

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: April 24, 2006.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

**PART 180—AMENDED**

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

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.473 is amended by adding text to paragraph (d) after the paragraph heading to read as follows:

**§ 180.473 Glufosinate ammonium; tolerances for residues.**

\* \* \* \* \*

(d) \* \* \* Tolerances are established for indirect or inadvertent residues of the herbicide glufosinate ammonium, butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-, monoammonium salt and its metabolite, 3-methylphosphinopropionic acid in or on the following raw agricultural commodities when present therein as a result of the application of glufosinate ammonium to crops listed in paragraph (a) of this section:

Commodity	Parts per million
Barley, hay .....	0.40
Barley, straw .....	0.40
Buckwheat, fodder .....	0.40
Buckwheat, forage .....	0.40
Oat, forage .....	0.40
Oat, hay .....	0.40
Oat, straw .....	0.40
Rye, forage .....	0.40
Rye, straw .....	0.40
Teosinte .....	0.40
Triticale .....	0.40
Wheat, forage .....	0.40
Wheat, hay .....	0.40
Wheat, straw .....	0.40

[FR Doc. 06-4162 Filed 5-2-06; 8:45 am]

**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2006-0073; FRL-8062-6]

**Fomesafen; Pesticide Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of fomesafen in or on dry bean, snap bean and cotton. Interregional Research Project No. 4 (IR-4), and Syngenta Crop Protection 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 May 3, 2006. Objections and requests for hearings must be received on or before July 3, 2006.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number EPA-HQ-

OPP-2006-0073. All documents in the docket are listed on the *regulations.gov* Web site. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at <http://www.regulations.gov>. Follow the on-line instructions). Although listed in the index, some information is not publicly available, i.e., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., 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.

• **Important Note:** OPP will be moving to a new location the first week of May 2006. As a result, from Friday, April 28 to Friday, May 5, 2006, the OPP Regulatory Public Docket will NOT be accepting any deliveries at the Crystal Mall #2 address and this facility will be closed to the public. Beginning on May 8, 2006, the OPP Regulatory Public Docket will reopen at 8:30 a.m. and deliveries will be accepted in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202. The mail code for the mailing address will change to (7502P), but will otherwise remain the same. The OPP Regulatory Public Docket telephone number and hours of operation will remain the same after the move.

**FOR FURTHER INFORMATION CONTACT:** Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6224; e-mail address: [miller.joanne@epamail.epa.gov](mailto:miller.joanne@epamail.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 Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket>), 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 at 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>.

##### II. Background and Statutory Findings

In the **Federal Register** of March 1, 2006 (71 FR 10508) (FRL-7763-1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 1E6228, 6E4653, and 1F5068) by Interregional Research Project No. 4 (IR-4), 681 U. S. Highway No. 1 South, North Brunswick, NJ 08902-3390; and Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27410. The petitions requested that 40 CFR 180.433 be amended by establishing tolerances for residues of the herbicide sodium salt of fomesafen, 5-[2-chloro-4-(trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-nitrobenzamide, in or on the food commodities dry beans (PP 1E6228), snap beans (PP 6E4653),

cotton seed and cotton gin byproducts (1F5068) at 0.025 parts per million (ppm). That notice included a summary of the petition prepared by IR4 and Syngenta Crop Protection, Inc, the registrant. There were no comments received in response to the notice of filing. EPA has determined that the residue of concern is fomesafen, *per se*. The tolerance expression is revised by removing the phrase "sodium salt of".

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish tolerances (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 the FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

##### 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 tolerances for residues of fomesafen on bean, dry; bean, snap, succulent; cotton, undelinted seed and cotton, gin byproducts at 0.025 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

###### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the

studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including

infants and children. Specific information on the studies received and the nature of the toxic effects caused by fomesafen 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.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3050	28-Day oral toxicity -- rodents (mouse)	NOAEL = 209 milligrams/kilogram/day (mg/kg/day) for males (M) and 247 mg/kg/day for females (F) LOAEL = 917 mg/kg/day (M) and 1247 mg/kg/day (F) based on decreased body weights and body weight gains, decreased food efficiency, hematology (decreased erythrocyte count, hemoglobin, mean corpuscular volume, and mean corpuscular hemoglobin), bile duct hyperplasia, decreased uterine size in females, and decreased size of the seminal vesicles in males
870.3100	90-Day oral toxicity -- rodents (rat)	NOAEL = 0.5 mg/kg/day LOAEL = 10 mg/kg/day based on hyalinization of hepatocytes, increased eosinophilia, reduced granulation, increased liver weights in males and females, and increases in plasma alkaline phosphatase, alanine transaminase and aspartate transaminase in males
870.3150	26-Week oral toxicity -- nonrodents (dog)	NOAEL = 1 mg/kg/day LOAEL = 25 mg/kg/day based on hematology (decreased hemoglobin and hematocrit concentrations and erythrocyte count and increased platelet count and prothrombin time)
870.3200	21-Day dermal toxicity (rabbit)	NOAEL = 1,000 mg/kg/day, Highest Dose Tested (HDT)
870.3700	Prenatal developmental -- rodents (rat)	Maternal NOAEL = 100 mg/kg/day Maternal LOAEL = 200 mg/kg/day based on staining of the ventral fur and significantly decreased body weight gain ( $\leq 10\%$ ) . Developmental NOAEL = 100 mg/kg/day Developmental LOAEL = 200 mg/kg/day based on postimplantation loss
870.3800	Reproduction and fertility effects (rat)	Parental/Systemic NOAEL = 12.5 mg/kg/day Parental/Systemic LOAEL = 50 mg/kg/day based on liver histopathology in males and females of both generations. Reproductive NOAEL = 50 mg/kg/day, HDTReproductive LOAEL = Not established Offspring NOAEL = 12.5 mg/kg/day Offspring LOAEL = 50 mg/kg/day based on increased incidence of liver hyalinization in males
870.4200	Carcinogenicity-mice	NOAEL = 1.5 mg/kg/day LOAEL = 15 mg/kg/day based on the presence of liver tumors and liver weight increases in male and female mice
870.4300	Chronic toxicity/Carcinogenicity-rat	NOAEL = 0.25 mg/kg/day LOAEL = 5 mg/kg/day based on hyalinization of the liver in males
870.5100	Gene mutation - bacterial	Negative
870.5300	Gene mutation - mammalian	Negative
870.5375	Structural chromosomal aberrations	Negative
870.5395	Other genotoxic effects	Negative

**B. Toxicological Endpoints**

For hazards that have a threshold below which there is no appreciable risk, 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 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 X 10<sup>-5</sup>), one in a million (1 X 10<sup>-6</sup>), or one in ten million (1 X 10<sup>-7</sup>). 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 fomesafen used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FOMESAFEN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13–50 years of age)	An endpoint of concern for females 13–50 years of age attributable to a single dose was not identified in the hazard database.		
Acute Dietary (General population including infants and children)	An endpoint of concern for the general population attributable to a single dose was not identified in the hazard database.		
Chronic Dietary (All populations)	NOAEL= 0.25 mg/kg/day UF = 100 Chronic RfD = 0.0025 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD +Special FQPA SF = 0.0025 mg/kg/day	Chronic toxicity - rat LOAEL = 5 mg/kg/day based on hyalinization of the liver in males
Cancer (oral, dermal, inhalation)	In accordance with the EPA Final Guidelines for Carcinogen Risk Assessment (March 29, 2005), EPA classified fomesafen as "Not likely to be carcinogenic to humans". This decision was based on the weight-of-evidence which supports activation of peroxisome proliferator-activated receptor alpha (PPAR) as the mode of action for fomesafen-induced hepatocarcinogenesis in mice. The data did not support either mutagenesis or cytotoxicity followed by regenerative proliferation as alternative modes of action. While the proposed mode of action for liver tumors in mice is theoretically plausible in humans, it is quantitatively implausible and unlikely to take place in humans based on quantitative species differences in PPAR activation and toxicokinetics.		

**C. Exposure Assessment**

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.433) for the

residues of sodium salt of fomesafen, in or on soybeans. Risk assessments were conducted by EPA to assess dietary exposures from fomesafen in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern

occurring as a result of a 1-day or single exposure.

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

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), 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: For the chronic analyses, tolerance-level residues were assumed for all food commodities with current or proposed fomesafen tolerances, and it was assumed that all of the crops included in the analysis were treated. Percent Crop Treated (PCT) and/or anticipated residues were not used in the chronic risk assessment.

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

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening concentration in ground water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporates an index reservoir environment in place of the previous pond scenario. 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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health LOC.

Since the models used are considered to be screening tools in the risk assessment process, the Agency uses 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 percent Reference dose (%RfD) or percent population adjusted dose (%PAD).

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of fomesafen for chronic exposures are estimated to be 10.535 parts per billion (ppb) for surface water and 1.0 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).

Fomesafen 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 the 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 fomesafen and any other substances and fomesafen 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 fomesafen 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 Office of Pesticide Programs 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. 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 10X 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 is no concern and/or residual uncertainty with regard to prenatal and/or postnatal increased susceptibility. The requirement for an acceptable "guideline" developmental toxicity study in a second species has not been satisfied. The study in rabbits is deficient. Individual animal data were not reported and all fetuses were not examined for both soft tissue and skeletal alterations; and historical control data were not provided. Additionally, animals had an intercurrent infection that confounded interpretation of the results of the study. Therefore, the developmental toxicity study in the rabbit was classified "Unacceptable/Guideline". However, a new developmental toxicity study in rabbits is not required at this time because sufficient numbers of fetuses were available for examination in the rabbit developmental toxicity study. There was no increase in fetal deaths at the highest dose tested even though the dams suffered with an intercurrent infection. There were no external or internal malformation/abnormalities, soft tissue or skeletal that could be related to treatment with the test material at any of the three dosage levels tested including the highest dose level of 40 mg/kg/day. The study does not meet current guideline standards, but it does provide sufficient information on the possible effects the test material

might have on the developing rabbit fetus, especially since the maternal animals were additionally under considerable stress from infection.

3. *Conclusion.* The fomesafen toxicity database is adequate for the risk assessment since we are not asking for a repeat developmental toxicity study in rabbits at this time. In addition, there is no evidence of increased susceptibility, no residual uncertainty in the database, and exposure data are complete or are estimated based on that, reasonably account for potential exposures. Accordingly, the additional 10X factor for the protection of infants and children is removed.

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

1. *Acute risk.* An endpoint of concern attributable to a single dose exposure to fomesafen was not identified in the hazard database. Therefore there are no acute toxicological concerns for fomesafen.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fomesafen from food and drinking water will utilize 9.5% of the cPAD for the U.S. population, 31% of the cPAD for all infants (< 1 year old), and 15% of the cPAD for children 1–2 years old. Fomesafen 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 LOC.

3. *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 fomesafen residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (chemical derivatization followed by gas chromatography with Nitrogen-Phosphorus detection) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### *B. International Residue Limits*

No Codex Maximum residue levels (MRLs) have been established for residues of fomesafen. Canadian MRLs have been established for residues of fomesafen in or on dry beans; lima

beans; snap beans; and soybeans at 0.05 ppm, and a Mexican MRL of 0.05 mg/kg has been established for residues of fomesafen in or on soybeans. Syngenta Canada will be submitting a request to lower the fomesafen MRLs in Canada to match those being proposed for the USA. Therefore the MRLs will eventually be harmonized.

#### **V. Conclusion**

Therefore, the tolerance is established for residues of fomesafen, 5-[2-chloro-4-(trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-nitrobenzamide, in or on bean, dry; bean, snap, succulent; cotton, undelinted seed and cotton, gin byproducts at 0.025 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 EPA–HQ–OPP–2006–0073 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 July 3, 2006.

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 issue(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 (1900L), 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 Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A.1., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number EPA–HQ–OPP–2006–0073, to: Public Information and Records Integrity Branch, Information Technology and Resources Management 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 **ADDRESSES**.

##### *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 issue(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: April 27, 2006.  
**Lois Rossi**,  
 Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

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

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.433 is revised to read as follows:

**§ 180.433 Fomesafen; tolerances for residues.**

(a) *General.* Tolerances are established for the residues of fomesafen 5-[2-chloro-4-(trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-nitrobenzamide from the application of its sodium salt in or on the following commodities:

Commodity	Parts per million
Bean, dry .....	0.025
Bean, snap, succulent .....	0.025
Cotton, gin byproducts .....	0.025
Cotton, undelinted seed .....	0.025
Soybean .....	0.05

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

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

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

[FR Doc. 06-4160 Filed 5-2-06; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2004-0398; FRL-8057-5]

**Flumioxazin; Pesticide Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of flumioxazin, 2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propynyl)-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isoindole-1,3(2H)-dione in or on pome fruit crop group 11, stone fruit crop group 12 and strawberry. Valent U.S.A. Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).