Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective August 7, 2002. Objections and requests for hearings, identified by docket ID number OPP-2002-0160, must be received on or before October 7, 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-2002-0160 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: James A. Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection

Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5697; e-mail address: Tompkins.jim@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](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/oppts/>

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-2002-0160. 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 March 19, 1998 (63 FR 13401) (FRL-5776-7), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide petition (PP 3F4215) by E.I. du Pont de Nemours & Company, Agricultural Products, P. O. Box 80038, Wilmington, DE 19880-0038. This notice included a summary of the petition prepared by E.I. Du Pont de Nemours & Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.428 be amended by establishing tolerances for combined residues of the herbicide metsulfuron methyl, methyl-2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl] amino]sulfonyl] benzoate, in or on sorghum grain at 0.1

ppm, sorghum forage at 0.2 ppm, and sorghum fodder at 0.2 ppm. Since the publication of the notice of filing, the name and address of the registrant has changed to E.I. DuPont de Nemours and Company, Crop Protection, Stine-Haskell Research Center, P.O. Box 30, Newark, DE 19714-0030. During the course of the review, the Agency determined the commodity listing for grain sorghum should be defined as sorghum, grain, forage; sorghum, grain, grain; and sorghum, grain, stover. The Agency also determined that the metabolite, methyl-2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino] sulfonyl]-4-hydroxybenzoate should be included in the tolerance expression for the sorghum, grain commodities. The Agency is also removing the time-limited tolerances established under paragraph b for sorghum, fodder at 0.5 ppm, sorghum, forage at 0.3 ppm, and sorghum, grain at 0.4 ppm, since these will be replaced by these tolerances.

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 tolerances for combined residues of metsulfuron methyl (methyl 2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]benzoate) and its metabolite methyl 2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]-4-hydroxybenzoate on sorghum, grain, forage at 0.2 ppm; sorghum, grain, grain at 0.1 ppm; and sorghum, grain, stover at 0.2 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 metsulfuron methyl 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	NOAEL = 68/64 (M/F) milligrams/kilograms/day (mg/kg/day) LOAEL = 521/659 (M/F) mg/kg/day based on transient decreases in body weight gain.
870.3200	21-Day dermal toxicity	dermal NOAEL = 125 mg/kg/day dermal LOAEL = 500 mg/kg/day based on skin lesions characterized by diffuse/multifocal dermatitis. systemic NOAEL: 125 mg/kg/day systemic LOAEL: 500 mg/kg/day based on increased incidence of diarrhea.

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

Guideline No.	Study Type	Results
870.3700a	Prenatal developmental in rodents	Maternal NOAEL = 250 mg/kg/day LOAEL = 1,000 mg/kg/day based on salivation and decreased body weight gain-compensatory increase after dosing stopped. Developmental NOAEL ≤ 1,000 mg/kg/day highest dose tested (HDT) LOAEL > 1000 mg/kg/day HDT.
870.3700b	Prenatal developmental in nonrodents	Maternal NOAEL = 25 mg/kg/day LOAEL = 1,000 mg/kg/day based on increased mortality, decreased body weight gains, and clinical signs of anorexia, red/orange urine and /or exudate. Developmental NOAEL ≥ 700 mg/kg/day HDT LOAEL > 700 mg/kg/day HDT.
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = 34/43(M/F) mg/kg/day LOAEL = 342/475 (M/F) mg/kg/day based on decreased pre-mating body weight gains by F0 males and females. Reproductive NOAEL ≥ 342/475 (M/F) mg/kg/day HDT LOAEL > 342/475 (M/F) mg/kg/day HDT. Offspring NOAEL ≥ 342/475 (M/F) mg/kg/day HDT LOAEL = 342/475 (M/F) mg/kg/day HDT.
870.4100a	Chronic toxicity rodents	NOAEL = 25 (M/F) mg/kg/day LOAEL = 250 (M/F) mg/kg/day based on decreased body weight and body weight gain.
870.4100b	Chronic toxicity dogs	NOAEL ≥ 125 (M/F) mg/kg/day HDT LOAEL = not determined
870.4200	Carcinogenicity rats	NOAEL = 25 (M/F) mg/kg/day LOAEL = 250 (M/F) mg/kg/day based on decreased body weight and body weight gain. (no) evidence of carcinogenicity
870.4300	Carcinogenicity mice	NOAEL ≥ 666/836 (M/F) mg/kg/day HDT LOAEL = not determined (no) evidence of carcinogenicity
870.5100	Gene Mutation <i>Salmo nella typhimurium</i> , Ames Test	Not mutagenic under the conditions of this study
870.5375	Cytogenetics <i>In vitro</i> mammalian chromosome aberrations-CHO cells (2 studies)	Metsulfuron methyl is not a clastogen under the conditions of this study.
870.5385	<i>In vivo</i> mammalian chromosome aberrations-rat bone marrow	Metsulfuron methyl did not induce a significant increase in chromosome aberrations in bone marrow cells when compared to the vehicle control group.
870.5395	<i>In vivo</i> mammalian cytogenetics-micronucleus assay in mice	Metsulfuron methyl is negative at the limit dose for clastogenic activity in the micronucleus assay in bone marrow cells.
870.5550	Other Effects UDS assay in primary rat hepatocytes/ mammalian cell culture	Metsulfuron methyl tested negatively for UDS in mammalian hepatocytes <i>in vivo</i>

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

Guideline No.	Study Type	Results
870.7485	Metabolism and pharmacokinetics	<p>Overall recovery of metsulfuron methyl among the treatment groups was acceptable (–91.6–103.8 %). The primary route of excretion was via the urine which accounted for approx. 71–95% (78–96% if cage wash radioactivity is considered) among the various treatment groups. Fecal elimination was 4.8–13.3%. Excretion was almost complete within 48 hours. Based on time course urinary and fecal excretion data, elimination half-lives (males and females) were estimated to be 13–16 hours for Group I (single low dose), 9–12 hours for Group II (21–day dietary exposure), and 23–29 hours for Group III (single high dose) which affirmed notable alteration of absorption and/or excretion processes in the high-dose group.</p> <p>Tissue burdens were minimal (generally &lt; 0.1% to 1%) regardless of exposure protocol; the gastrointestinal tract, carcass, and skin had the highest concentrations of radioactivity. For the single or repeated low dose groups, the tissue content was generally ≤0.03 ppm. In the high-dose group, females had somewhat higher tissue burdens (ranging from 0.8 ppm in brain to 7.1 ppm in liver and 8.0 ppm in kidneys) than did males (0.1 ppm in blood to 1.6 ppm in liver and 2.6 ppm in kidneys). No evidence for sequestration of the test article or its biotransformation products.</p> <p>Four metabolites and parent were recovered in both urine and feces in all treatment groups. Parent compound accounted for most of the urinary and fecal radioactivity (77–90% and 1.8–6.2% of the administered dose, respectively). Metab. I was consistent with (methyl 2-[(amino)sulfonyl] benzoate); Metab. II - (2-[(amino)sulfonyl]-benzoic acid); and Metab. III was consistent with (methyl 2-[[[(amino)carbonyl]amino] sulfonyl] benzoate). Metab. I and II appeared to result from sequential hydrolysis reactions terminating in the formation of saccharin while Metab. III was formed by cleavage of the two ring structures. Total metabolites (in urine + feces of each group) accounted for approximately 5.4–8.2% of the administered dose. The metabolite profiles were qualitatively similar for urine and feces in that parent compound and the four metabolites (saccharin, Metabolites I, II, and III) were found in both matrices.</p>

### 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 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<sup>-6</sup> 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<sub>cancer</sub> = point of departure/exposures) is calculated. A summary of the toxicological endpoints for metsulfuron methyl used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR METSULFURON METHYL 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 general population including infants and children	NA	NA	An endpoint attributable to a single dose was not identified. Quantitation of acute dietary risk is not appropriate
Chronic Dietary all populations	NOAEL= 25 mg/kg/day UF = 100 Chronic RfD = 0.25 mg/kg/day	FQPA SF = 1 cPAD = 0.25 mg/kg/day	Chronic/oncogenicity study in the rat LOAEL = 250 mg/kg/day based on decreased body weight and body weight gain.
Short- and Intermediate-Term Incidental Oral (1 to 30 days and 1 month to 6 months) (Residential)	NOAEL= 34 mg/kg/day	LOC for MOE = 100 (Residential)	2-generation reproduction study in rats based on decreased pre-mating (F0) body weights in male and female rats; systemic effects were seen up to 13 weeks at the LOAEL of 342 mg/kg/day.
Short-, Intermediate-, and Long-Term Dermal (1 to 30 days; 1 month to 6 months; and > 6 months) (Residential)	NOAEL= 125 mg/kg/day	LOC for MOE = 100 (Residential)	21-day dermal toxicity in rabbits based on an increased incidence of diarrhea in rabbits at the LOAEL of 500 mg/kg/day.
Short- and Intermediate-Term Inhalation (1 to 30 days and 1 month to 6 months) (Residential)	oral study NOAEL= 34 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	2-generation reproduction study in rats LOAEL = 342 mg/kg/day based on decreased body weights in pre-mating (F0) animals for up to 13 weeks.
Long-Term Inhalation (6 months to lifetime) (Residential)	oral study NOAEL= 25 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Chronic/oncogenicity study in the rat LOAEL = 250 mg/kg/day based on decreased body weight and body weight gain.
Cancer (oral, dermal, inhalation) - not likely to be carcinogenic.			

\* 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.* Tolerances have been established (40 CFR 180.428) for the combined residues of metsulfuron methyl and its metabolite methyl 2-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]-4-hydroxybenzoate, in or on a variety of raw agricultural commodities.

Tolerances have been established for residues of metsulfuron methyl in fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.1 ppm; kidney of cattle, goats, hogs, horse, and sheep at 0.5 ppm, and milk at 0.05 ppm. Risk assessments were conducted by EPA to assess dietary exposures from metsulfuron methyl 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 one day or single exposure. No acute dietary endpoint attributable to a single dose was identified. Therefore, quantification of acute dietary risk was not performed.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment 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 chronic exposure assessments: Tolerance residue levels, 100% crop treated (CT) for all commodities, and DEEM® defaults for all processing factors. In addition, the chemical iodosulfuron methyl recently received a favorable recommendation for tolerances on corn, field, grain at 0.03 ppm, and corn, field, stover and forage at 0.05 ppm. Since the major metabolite of iodosulfuron methyl is metsulfuron methyl, these tolerances were included in the dietary exposure assessment.

iii. *Cancer.* Since metsulfuron methyl has been classified as “Not likely to be a human carcinogen”, a cancer risk assessment was not performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for 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 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 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 metsulfuron methyl they are further discussed in the aggregate risk sections in Unit E.

Based on the PRZM/EXAMS used to estimate the concentration of metsulfuron methyl in surface water and FIRST to estimate the concentration of metsulfuron methyl as a metabolite of iodosulfuron methyl since FIRST has been used in estimating the drinking water values for corn use with the proposed label for iodosulfuron methyl and SCI-GROW models the EECs of metsulfuron methyl for acute exposures are estimated to be 1.37 parts per billion (ppb) for surface water and 0.104 ppb for ground water. The EECs for chronic exposures are estimated to be 0.332 ppb for surface water and 0.104 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).

Metsulfuron methyl is currently registered for use on the following residential non-dietary sites: ornamental turf such as lawns, parks, cemeteries, golf courses (fairways, aprons, tees, and

roughs) and similar non-crop areas. It has been determined that there is a potential for exposure in residential settings during the application process for homeowners who purchase and use products containing metsulfuron methyl. There is also a potential for exposure from entering areas previously treated with metsulfuron methyl such as turf (i.e., lawns and parks) and golf courses that could lead to exposures for adults and children. As a result, risk assessments have been completed for both residential handler and postapplication scenarios. Based on the use pattern, short-term exposure is expected. The risk assessment was conducted using the following residential exposure assumptions: The assumptions and factors used in the risk calculations for handler exposure scenarios include:

- Exposure factors used to calculate daily exposures to handlers are based on applicable data if available. For lack of appropriate data, values from a scenario deemed similar enough by the assessor might be used.

- The Agency always considers the maximum application rates allowed by labels in its risk assessments to consider what is legally possible based on the label. If additional information such as average or typical rates are available, these values are also used to allow risk managers to make a more informed risk management decision.

The Agency bases calculations for residential risk assessments on what would reasonably be treated by homeowners such as the size of the lawn, or the size of a garden. This information was used by the Agency to define chemical values for handlers which in turn are coupled with unit exposure to calculate risks.

Noncancer risk were calculated using the Margins of Exposure (MOE) for two scenarios, (1) low pressure handwand and (2) hose-end sprayer. Residential risk assessments apply an additional FQPA safety factor to the risk when appropriate, which defines the level of concern. In the case of metsulfuron methyl, no additional safety factor (1x) is necessary to protect the safety of infants and children in assessing metsulfuron methyl risks and exposure.

Children may also be exposed by incidental non-dietary ingestion of pesticide residues on residential lawns from hand to mouth transfer. This scenario assumes that pesticide residues are transferred to the skin of toddlers playing on recreational or residential lawns and turfs and are subsequently ingested as a result of hand-to-mouth transfer. The method for estimating postapplication incidental ingestion

dose from pesticide residues on turf is based on the following assumptions.

- On the day of application 5% of the application rate are available on the turfgrass as dislodgeable residue. The 5% transfer factor is based on data by Clothier (2000). (Science Advisory Council for Exposure Policy #12: Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessments; Revised February 22, 2001).

- Postapplication activities are assessed on the same day the pesticide is applied since it is assumed that toddlers could play on the lawn immediately after application. For subsequent days after application, an assumed 10% pesticide dissipation rate is used.

- The median surface area of both hands is 20 cm<sup>2</sup> for a toddler. Since the hand-to-mouth has been defined by the February 1999 Science Advisory Panel (SAP) as 1 to 3 fingers (5.7 to 17.1 cm<sup>2</sup>) a screening level of 20 cm<sup>2</sup> was selected based on the assumption that each hand-to-mouth event equals 3 fingers (Science Advisory Council for Exposure Policy #12: Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessments; Revised February 22, 2001).

- It is assumed that there is a one-to-one relationship between the dislodgeable residues on the turf and on the surface area of the skin after contact.

- The mean rate of hand-to-mouth activity is 20 events/hr for toddlers age 2 to 5 years old for short-term exposure. The 1999 SAP recommended the use of the 90<sup>th</sup> percentile value of 20 events based on reported hourly frequencies of hand-to-mouth events in pre school children aged 2 to 5 years observations using video tapes by Reed et al. (Science Advisory Council for Exposure Policy #12: Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessments; Revised February 22, 2001).

- The duration of exposure for toddlers is assumed to be 2 hours per day. This is based on the 75<sup>th</sup> percentile value (i.e., 120 min/day) for playing on grass for ages 1 to 4 years and 5-11 years (Tsang and Klepeis 1996 as cited on pag 15-79 of EPA 1997, Exposure Factors Handbook EFH).

- Toddlers (age 3 years) used to represent the 1 to 6 year old group, are assumed to weigh 15 kg. This is the mean of the median values for male and female children (US EPA 1996a).

- A saliva extraction factor of 50% was used (Science Advisory Council for Exposure Policy # 12: Recommended Revisions to the Standard Operating

Procedures (SOPs) for Residential Exposure Assessments; Revised February 22, 2001).

These values were used to calculate the MOE for incidental ingestion of pesticide residues from hand to mouth transfer.

Children (toddlers) may be exposed postapplication through ingestion of pesticide treated turfgrass. This scenario assumes that turf is ingested by toddlers who play on treated areas (i.e., yards, playgrounds). The method for estimating postapplication ingestion exposure to pesticide residues in turfgrass is based on the following assumptions:

- On the day of application 5% of the application rate are available to be ingested. This is assumed to represent an upper-percentile input.
- Postapplication must be assessed on the same day the pesticide is applied because it is assumed that toddlers could play on the lawn immediately after application.
- The assumed ingestion rate for grass for toddlers (age 3 years) is 25 cm<sup>2</sup>/day. This value is intended to represent the approximate area from which a child may grasp a handful of grass. This is assumed to represent an upper-percentile input.
- Toddlers (age 3 years), used to represent the 1 to 6 year old age group, are assumed to weigh 15 kg (U.S. EPA, 1996).

These values were then used to calculate the MOE for ingestion of pesticide treated turf. Children may be exposed postapplication through ingestion of soil from pesticide treated residential areas. This scenario assumes that pesticide residues in soil are ingested by toddlers who play on treated areas as a result of normal mouthing activities. The method for estimating postapplication ingestion exposure to pesticide residues in soil is based on the following assumptions:

- On the day of application, it is assumed that 100% of the application rate are located within the soil's uppermost 1 cm.
- Postapplication must be assessed on the same day the pesticide is applied because it is assumed that toddlers could play on the lawn or other outdoor treated area immediately after application.
- The assumed soil ingestion rate for children (ages 1-6) is 100 mg/day. This is the mean soil ingestion rate value recommended by EPA for use in exposure/risk assessments (U.S. EPA, 1996).
- Toddlers (age 3 years), used to represent the 1 to 6 year old age group,

are assumed to weigh 15 kg (U.S. EPA, 1996).

These values were then used to calculate the MOE for soil ingestion of pesticide treated areas.

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 metsulfuron methyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, metsulfuron methyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that metsulfuron methyl has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *In general.* FFDC 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 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 no quantitative or qualitative evidence of increased susceptibility in the pre-natal studies in rat and rabbit or in the multi-generation reproduction study evaluating pre- and post-natal exposure.

3. *Conclusion.* There is a complete toxicity data base for metsulfuron methyl and exposure data are complete

or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed because there is no quantitative or qualitative evidence of increased susceptibility in the pre-natal studies in rat and rabbit or in the multi-generation reproduction study evaluating pre- and post-natal exposure; a developmental neurotoxicity study is not required, and there are no data deficiencies or residual uncertainties identified in the hazard and exposure databases for metsulfuron methyl. The only study outstanding for metsulfuron methyl is a 28-day inhalation (nose only) study which is required due to the concern for the occupational exposure via this route based on current use pattern.

#### *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 USEPA 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, EPA concludes with reasonable certainty that exposures

to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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, EPA 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.* Because there was no acute endpoint attributable to a single dose identified for metsulfuron methyl, EPA does not expect metsulfuron methyl to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to metsulfuron methyl from food will utilize < 1% of the cPAD for the U.S. population, < 1% of the

cPAD for all infants and <1% of the cPAD for children 1–6 years old. Based on the use pattern, chronic residential exposure to residues of metsulfuron methyl is not expected. In addition, there is potential for chronic dietary exposure to 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 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO METSULFURON METHYL

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.25	<1	0.332	0.104	8700
Children 1–6 years	0.25	<1	0.332	0.104	2500
Females 13–50 years	0.25	<1	0.332	0.104	7500
Males 13–19 years	0.25	<1	0.332	0.104	8700

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

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

and water and short-term exposures for metsulfuron methyl.

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 12,000 for children-short term aggregate, and 39,000 for adults-short term aggregate. These aggregate MOEs do not exceed the Agency's level of concern for aggregate

exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of metsulfuron methyl in ground and surface water. 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 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO 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)
Children	12,000	100	0.332	0.104	3,400
Adult	39,000	100	0.332	0.104	12,000

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

Though residential exposure could occur with the use of metsulfuron methyl, the potential intermediate-term exposures were not aggregated with chronic dietary food and water exposures because the short- and intermediate-term endpoints are the same (NOAEL = 34 mg/kg/day) and the short-term aggregate risk assessment which includes the same routes of exposure is worst-case and below the Agency level of concern. Therefore, based on the best available data and current policies, potential risks do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* Since metsulfuron methyl has been classified as "Not likely to be a human carcinogen", metsulfuron methyl 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, and to infants and children from aggregate exposure to metsulfuron methyl residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate methods are available for enforcement of tolerances for residues of metsulfuron methyl in/on plant and animal commodities. PAM Vol. II lists Methods I and III which are respectively

capable of determining residues of metsulfuron methyl *per se* (LOQ = 0.02 ppm for wheat grain; 0.05 ppm for forage and straw) and combined Metabolites A and A1 (LOQ = ppm for grain and forage; 0.1 ppm for straw); Method II determines parent compound in ruminant tissues and milk to a lower limit of 0.02–0.05 ppm.

##### B. International Residue Limits

There are currently no Codex, Canadian, or Mexican maximum residue levels (MRLs) for metsulfuron methyl, thus international harmonization is not an issue.

##### C. Conditions

A 28-day inhalation (nose-only) study is required as a condition of registration.

## V. Conclusion

Therefore, tolerances are established for combined residues of metsulfuron methyl, methyl 2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]benzoate and its metabolite methyl 2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]-4-hydroxybenzoate in or on sorghum, grain, forage at 0.2 ppm; sorghum, grain, grain at 0.1 ppm; and sorghum, grain, stover at 0.2 ppm. The text of paragraph (b) is removed and reserved.

## 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 ID number OPP-2002-0160 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 October 7, 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 (1900), 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. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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 (202) 260-4865.

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](mailto: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-2002-0160, 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](mailto: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). 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 FFDC 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 FFDC 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: July 24, 2002

**Peter Caulkins,**

*Acting 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), 346(a) and 371.

2. Section 180.428 is amended as follows:

i. By alphabetically adding entries for the commodities "sorghum, grain, forage;" "sorghum, grain, grain", and "sorghum, grain, stover" to the table in paragraph (a)(1) as set forth below.

ii. The text of paragraph (b) is removed and reserved.

#### § 180.428 Metsulfuron methyl; tolerances for residues.

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

Commodity	Parts per million
* * *	* *
Sorghum, grain, forage ...	0.2
Sorghum, grain, grain .....	0.1
Sorghum, grain, stover ...	0.2
* * *	* *

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

\* \* \* \* \*

[FR Doc. 02-19807 Filed 8-6-02; 8:45 am]

BILLING CODE 6560-50-S

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[OPP-2002-0148; FRL-7188-3]

#### 2-Propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt; Tolerance Exemption

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of 2-propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt; when used as an inert ingredient in or on growing crops, when applied to raw agricultural commodities after harvest, or to animals. MeadWestaco Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 2-propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt.

**DATES:** This regulation is effective August 7, 2002. Objections and requests for hearings, identified by docket ID number OPP-2002-0148, must be received on or before October 7, 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 VIII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify