BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0139; FRL-9381-7]

Flumioxazin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flumioxazin in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0139, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9367; email address: *ertman.andrew@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, 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-2012-0139 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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 (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0139, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 2, 2012 (77 FR 25954) (FRL-9346-1), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E7982) by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition 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)-2*H*-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1*H*-isoindole-1,3(2*H*)-dione, in or on artichoke at 0.02 parts per million (ppm); cabbage and Chinese cabbage (tight-headed varieties only) at 0.02 ppm; olives, and olive oil at 0.02 ppm; pomegranate at 0.02 ppm; cactus fruit at 0.1 ppm, and cactus pads at 0.05 ppm. That document referenced a summary of the petition prepared by Valent U.S.A. Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the levels at which tolerances are being established for some commodities. The reason for these changes is explained in Unit IV.C.

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...."

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 flumioxazin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with flumioxazin 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.

In general, flumioxazin has mild or low acute toxicity. Also, the subchronic and chronic toxicity studies demonstrated that toxic effects associated with flumioxazin include anemia as well as effects on the liver and the cardiovascular system. Developmental effects were observed in developmental rat studies but not in developmental rabbit studies. Hematologic (hematopoietic) effects of anemia were noted in rats, consisting of alterations in hemoglobin parameters. Increased renal toxicity in male rats was also reported following chronic exposure. There is no evidence of neurotoxicity or immunotoxicity in the recently submitted guideline studies. Increased quantitative susceptibility was seen in the rat developmental toxicity studies. Fetal effects were observed in the absence of maternal toxicity. In addition, both increased qualitative and quantitative susceptibility were observed in the rat reproduction study. Severe fetal effects were observed at lower doses than milder parental effects. In most of the available mutagenicity studies, flumioxazin was negative for mutagenicity; however, aberrations were seen in a chromosomal aberration assay (CHO cells). Based on the lack of evidence of carcinogenicity in mice and rats, flumioxazin is classified as "not likely to be carcinogenic to humans."

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 docket ID number EPA-HQ-OPP-2012-0139 on pages 43-48 of the document titled "Flumioxazin. Human Health Risk Assessment for the Proposed Uses on Artichoke, Cabbage, Olive, Pomegranate, and Prickly Pear Cactus".

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. 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/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for flumioxazin used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of September 21, 2012 (77 FR 58493) (FRL-9358-3).

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.

Such effects were identified for flumioxazin. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA) from 2003-2008. As to residue levels in food, EPA assumed tolerance level residues and 100 percent crop treated (PCT) for all proposed and registered commodities. In addition, EPA used default concentration factors to estimate residues of flumioxazin in processed commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA from 2003-2008. As to residue levels in food, EPA assumed tolerance level residues and 100 PCT for all proposed and registered commodities. In addition, EPA used default concentration factors to estimate residues of flumioxazin in processed commodities.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that flumioxazin does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for flumioxazin. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. In the environment flumioxazin photodegrades very rapidly in water and on soil. Concentrations of flumioxazin and its major degradates (482-HA, APF, and THPA) are expected to be found in water; however, flumioxazin and the metabolites 482-HA and APF have been identified as the residues of concern in drinking water.

To estimate concentrations of flumioxazin including its major degradates of concern (482-HA and APF) in ground water, the Agency used a screening level water exposure model in the dietary exposure analysis and risk assessment. This simulation model took into account data on the physical, chemical, and fate/transport characteristics of flumioxazin. Since this chemical is currently registered for direct applications to water, surface water estimates are based on the use of flumioxazin as an aquatic herbicide where a maximum 400 parts per billion (ppb) concentration is maintained. Hydrolysis is considered the major route of dissipation for flumioxazin in the environment and the levels of degradates (482-HA and APF) increase continuously with time.

Based on the Screening Concentration in Ground Water (SCI-GROW) model the estimated drinking water concentrations (EDWCs) for both acute and chronic exposures of 482-HA and APF are estimated to be 45.27 ppb and 2.66 ppb, respectively, in ground water. EDWCs of parent flumioxazin are estimated to be negligible in ground water for both acute and chronic exposures. For surface water, the EDWCs for flumioxazin are estimated to be 400 ppb for acute exposures and no 482-HA and APF is expected to be present. For chronic exposures, EDWCs of flumioxazin and its major degradates (482–HA and APF) are estimated to be 9.4, 21.6, and 110.1 ppb, respectively, for surface water resulting in an EDWC of 142 ppb (total).

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 400 ppb was used to assess the contribution to drinking water of flumioxazin. For chronic dietary risk assessment, the water concentration of value 142 ppb (the total EDWC for flumioxazin**,** 482–HA and APF in surface water) was used to assess the contribution to drinking water of flumioxazin and its major degradates (482–HA and APF).

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*.

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 currently registered for uses that could result in residential exposures, including aquatic areas, ornamental gardens, ornamental trees, turf, and golf courses. EPA assessed residential exposure with the assumption that homeowner handlers wear shorts, short-sleeved shirts, socks, and shoes, and that they complete all tasks associated with the use of a pesticide product including mixing/loading, if needed, as well as the application. Residential handler exposure scenarios for both dermal and inhalation are considered to be short-term only, due to the infrequent use patterns associated with homeowner products.

EPA uses the term ''postapplication'' to describe exposure to individuals that occur as a result of being in an environment that has been previously treated with a

pesticide. Flumioxazin is registered for use in many areas that can be frequented by the general population including residential areas, golf courses, lakes, and ponds. As a result, individuals can be exposed by entering these areas if they have been previously treated. Therefore, short-term and intermediate dermal postapplication exposures and risks were assessed for adults and children. In addition, oral post-application exposures and risks were assessed for children to be protective of possible hand-to-mouth, object-to-mouth, and soil ingestion activities that may occur on treated turf areas**.** Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

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."

EPA has not found flumioxazin to share a common mechanism of toxicity with 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 assumed that flumioxazin does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. Evidence of increased susceptibility to fetuses was observed in the oral and dermal developmental rat studies i.e. cardiovascular anomalies (ventricular septal defect) that occurred in the absence of maternal toxicity. Additionally, the rat reproduction study demonstrated evidence of qualitative and quantitative post-natal susceptibility because reproductive effects in offspring were observed at doses lower than those that caused parental/systemic toxicity, and because the reproductive effects in offspring were considered to be more severe than the parental/systemic effects.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for oral and dermal exposures, but be retained at 10X for inhalation exposures. That decision is based on the following findings:

i. The toxicity database for flumioxazin is largely complete with the exception of an inhalation developmental study, which was recently determined necessary, in order to better assess route-specific inhalation risks. In the absence of this study, a 10X FQPA

safety factor to account for database uncertainty is needed to protect the safety of infants and children to assess risks for all inhalation exposure scenarios. The toxicity profile can be characterized for all effects, including potential developmental and reproductive toxicity, immunotoxicity and neurotoxicity with the current database.

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 increased susceptibility was seen in the rat developmental and reproductive studies, EPA's concern for these effects is low, and there are no residual uncertainties for pre- and/or postnatal toxicity because:

a. The developmental toxicity NOAELs/LOAELs are well characterized after oral and dermal exposure;

b. The offspring toxicity NOAEL and LOAEL are well characterized in the reproduction study and

c. The points of departure for assessing risk to developing fetuses, infants, and children have been selected either from the developmental and reproductive toxicity studies from the chronic study which established a lower point of departure for chronic effects than the studies in pre- and postnatal animals. Thus, the regulatory endpoints for flumioxazin are protective of the increased susceptibility seen in the developmental and reproduction studies, and there are no residual concerns for these effects.

iv. There are no residual uncertainties identified in the exposure databases. The acute and chronic dietary analyses were based on tolerance-level residues and 100 PCT assumptions for all commodities. The dietary drinking water assessment utilized water

concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations. The residential exposure assessment incorporates similarly conservative assumptions in the assessment of post-application exposure to children and in the incidental oral exposure assessment for children.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

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 75% of the aPAD for females 13-49 years old, the only population group of concern for acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to flumioxazin from food and water will utilize 44% of the cPAD for all infants less than 1 year old, the population subgroup receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of flumioxazin is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Flumioxazin is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to flumioxazin.

Different methodologies were used for the presentation of short-term aggregate risk for adults and children. An aggregate risk estimate (ARI) approach was required to estimate short-term adult aggregate risk because there are different levels of concern (LOCs) for adult dermal and inhalation exposures, 100 and 1,000, respectively. For short-term child aggregate risk, the combined MOE approach was used because the endpoint of concern (decreased pup weight) and the LOC are the same. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate ARI of 1.12 for adults and aggregate MOE of 182 for children. Because EPA's level of concern for flumioxazin is an ARI of 1 or below and a MOE of 100 or below, these aggregate risk estimates are not of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Since the short- and intermediate-term toxicological endpoints for flumioxazin are the same for each route of exposure, only short-term exposures were assessed.

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, flumioxazin is not expected to pose a cancer risk to humans.

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 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 (GC/NPD) method, Valent Method RM30-A-1) 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; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is

different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for flumioxazin for any of the commodities covered by this document.

C. Revisions to Petitioned-For Tolerances

The Agency has revised the levels for prickly pear cactus fruit and pads from 0.1 and 0.05 to 0.07 and 0.06, respectively. The modifications were due to the Agency's use of the Organization for Economic Co-operation and Development (OECD) calculation procedures to determine the appropriate tolerance levels.

Additionally, the petition proposed a tolerance for olive oil at 0.02 ppm. The Agency reviewed an olive oil processing study and found that the residue levels found in olive oil were the same as those found in olives. As such, the Agency has determined that a tolerance for olive is appropriate, and a separate tolerance on olive oil is not necessary.

V. Conclusion

Therefore, tolerances are established for residues of flumioxazin, 2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propynyl)-2*H*-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1*H*-isoindole-1,3(2*H*)-dione, in or on artichoke, globe at 0.02 ppm; cabbage at 0.02 ppm; cabbage, Chinese, napa at 0.02 ppm; olive at 0.02 ppm; pomegranate at 0.02 ppm; prickly pear, fruit at 0.07 ppm; and prickly pear, pads at 0.06 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has

exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "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 FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

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 FFDCA section 408(n)(4). 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 9, 2000) do not apply to this final rule. In addition, this final 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) (2 U.S.C. 1501 *et seq*.).

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) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action 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 28, 2013.

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. In § 180.568, add alphabetically the following commodities to the table in paragraph (a) to read as follows:

§ 180.568 Flumioxazin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Artichoke, globe	0.02
* * * * *	
Cabbage	0.02
Cabbage, Chinese, napa	0.02
* * * * *	
Olive	0.02
* * * * *	
Pomegranate	0.02
Prickly pear, fruit	0.07
Prickly pear, pads	0.06
* * * * *	

* * * * *

[FR Doc. 2013-07980 Filed 04/04/2013 at 8:45 am; Publication Date: 04/05/2013]