be accomplished by the new operator per the previous operator's schedule and inspection method, or the new operator's schedule and inspection method, at whichever time would result in the earlier accomplishment for that SSI inspection. The compliance time for accomplishment of this inspection must be measured from the last inspection accomplished by the previous operator. After each inspection has been performed once, each subsequent inspection must be performed per the new operator's schedule and inspection method.

(2) For airplanes that have not been inspected per this AD, the inspection of each SSI required by this AD must be accomplished either prior to adding the airplane to the air carrier's operations specification, or per a schedule and an inspection method approved by the Manager, Seattle ACO. After each inspection has been performed once, each subsequent inspection must be performed per the new operator's schedule.

Alternative Methods of Compliance

(g)(1) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

(2) Alternative methods of compliance, approved previously per AD 94–15–12, amendment 39–8983, are approved as alternative methods of compliance with paragraphs (a) and (e) of this AD.

(3) Alternative methods of compliance, approved previously per AD 94–15–18, amendment 39–8989, are approved as alternative methods of compliance with paragraphs (b) and (e) of this AD.

(4) Alternative methods of compliance, approved previously per AD 94–15–18 and AD 94–15–12 that provide alternative inspections are approved as alternative methods of compliance for the inspections of that area only in this AD.

Note 7: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(h) Special flight permits may be issued per sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(i) Unless otherwise specified in this AD, the actions shall be done in accordance with Boeing Document No. D6–35655, ''Supplemental Structural Inspection Document for 747–100SR,'' dated April 2, 1986; Boeing Document No. D6–35022, Volumes 1 and 2, ''Supplemental Structural Inspection Document (SSID) for Model 747 Airplanes,'' Revision E, dated June 17, 1993; and Boeing Document No. D6–35022, ''Supplemental Structural Inspection Document (SSID) for Model 747 Airplanes,'' Revision G, dated December 2000; as applicable.

(1) The incorporation by reference of Boeing Document D6–35022, ''Supplemental Structural Inspection Document (SSID) for Model 747 Airplanes,'' Revision G, dated December 2000, is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This document contains the following effective pages:

Revision level page number	Shown on page
List of Effective Pages. Pages A.1 thru A.10	G

(The issue date of Revision G is indicated only on the title page; no other page of the document is dated.)

(2) The incorporation by reference of Boeing Document No. D6–35022, Volumes 1 and 2, ''Supplemental Structural Inspection Document (SSID) for Model 747 Airplanes,'' Revision E, dated June 17, 1993, was approved previously by the Director of the Federal Register as of September 12, 1994 (59 FR 41233, August 11, 1994).

(3) The incorporation by reference of Boeing Document No. D6–35655, ''Supplemental Structural Inspection Document for 747–100SR,'' dated April 2, 1986, was approved previously by the Director of the Federal Register as of August 10, 1994 (59 FR 37933, July 26, 1994).

(4) Copies may be obtained from Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(j) This amendment becomes effective on May 12, 2004.

Issued in Renton, Washington, on March 24, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–7449 Filed 4–6–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 606, and 610

[Docket No. 2002N–0204]

Bar Code Label Requirement for Human Drug Products and Biological Products; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of February 26, 2004 (69 FR 9120). The document included typographical and inadvertent errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy and Planning (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0587.

SUPPLEMENTARY INFORMATION: In FR Doc. 04–4249, appearing on page 9120 in the **Federal Register** of Thursday, February 26, 2004, the following corrections are made:

■ 1. On page 9151, in the third column, the first sentence of the first full paragraph, is corrected to read ''We estimate that the rule provides net benefits to society of $4.3 billion to $4.5 billion annually, depending on whether a discount rate of 3 percent or 7 percent is used.''

■ 2. On page 9167, in the first column, the first sentence under the heading ''*P. Small Business Analysis and Discussion of Alternatives*'' is corrected to read ''For the reasons cited in the following paragraphs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.''

Dated: March 31, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–7815 Filed 4–6–04; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0257; FRL–7351–4]

Mesosulfuron-Methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of mesosulfuron-methyl in or on wheat. Bayer CropScience 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 April 7, 2004. Objections and requests for hearings, identified by docket ID

number OPP–2003–0257, must be received on or before June 7, 2004.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; 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 potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., Agricultural workers; Greenhouse, nursery, and floriculture workers; Farmers.
- Animal production (NAICS 112), e.g., Cattle ranchers and farmers, Dairy cattle farmers, Livestock farmers.
- Food manufacturing (NAICS 311), e.g., Agricultural workers; Farmers; Greenhouse, nursery, and floriculture workers; Ranchers; Pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., Agricultural workers; Commercial applicators; Farmers; Greenhouse, nursery, and floriculture workers; Residential users.

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

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0257. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRI), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of October 22, 2003 (68 FR 60378) (FRL–7322–5), 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 1F6298) by Bayer CropScience, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. That notice included a summary of the petition prepared by Bayer CropScience, the registrant. One comment was received in response to the notice of filing from a private citizen.

The petition requested that 40 CFR 180.428 be amended by establishing a tolerance for residues of the herbicide methyl 2-[[[[(4,6-dimethoxy-2-pyrimidinyl) amino]carbonyl]amino]sulfonyl]-4-[[(methylsulfonyl)amino] methyl]benzoate, mesosulfuron-methyl, in or on the raw agricultural commodities wheat grain at 0.03, wheat forage at 0.60, wheat straw at 0.30, wheat hay at 0.06, wheat germ at 0.10, aspirated grain fractions at 0.25, and milled byproducts at 0.03 parts per million (ppm). EPA determined that the tolerance for aspirated grain fractions should be 0.60 ppm instead of 0.25 ppm as was proposed by the registrant based on the results of submitted residue studies. Further, based on the results of submitted studies of residues in animal commodities, EPA determined that a tolerance should be set for meat byproducts of cattle, goat, horse, and sheep at the limit of quantitation (LOQ) for the enforcement method, which is 0.01 ppm. EPA also determined that no tolerance is needed for milled byproducts because mesosulfuron does not concentrate in milled byproducts and, therefore, residues in milled byproducts are covered by the tolerance for wheat grain.

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA 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) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this

action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of mesosulfuron-methyl on the raw agricultural commodities aspirated grain fractions at 0.60 ppm, meat byproducts of cattle, goat, horse, and sheep meat byproducts at 0.01 ppm, wheat forage at 0.60 ppm, wheat germ at 0.10 ppm, wheat grain at 0.03 ppm, wheat hay at 0.06 ppm, and wheat straw at 0.30 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 mesosulfuron-methyl are discussed in Table 1 of this unit 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.—TOXICOLOGY PROFILE FOR MESOSULFURON-METHYL

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents	NOAEL = 908/977 Male/Female (M/F) milligram/kilogram/day (mg/kg/day) LOAEL = not observed.
870.3100	90-Day oral toxicity rodents	NOAEL = 1,238.3/ 1,603.4 M/F mg/kg/day LOAEL = not observed.
870.3150	90-Day oral toxicity in nonrodents	NOAEL = 648/734 M/F mg/kg/day LOAEL = not observed.
870.3200	21/28-Day dermal toxicity	Study not required.
870.3250	90-Day dermal toxicity	Study not required.
870.3465	90-Day inhalation toxicity	Study not required.
870.3700	Prenatal developmental in rodents	Maternal NOAEL = 1,000 mg/kg/day LOAEL = not observed Developmental NOAEL = 1,000 mg/kg/day LOAEL = not observed
870.3700	Prenatal developmental in nonrodents	Maternal NOAEL = 1,000 mg/kg/day LOAEL = not observed Developmental NOAEL = 1,000 mg/kg/day LOAEL = not observed
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = 1,175.2/ 1,387.6 M/F mg/kg/day LOAEL = not observed Reproductive NOAEL = 1,175.2/ 1,387.6 M/F mg/kg/day LOAEL = not observed Offspring NOAEL = 1,175.2/ 1,387.6 M/F mg/kg/day LOAEL = not observed
870.4100	Chronic toxicity rodents	NOAEL = 764/ 952 M/F mg/kg/day LOAEL = not observed.
870.4100	Chronic toxicity dogs	NOAEL = 155 M mg/kg/day LOAEL = 574 M mg/kg/day based on increased mucus secretion in the cardiac and fundic sections of the stomach of the males dogs (highest dose tested (HDT)) and chronic superficial gastritis (1/6).
870.4200	Carcinogenicity rats	NOAEL = 764/952 M/F mg/kg/day LOAEL = not observed. (no) evidence of carcinogenicity
870.4300	Carcinogenicity mice	NOAEL = 1,069.4/ 1,355.6 M/F mg/kg/day LOAEL = not observed. (no) evidence of carcinogenicity
870.5100 Gene Mutation	Bacterial reverse mutation assay	Negative ± S9 up to cytotoxic 5,000 μgram (g)/milliliter (ml) plate
870.5300 Gene Mutation	Mammalian cell culture	Negative ± S9 up to cytotoxic 2,500 μg/ml and precipitation 250 μg/ml
870.5395 Cytogenetics	Micronucleus test on mouse	Negative at the HDT (limit dose) 2,000 mg/kg.

TABLE 1.—TOXICOLOGY PROFILE FOR MESOSULFURON-METHYL—Continued

Guideline No.	Study Type	Results
870.5375 Cytogenetics	Chromosomal aberrations	Negative ± S9 precipitation ≥100 μg/ml
870.5550 Other Effects	Unscheduled DNA	Negative ± S9 precipitation ≥100 μg/ml
870.6200	Acute neurotoxicity screening battery	Study not required.
870.6200	Subchronic neurotoxicity screening battery	Study not required.
870.6300	Developmental neurotoxicity	Study not required.
870.7485	Metabolism and pharmacokinetics	Overall recovery of the radioactive dose was 98–103%, predominantly recovered in the feces within 24 hours (80–97% dose). The onset of absorption was quick (detected in the blood 15 minutes post-dose), but the quantity absorbed was low. At 72 hours post-dose (or 168 hours following the final dose of the repeated study), urinary excretion accounted for 1–4% (except 13–14% in the 10 mg/kg animals), and radioactivity in the bile of the 10 mg/kg animals was only 7–9% dose by 12 hours post-dose. The 10 mg/kg rats had slightly more radioactivity in urine and slightly less radioactivity in feces compared to the 1,000 mg/kg rats. Bioaccumulation was not observed, and radioactivity in tissues was <0.1% dose in all animals at each study termination.
870.7600	Dermal penetration	100% dermal absorption factor (default value)
Special studies		Study not required.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (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 intraspecies differences.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

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 an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). 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 mesosulfuron-methyl used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR MESOSULFURON-METHYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary: (All populations)	No study in the toxicology database indicated there is an acute dietary endpoint of concern.		
Chronic Dietary: (All populations)	NOAEL= 155 mg/kg/day UF = 100 Chronic RfD = 1.55 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD/FQPA SF = 1.55 mg/kg/day	Chronic oral toxicity study in dogs. LOAEL = 574 mg/kg/day [M] based on increased mucus secretion in the cardiac and fundic sections of the stomach, and chronic superficial gastritis (1/6) of male dogs.
Incidental Oral: (Short- and Intermediate-Term)	No residential uses are proposed for mesosulfuron-methyl.		
Dermal Exposure: (Short-, Intermediate-, and Long-Term)	Quantification of dermal risk is not required for this route of exposure due to the lack of dermal, systemic, neurological, and developmental toxicity concerns.		
Inhalation Exposure: (Short-, Intermediate-, and Long-Term)	Oral NOAEL= 155 mg/kg/day (100% Oral Absorption Factor)	Residential LOC for MOE = NA Occupational LOC for MOE = 100	Chronic oral toxicity study in dogs. LOAEL = 574 mg/kg/day [M] based on increased mucus secretion in the cardiac and fundic sections of the stomach, and chronic superficial gastritis (1/6) of male dogs.
Cancer: (Oral, Dermal, and Inhalation)	"Not likely to be carcinogenic to humans" based on the lack of evidence of carcinogenicity in the rats and mice.		

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no-observed-adverse-effect-level, LOAEL = lowest-observed-adverse-effect-level, PAD = population adjusted dose (a = acute, c = chronic), RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have been proposed wheat and meat byproducts of cattle, goat, horse, and sheep. Risk assessments were conducted by EPA to assess dietary exposures from mesosulfuron-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 1-day or single exposure.

Based on available data, a suitable endpoint for acute dietary risk assessment was not identified because no effects were observed in oral toxicity studies (including developmental studies) which could be attributed to a single-dose exposure. Therefore, an acute dietary risk assessment was not performed.

ii. *Chronic exposure*. In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID^T) and the Lifeline^T Model Version 2.0,, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: tolerance level residues, default processing factors, and 100% crop treated data, with no refinements.

iii. *Cancer*. A quantitative cancer dietary exposure cancer dietary assessment was not conducted because mesosulfuron-methyl was classified as "not likely to be carcinogenic to humans.''

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

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/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. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include 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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used 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 mesosulfuron-methyl they are further discussed in the aggregate risk sections in Unit III.E.

EPA determined that three degradates may be present at sufficient quantities (found in aerobic soil and aerobic and anaerobic aquatic environments at levels ranging from 5% to 20% of the applied dose) to warrant inclusion in the drinking water assessment. The three degradates are 2-[3-(4,6-dimethoxypyrimidin-2-yl)ureidosulfonyl]-4-methanesulfonamidomethyl benzoic acid (AE F154851), methyl-2-[3-(4-hydroxy-6-methoxypyrimidin-2-yl)ureidosulfonyl]-4-methanesulfonamidomethylbenzoate (AE F160459), and 2-[3-(4-hydroxy-6-methoxypyrimidine-2-yl)ureidosulfonyl]-4-methanesulfonamidomethyl benzoic acid (AE F160460). EPA determined that these degradates were not of concern for food due to low toxicity and low level of exposure in food, and that, for food, parent mesosulfuron-methyl is the only residue of concern.

Based on the FIRST and SCI-GROW models, the EECs of mesosulfuron-methyl and its degradates for chronic exposures are estimated to be 0.15 parts per billion (ppb) for surface water and 0.015 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).

Mesosulfuron-methyl is not registered for use on any sites that would result in residential exposure.

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to mesosulfuron-methyl and any other substances and mesosulfuron-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 mesosulfuron-methyl has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. There are no concerns or residual uncertainties for pre- and/or post-natal toxicity.

3. *Conclusion*. There is a complete toxicity data base for mesosulfuron-methyl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X FQPA safety factor to protect infants and children should be removed. The FQPA factor is removed because:

i. There is no evidence of increased quantitative/qualitative susceptibility in the available acceptable guideline studies.

ii. There are no residual uncertainties for pre- and/or post-natal toxicity.

iii. Clear NOAELs have been identified for the effects of concern.

iv. No adverse effects were noted at the highest dose tested in the acceptable guideline developmental toxicity and reproduction studies in rats, and developmental toxicity study in rabbits.

v. There are no proposed residential uses.

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 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 EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/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*. Based on available data, a suitable endpoint for acute dietary risk assessment was not identified because no effects were observed in oral toxicity studies (including developmental studies) which could be attributed to a single-dose exposure. Therefore, mesosulfuron-methyl is not expected to pose an acute dietary risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to mesosulfuron-methyl from food will utilize <1% of the cPAD for the U.S. population, <1% of the cPAD for infants < 1 year old, and <1% of the cPAD for children 1–12. There are no residential uses for mesosulfuron-methyl that result in chronic residential exposure to mesosulfuron-methyl. In addition, there is potential for chronic dietary exposure to mesosulfuron-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 Table 3 of this unit:

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

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
General U.S. Population	1.55	<1	0.154	0.015	54,000
All Infants (< 1 year old)	1.55	<1	0.154	0.015	16,000
Children 1–2 years old	1.55	<1	0.154	0.015	16,000
Children 3–5 years old	1.55	<1	0.154	0.015	16,000
Children 6–12 years old	1.55	<1	0.154	0.015	16,000
Youth 13–19 years old	1.55	<1	0.154	0.015	47,000
Females 13–49 years old	1.55	<1	0.154	0.015	47,000
Adults 20–49 years old	1.55	<1	0.154	0.015	54,000

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).

Mesosulfuron-methyl is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

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).

Mesosulfuron-methyl is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. The EPA classified mesosulfuron-methyl as "not likely to be carcinogenic to humans.'' Therefore, mesosulfuron-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 mesosulfuron-methyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Method EM F08/99-0 (liquid chromatography/mass spectroscopy/mass spectroscopy) is adequate for tolerance enforcement for mesosulfuron-methyl in plant commodities. The method has been subjected to successful independent laboratory validations (ILVs), satisfactory radiovalidation data have been submitted, and the method has been reviewed by an EPA chemist.

Method EM F07/00-0 (liquid chromatography/mass spectroscopy/mass spectroscopy) is adequate for tolerance enforcement for mesosulfuron-methyl in livestock commodities. The method has been reviewed by an EPA chemist. Although there has been no independent lab validation of this method in animal commodities, EPA determined that independent lab validation is not necessary because:

1. This method (F07/00-0) is essentially identical to the plant method (EM F08/99-0), which was succesfully validated in an independent laboratory, and

2. EPA has previously validated single-analyte methods for members of this class of chemicals which use similar extraction and cleanup procedures.

Both methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are currently no Codex, Canadian, or Mexican MRL's or tolerances for mesosulfuron-methyl on wheat.

C. Conditions

The following are being imposed as conditions of registration of mesosulfuron-methyl:

- A one year storage stability (guideline 830.6317) and corrosion characteristics (guideline 830.6320) must be submitted to EPA by October 1, 2005.
- Storage stability data must be submitted to demonstrate the stability of mesosulfuron-methyl residues in/on wheat forage stored frozen for up to 26 months and in/on wheat grain and straw stored frozen for up to 25 months by October 1, 2005.

D. Response to Comments

The one comment received on the tolerance petition stated: "I oppose any tolerance allowance granted for mesosulfuron-methyl on any food product. I am totally against any chemicals in the food I eat. I do not think we should allow these chemical polluters in our food. I know industry waves lots of money to get these

approvals. The American public disapproves of EPA granting these. EPA is even being sued for these approvals. I am totally against granting approval of this pesticide on any food in any amount at all. I prefer zero tolerance.''

Response: This commenter has a disagreement not with how EPA is implementing FFDCA section 408 as it applies to the tolerance petition on mesosulfuron-methyl but with FFDCA section 408 itself. The commenter—and in the commenter's view the general American public as well—would prefer that FFDCA section 408 bar the establishment of any tolerance permitting any pesticide residues to remain on food. That, however, is not the law. Rather, FFDCA section 408 as it is currently written establishes a safety standard under which EPA must evaluate petitions to establish tolerances. EPA has applied that safety standard in ruling on the mesosulfuron-methyl tolerance petition. EPA cannot take a commenter's policy preference on what the FFDCA should say into account in ruling on application of the FFDCA to a particular situation.

V. Conclusion

Therefore, the tolerance is established for residues of methyl 2-[[[[[(4,6-dimethoxy-2-pyrimidinyl) amino]carbonyl]amino]sulfonyl]-4-[[(methylsulfonyl)amino] methyl]benzoate]], mesosulfuron-methyl, in or on the raw agricultural commodities aspirated grain fractions at 0.60 ppm; meat byproducts of cattle, goat, horse, and sheep at 0.01 ppm; wheat forage at 0.60 ppm; wheat germ at 0.10 ppm; wheat grain at 0.03 ppm; wheat hay at 0.06 ppm; and wheat straw at 0.30 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. 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–2003–0257 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 June 7, 2004.

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 20460–0001. 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 20460–0001.

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 20460–0001.

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.1. Mail your copies, identified by docket ID number OPP–2003–0257, 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. 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. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' "Policies that have federalism implications'' is defined in the Executive order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' "Policies that have tribal implications'' is defined in the Executive order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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: March 26, 2004.

James Jones,

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), 346a and 371.

■ 2. Section 180.597 is added to read as follows:

§ 180.597 Mesosulfuron-methyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide mesosulfuron-methyl, (methyl 2-[[[[(4,6-dimethoxy-2-pyrimidinyl) amino]carbonyl]amino]sulfonyl] -4-[[(methylsulfonyl)amino] methyl]benzoate]) in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, meat byproducts	0.01
Goat, meat byproducts	0.01
Grain, aspirated fractions	0.60
Horse, meat byproducts	0.01
Sheep, meat byproducts	0.01
Wheat, forage	0.60
Wheat, germ	0.10
Wheat, grain	0.03
Wheat, hay	0.06
Wheat, straw	0.30

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

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

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

[FR Doc. 04–7781 Filed 4–6–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0296; FRL–7339–4]

Fosthiazate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of