

Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

## VII. Congressional Review Act

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

### List of Subjects in 40 CFR Part 180

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

Dated: February 14, 2008.

**Donald R. Stubbs,**

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

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

### PART 180—AMENDED

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

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

■ 2. Section 180.544 is amended by:

■ i. Revising the entries "canistel"; "mango"; "papaya"; "sapodilla"; "sapote, black"; "sapote, mamey"; and "star apple" in paragraph (a)(1).

■ ii. Alphabetically adding commodities to the table in paragraph (a)(1).

■ iii. Removing the text from paragraph (b) and reserving the heading.

■ iv. Revising the tables in paragraphs (d)(1) and (d)(2) to read as follows:

#### § 180.544 Methoxyfenozide; tolerances for residues.

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

Commodity	Parts per million
Acerola .....	0.4
* * *	* * *
Animal feed, nongrass, group 18, forage .....	50.0
Animal feed, nongrass, group 18, hay .....	150.0
* * *	* * *
Avocado .....	0.6
Bean, dry, seed .....	0.24
* * *	* * *
Bushberry subgroup 13-07B .....	3.0
Canistel .....	0.6
* * *	* * *
Feijoa .....	0.4
* * *	* * *
Grass, forage, fodder and hay, group 17, forage .....	18.0
Grass, forage, fodder and hay, group 17, hay .....	30.0
Guava .....	0.4
* * *	* * *
Jaboticaba .....	0.4
* * *	* * *
Mango .....	0.6
* * *	* * *
Onion, green, subgroup 3-07B .....	5.0
Papaya .....	0.6
Passionfruit .....	0.4
* * *	* * *
Peanut .....	0.02
Peanut, hay .....	55.0
Peanut, oil .....	0.04
* * *	* * *
Sapodilla .....	0.6
Sapote, black .....	0.6
Sapote, mamey .....	0.6
* * *	* * *
Star apple .....	0.6
Starfruit .....	0.4

Commodity	Parts per million
* * *	* * *
Vegetable, tuberous and corm, except potato, subgroup 1D .....	0.02
Wax jambu .....	0.4

(b) *Section 18 emergency exemptions.*

[Reserved]

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

(d) \* \* \*

(1) \* \* \*

Commodity	Parts per million	Expiration/revocation date
Vegetable, bulb, group 3-07 .....	0.20	9/30/10
Vegetable, leaves of root and tuber, group 2 .....	0.20	9/30/10
Vegetable, root and tuber, group 1 .....	0.10	9/30/10

(2) \* \* \*

Commodity	Parts per million	Expiration/revocation date
Animal feed, non-grass, group 18 .....	10.0	9/30/10
Grain, cereal, forage, fodder and straw, group 16 .....	10.0	9/30/10
Grass, forage, fodder and hay, group 17 .....	10.0	9/30/10
Herb and spice, group 19 .....	10.0	9/30/10
Vegetable, foliage of legume, group 7 .....	10.0	9/30/10
Vegetable, legume, group 6 .....	0.10	9/30/10

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2007-0308; FRL-8352-5]

### Flumioxazin; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of flumioxazin in or on alfalfa, forage; alfalfa, hay; asparagus; bean, dry seed; bushberry subgroup 13-07B; melon, subgroup 9A;

nut, tree, group 14; okra; and vegetable, fruiting, group 8. The Interregional Research Project #4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also modifies 40 CFR 180.568(b) by deleting existing time-limited tolerances in/on alfalfa, forage and alfalfa, hay at 0.13 and 0.45 ppm, respectively, made redundant by the newly-established tolerances.

**DATES:** This regulation is effective March 5, 2008. Objections and requests for hearings must be received on or before May 5, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0308. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7610; e-mail address: [jackson.sidney@epa.gov](mailto:jackson.sidney@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 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 to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### *B. How Can I Access Electronic Copies of this Document?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

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

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure

proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2007-0308 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before May 5, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2007-0308, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

### **II. Petition for Tolerance**

In the **Federal Registers** of June 27, 2007, (72 FR 35237; FRL-8133-4) and September 28, 2007, (72 FR 55204; FRL-8147-1), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 6E7151 and PP 6F7092, respectively,) by the IR-4 Project Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08540 and the registrant, Valent U.S.A. Corporation. The petitions requested that 40 CFR 180.568 be amended by establishing tolerances for residues of the herbicide, flumioxazin, 2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propynyl)-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isindole-1,3(2H)-dione in or on, commodities alfalfa, forage at 1.0 parts per million (ppm), alfalfa, hay at 2.0 ppm (PP 6F7092), asparagus, aronia berry, buffalo currant, Chilean guava, European barberry, highbush cranberry, honeysuckle, jostaberry, junberry, lingonberry, native currant, salal, sea

buckthorn, and okra at 0.02 ppm, bushberry subgroup 13B at 0.02 ppm, melon subgroup 9A at 0.02 parts per million (ppm), dry bean at 0.10 ppm, vegetable, fruiting, crop group 8 at 0.02 ppm, and nut, tree, crop group 14, at 0.02 ppm (PP 6E7151). These notices referenced a summary of the petition prepared by Valent U.S.A. Corporation, the registrant, which is available to the public in the docket, <http://www.regulations.gov>.

There were no comments received in response to the notices of filing.

Based upon review of the data supporting the petitions, EPA has revised certain proposed tolerance levels and corrected commodity definitions as follow:

1. The Agency determined that adequate data are available to support establishing a tolerance for the bushberry subgroup 13–07B. IR–4 petitioned for a tolerance for bushberry subgroup 13B as well as individual tolerances on aronia berry, buffalo currant, Chilean guava, European barberry, highbush cranberry, honeysuckle, jostaberry, junberry, lingonberry, native currant, salal, and sea buckthorn (PP 6E7151). In the **Federal Register** of December 7, 2007 (72 FR 69150–69158) (FRL–8340–6), EPA issued a final rule that revised the crop grouping regulations. As part of this action, EPA expanded and revised berries group 13. Changes to crop group 13 (berries) included adding new commodities, revising existing subgroups and creating new subgroups (including a bushberry subgroup 13–07B consisting of the commodities requested in PP 6E7151 and cultivars, varieties, and/or hybrids of these).

EPA indicated in the December 7, 2007 final rule as well as the earlier May 23, 2007 proposed rule (72 FR 28920–28930) that, for existing petitions for which a Notice of Filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA is establishing tolerances on Bushberry subgroup 13–07B. Bushberry subgroup 13–07B consists of the berries for which tolerances were requested in PP 6E7151.

EPA concludes it is reasonable to revise the petitioned-for tolerances so that they agree with the recent crop grouping revisions because:

i. Although the subgroup includes several new commodities, these commodities were proposed as individual tolerances and are closely related minor crops which contribute little to overall dietary or aggregate exposure and risk;

ii. Flumioxazin exposure from these added commodities was considered when EPA conducted the dietary and aggregate risk assessments supporting this action; and

iii. The representative commodities for the revised subgroup has not changed.

2. The proposed tolerance for bean, dry, was revised to bean, dry, seed and the tolerance level revised from 0.06 ppm to 0.05 ppm.

### III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....” These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerance for residues of flumioxazin on alfalfa, forage at 3.0 ppm; alfalfa, hay at 8.0 ppm; asparagus at 0.02 ppm; bushberry subgroup 13–07B at 0.02 ppm; melon, subgroup 9A at 0.02 ppm; bean, dry seed at 0.05 ppm; vegetable, fruiting, group 8 at 0.02 ppm; okra at 0.02 ppm; and nut, tree, group 14, at 0.02 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 their 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.

Flumioxazin has mild or no acute toxicity when administered orally, dermally, or by inhalation. It has little or no toxicity with regard to eye irritation or skin irritation. The chemical, flumioxazin, was not a dermal sensitizer. Subchronic and chronic toxicity studies demonstrated that the target organs of flumioxazin are the liver, spleen and cardiovascular system. Developmental effects were observed in developmental rat studies. These effects were fetal cardiovascular anomalies (especially ventricular septal defects).

Flumioxazin has been classified as a “Not Likely Human Carcinogen,” based on the lack of carcinogenicity in a 2–year rat study, an 18–month mouse study, and a battery of mutagenic studies.

Specific information on the studies received and the nature of the adverse effects caused by flumioxazin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document; “Flumioxazin; Human Health Risk Assessment for the Proposed Food Use of the Herbicide Flumioxazin on Alfalfa, Asparagus, Dry Beans, Fruiting Vegetables (Group 8, Including Okra), Melons (Subgroup 9A), Bushberries (Subgroup 13B), and Tree Nuts (Group 14), and a Request for an Amended Use on Garlic,” dated 28 Nov. 2007. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA–HQ–OPP–2007–0308–0003 in that docket.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, LOAEL is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose

(aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

A summary of the toxicological endpoints for flumioxazin used for human risk assessment can be found at <http://www.regulations.gov> in document; "Flumioxazin; Human Health Risk Assessment for the Proposed Food Use of the Herbicide Flumioxazin on Alfalfa, Asparagus, Dry Beans, Fruiting Vegetables (Group 8, Including Okra), Melons (Subgroup 9A), Bushberries (Subgroup 13B), and Tree Nuts (Group 14), and a Request for an Amended Use on Garlic," dated 28 Nov. 2007 in docket ID number EPA-HQ-OPP-2007-0308-0003.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to flumioxazin, EPA considered exposure under the petitioned-for tolerances as well as all existing flumioxazin tolerances in (40 CFR 180.568). EPA assessed dietary exposures from flumioxazin 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 effect was identified for the general population. However, EPA identified potential acute effects, e.g., cardiovascular effects in offspring, for the population subgroup, females 13 to 49 years.

In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed all foods for which there are tolerances

(current and proposed) were treated (100% crop treated (%CT or PCT) assumption) and contain tolerance-level residues. Percent crop treated (PCT) and/or anticipated residues were not used in the acute risk assessment.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996, and 1998 CSFII. As to residue levels in food, EPA assumed all foods for which there are tolerances (existing and proposed) were treated (100% crop treated assumption) and contain tolerance-level residues. PCT and/or anticipated residues were not used in the chronic risk assessment.

iii. *Cancer.* The Agency has determined that flumioxazin is "not likely to be a human carcinogen" based on the lack of carcinogenicity in a 2-rat study, an 18 month mouse study, and a battery of mutagenic studies. Therefore, a quantitative exposure assessment to evaluate cancer risk is unnecessary.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for flumioxazin and its degradates, 482-HA and APF, 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 environmental fate characteristics of flumioxazin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the FQPA Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of flumioxazin for acute exposures are estimated to be 34 parts per billion (ppb) for surface water and 48 ppb for groundwater. The EECs for chronic exposures are estimated to be 18 ppb for surface water and 48 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 48 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 48 ppb was used to access the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure

(e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Flumioxazin 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 flumioxazin and any other substances and flumioxazin 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 flumioxazin 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 EPA's website 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 ("10X") tenfold margin of safety for infants and children in the case of threshold effects to account for pre-natal and post-natal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. 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 FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Pre-natal and post-natal sensitivity.* The pre-natal and post-natal toxicity database for flumioxazin include the rat and rabbit developmental toxicity studies and the 2-generation reproduction toxicity study in rats. There is evidence of quantitative susceptibility following oral and dermal exposures to rats. Following *in-utero*

exposures, developmental effects (cardiovascular anomalies) were seen in the absence of maternal toxicity. There is no evidence (quantitative or qualitative) of susceptibility following *in-utero* oral exposure in rabbits. No developmental toxicity was seen at the highest dose tested (3x the Limit-Dose). There is quantitative evidence of susceptibility in the multi-generation reproduction study where effects in offspring were seen at doses lower than those which induced effects in parental animals.

Although increased pre-natal and post-natal quantitative susceptibility was seen in rats, the Agency concluded that there is a low concern and no residual uncertainties for pre-natal and/or post-natal toxicity effects of flumioxazin because:

- i. Developmental toxicity (including cardiovascular abnormalities) NOAELs and LOAELs from pre-natal exposure are well characterized after oral and dermal exposure,
- ii. The off-spring toxicity NOAEL and LOAEL from post-natal exposure are well characterized,
- iii. The dose selected for risk assessment is protective of all potential effects.

3. **Conclusion.** EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

- i. The toxicity database for flumioxazin is complete.
- ii. There is no indication that flumioxazin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. Although there is quantitative evidence of increased susceptibility in the prenatal developmental studies and post-natal multi-generation study in rats, EPA did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of flumioxazin. The degree of concern for pre-natal and/or post-natal toxicity is low.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100%CT and tolerance-level residues for all commodities. By using these screening-level assumptions, chronic exposures/risks will not be underestimated. The dietary drinking water assessment utilizes values generated by models and associated modeling parameters which are designed to provide conservative,

health protective, high-end estimates of water concentrations. These assessments will not underestimate the exposure and risks posed by flumioxazin.

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

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. **Acute risk.** Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to flumioxazin will occupy 8.0% of the aPAD at the 95th percentile of exposure for the population group, females 13 to 49 years old (the only subpopulation for which an acute endpoint was selected).

2. **Chronic risk.** Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to flumioxazin by the general U.S. population and all population subgroups have risk estimates below LOC. Exposure to flumioxazin from food and water will utilize 18% of the cPAD for infants less than 1 year old, the population group with greatest exposure. The general U.S. population utilize 6% of the cPAD. There are no residential uses for flumioxazin that result in chronic residential exposure to flumioxazin.

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

Flumioxazin 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.

4. **Determination of safety.** Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to flumioxazin residues.

## **IV. Other Considerations**

### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (gas chromatography /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*

There are no established or proposed Canadian, Mexican or Codex maximum residue levels (MRLs) for residues of flumioxazin in plant commodities subject to this action.

## **V. Conclusion**

Therefore, tolerances are established 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-isindole-1,3(2H)-dione in or on, commodities alfalfa, forage at 3.0 ppm; alfalfa, hay at 8.0 ppm; asparagus at 0.02 ppm; bushberry subgroup 13-07B at 0.02 ppm; melon subgroup 9A at 0.02 ppm; bean, dry seed at 0.05 ppm; vegetable, fruiting, except cucurbits group 8 at 0.02 ppm; okra at 0.02 ppm; and nut, tree, group 14, at 0.02 ppm.

## **VI. 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, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

## VII. Congressional Review Act

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

### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: February 22, 2008.

**Lois Rossi,**

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 180.568 is amended by alphabetically adding the following commodities to the table in paragraph (a), and by removing the text and reserving paragraph (b) to read as follows:

### § 180.568 Flumioxazin; tolerances for residues.

(a) \* \* \*

Commodity	Parts per million
Alfalfa, forage .....	3.0
Alfalfa, hay .....	8.0
* * *	* * *
Asparagus .....	0.02
Bean, dry seed .....	0.05
Bushberry subgroup 13-07B .....	0.02
* * *	* * *
Melon, subgroup 9A .....	0.02
Nut, tree, group 14 .....	0.02
Okra .....	0.02
* * *	* * *
Vegetable, fruiting, group 8 .....	0.02
* * *	* * *

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

\* \* \* \* \*

[FR Doc. E8-4102 Filed 3-4-08; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2007-0302; FRL-8351-6]

### Bifenazate; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for combined residues of bifenazate and its metabolite, diazinicarboxylic acid, 2-(4-methoxy-1,1'-biphenyl)-3-yl, 1-methylethyl ester (expressed as bifenazate), in or on acerola; black sapote; caneberry subgroup 13-07A; canistel; feijoa; guava;

jaboticaba; longan; lychee; mango; papaya; passionfruit; pea and bean, succulent shelled, subgroup 6B; pulasan; rambutan; sapodilla; sapote, mamey; soybean, succulent shelled; Spanish lime; star apple; starfruit; vegetable, legume, edible-podded, subgroup 6A; and wax jambu. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also deletes existing bifenazate tolerances on "pea, edible podded, succulent" and "pea, garden, succulent", which are superseded by the new tolerances on "vegetable, legume, edible-podded, subgroup 6A" and "pea and bean, succulent shelled, subgroup 6B", respectively.

**DATES:** This regulation is effective March 5, 2008. Objections and requests for hearings must be received on or before May 5, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0302. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington,