

action must be filed in the United States Court of Appeals for the appropriate circuit by February 17, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 81

Environmental protection, Administrative practice and procedure, Air pollution control, Designations and classifications, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: December 7, 2016.

Robert A. Kaplan,

Acting Regional Administrator, Region 5.

Part 81, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. Section 81.350 is amended by revising the entry for Sheboygan County, WI in the table entitled “Wisconsin—2008 8-Hour Ozone NAAQS (Primary and secondary)” to read as follows:

§ 81.350 Wisconsin.

* * * * *

WISCONSIN—2008 8-HOUR OZONE NAAQS
[Primary and secondary]

Designated area	Designation		Classification	
	Date ¹	Type	Date ¹	Type
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
Sheboygan County, WI; ² Sheboygan County.	1/18/2017	Nonattainment	Moderate.	
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *

¹ This date is July 20, 2012, unless otherwise noted.

² Excludes Indian country located in each area, unless otherwise noted.

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[FR Doc. 2016–30330 Filed 12–16–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0658; FRL–9955–45]

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. The Inter-Regional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 19, 2016. Objections and requests for hearings must be received on or before February 17, 2017, 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–2015–0658, 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), West William Jefferson Clinton 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: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; Main telephone number: (703) 305–7090; email address: RDfRNNotices@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://www.ecfr.gov/cgi-bin/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–2015–0658 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 February 17, 2017. 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–2015–0658, 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.html>.

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 November 23, 2015 (80 FR 72941) (FRL–9936–73), 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#5E8399) by Interregional Research No. 4 (IR–4), Rutgers, The State University of New Jersey, 500 College Road East, Suite 201–W, Princeton, NJ 08540. The Agency inadvertently republished this notice on March 16, 2016 (81 FR 14030) (FRL–9942–86). 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)-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isoindole-1,3(2H)-dione, in or on berry, low growing, subgroup 13–07G at 0.07 parts per million (ppm); caneberry,

subgroup 13–07A at 0.4 ppm; citrus, group 10–10 at 0.02 ppm; citrus oil at 0.1 ppm; clover, forage at 0.02 ppm; clover, hay at 0.15 ppm; fruit, pome, group 11–10 at 0.02 ppm; fruit, small vine climbing, except for fuzzy kiwifruit, subgroup 13–07F at 0.02 ppm; fruit, stone, group 12–12 at 0.02 ppm; head and stem brassica, subgroup 5A at 0.02 ppm; nut, tree, group 14–12 at 0.02 ppm; onion, bulb subgroup 3–07A at 0.02 ppm; and vegetable, fruiting, group 8–10 at 0.02 ppm.

The petitioner also requested the removal of the following established tolerances based on the establishment of tolerances for the commodities established in this action: Cabbage at 0.02 ppm; cabbage, Chinese, napa at 0.02 ppm; fruit, pome group 11 at 0.02 ppm; fruit, stone, group 12 at 0.02 ppm; garlic at 0.02 ppm; grape at 0.02 ppm; nut, tree group 14 at 0.02 ppm; okra at 0.02 ppm; onion, bulb at 0.02 ppm; pistachio at 0.02 ppm; shallot bulb at 0.02 ppm; strawberry at 0.07 ppm; and vegetable, fruiting group 8 at 0.02 ppm. That document referenced a summary of the petition prepared by Valent USA Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on these notices of filings. EPA's response to these comments is discussed 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.

Toxicity associated with flumioxazin includes anemia and effects on the cardiovascular system and liver. Specifically, alterations in hemoglobin parameters were observed in rats, as well as increased renal toxicity in male rats, and increased absolute and relative liver weights and increased alkaline phosphate values were seen in dogs. No evidence of neurotoxicity was seen in male or female rats in the acute or subchronic neurotoxicity studies. The oral and dermal developmental rat studies showed evidence of increased quantitative susceptibility of fetuses, as cardiovascular anomalies (ventral septal defects) were found. These developmental effects in the offspring were more severe and seen at doses lower than those that caused parental and systemic toxicity. The regulatory endpoints for flumioxazin are protective of this increased susceptibility, however, so there is low concern and no residual uncertainties for these effects. Flumioxazin was negative for mutagenicity in most of the available studies, however, there were aberrations in a chromosomal aberration assay. The lack of carcinogenicity in mice and rats permits flumioxazin to be 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 document Flumioxazin: Human Health Risk Assessment for the New Uses on Clover Grown for Seed; Citrus Group 10–10; Caneberry Subgroup 13–07A; Head and Stem Brassica Subgroup 5A; and Crop Group Expansion for Fruiting Vegetable Group 8–10; Low Growing Berry Subgroup 13–07G; Nut Tree Group 14–12; Onion Bulb Subgroup 3–07A; Pome

Fruit Group 11–10; Small Fruit, Vine Climbing, Except Fuzzy Kiwifruit Subgroup 13–07F; and Stone Fruit Group 12–12 at pages 15–22 and 42–55 in docket ID number EPA–HQ–OPP–2015–0658.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

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 for females 13–49. In estimating acute dietary exposure, EPA used food consumption information from the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 3.16. This software uses 2003–2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA incorporated tolerance-level residues, 100 percent crop treated (PCT) for all commodities and DEEM–FCID version 3.16.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM–FCID Version 3.16. This software uses 2003–2008 food consumption data from USDA's NHANES/WWEIA. As to residue levels in food, EPA incorporated tolerance-level residues, 100 PCT for all 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 percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for flumioxazin. Tolerance level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for flumioxazin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of flumioxazin. The estimated drinking water concentrations (EDWCs) are based on aquatic rates of the residues of concern for flumioxazin and its major degradates (482–HA, and APF), expressed as flumioxazin equivalents. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the First Index Reservoir Screening Tool (FIRST) model, the EDWCs in surface water for acute exposures are 400 parts per billion (ppb) for flumioxazin only and for chronic exposures are estimated to be 9.4 ppb, 21.6 ppb, and 110.1 ppb for flumioxazin, 482–HA and APF degradates, respectively, for a total

concentration of 141 ppb. Based on the Screening Concentration in Ground Water (SCI–GROW) model, for both acute and chronic (non-cancer) exposures, the EDWCs of 482–HA and APF are estimated to be 45.27 ppb and 2.66 ppb, respectively, for ground water. EDWCs of flumioxazin are estimated to be negligible in ground water for chronic exposures.

Estimates of drinking water concentrations were directly entered into the dietary exposure model as follows. The peak day zero of 0.400 ppm for flumioxazin (degradates 482–HA and APF were not detected) was used to assess the contribution to drinking water for the acute dietary risk assessment, and the day 30 total of 0.141 ppm for flumioxazin, 482–HA and APF degradates was used to assess the contribution to drinking water for the chronic dietary risk assessment.

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 the following uses that could result in residential exposures: Turf, gardens and trees, and aquatic weeds. 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 “post-application” to describe exposure to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. Flumioxazin can be used in many areas that can be frequented by the general population including residential areas, 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-term dermal post-application 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

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 Web site at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

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.* There is evidence of increased quantitative susceptibility of fetuses in the oral and dermal developmental rat studies, where cardiovascular abnormalities occurred in the absence of maternal toxicity. The rat reproduction study also showed evidence of qualitative and quantitative post-natal susceptibility since reproductive effects in offspring were more severe and were seen at lower doses than those that caused parental/systemic toxicity. Even with this observed increased

susceptibility, the Agency has concluded there is a low concern and no residual uncertainties for pre- and/or postnatal toxicity because the developmental toxicity NOAELs/LOAELs are well-characterized after oral and dermal exposure, and the offspring toxicity NOAEL and LOAEL are well characterized in the reproduction study.

Furthermore, the doses and endpoints have been selected from the developmental and reproductive toxicity studies for risk assessment of the relevant exposed populations (e.g., pregnant females and children), with the exception of the chronic dietary endpoint, for which a chronic study was selected. Therefore, regulatory endpoints for flumioxazin are protective of the increased susceptibility and there are no residual concerns for these 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 retained at 10X for inhalation exposures due to the lack of an inhalation study. That decision is based on the following findings:

i. The toxicity database for flumioxazin is sufficient for assessing the toxicity and characterizing the hazard of flumioxazin. An inhalation study is needed to characterize more completely the potential for adverse effects associated with the inhalation route of exposure; therefore, in order to account for any uncertainty attending the use of the dose and endpoint from an oral rat developmental toxicity study with an estimated 100% default absorption factor, the Agency is retaining the 10X FQPA safety factor for assessing inhalation risk.

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. There is evidence that flumioxazin may result in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. The Agency concluded that while there is an increased susceptibility, there is a low concern and no residual uncertainties for pre-and/or postnatal toxicity because the developmental toxicity NOAELs/LOAELs are well characterized after oral and dermal exposure; the offspring toxicity NOAEL and LOAEL are well characterized in the reproduction study; and the doses and endpoints have been selected from the developmental and reproductive

toxicity studies for the relevant populations, except for the chronic dietary endpoint, for which a chronic study was chosen. Therefore, 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 dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to flumioxazin in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by flumioxazin.

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 76% of the aPAD for females 13–49 years old, the population group receiving the greatest exposure.

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 <1 year old, the population group 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 and intermediate-term risk.* Short-term and intermediate-term aggregate exposure takes into account short-term and intermediate 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 and

intermediate residential exposures, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term and intermediate-term residential exposures to flumioxazin. Since the Agency has determined that the short-term and intermediate-term points of departure are the same the aggregate risks are the same for both short-term and intermediate-term exposures.

Using the exposure assumptions described in this unit for short-term and intermediate-term exposures, EPA has concluded the combined short-term and intermediate-term food, water, and residential exposures result in aggregate MOEs of 110 for adult females 13–49 years and 200 for children less than two years. Because EPA's level of concern for flumioxazin is a MOE of 100 or below, these MOEs are not of concern.

4. *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.

5. *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 (GC) using a nitrogen phosphorous detector (NPD)) 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 any MRLs for flumioxazin.

C. Response to Comments

EPA received five comments to the two published Notice of Filings. Two comments stated, in part and without any supporting information, that EPA should deny this petition because it is a harmful and toxic chemical with no benefits. The Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops. The existing legal framework provided by section 408 of the FFDCA, however, states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. EPA has assessed the effects of this chemical on human health and determined that aggregate exposure to it will be safe. These comments provide no information to support an alternative conclusion.

Another comment submitted by the Center for Biological Diversity was primarily concerned about the environmental risks and Agency compliance with any relevant obligations under the Endangered Species Act. This comment is not relevant to the Agency's evaluation of safety of the flumioxazin tolerances; section 408 of the FFDCA focuses on potential harms to human health and does not permit consideration of effects on the environment. Additional comments were submitted in support of this petition by Interregional Research Project Number 4 (IR–4) and Dr. A. Stanley Culpepper from the University of Georgia Cooperative Extension.

D. Revisions to Petitioned-For Tolerances

The petitioner proposed a tolerance of flumioxazin on caneberries at 0.4 ppm. Both the petitioner and the Agency used the Organization for Economic Cooperation & Development (OECD) spreadsheet calculator; however, the Agency did not consider the two Oregon trials to be independent since they were conducted at the same location on the same variety of raspberries and applications were made within 30 days of each other. Therefore, the four samples were accounted as two, resulting in an Agency recommended tolerance of 0.5 ppm. All other

tolerances are recommended to be at the same levels as petitioned.

The petitioner proposed a tolerance for head and stem brassica, subgroup 5A at 0.02 ppm; however, the EPA is establishing a tolerance for Vegetable, brassica, head and stem, group 5–16 at 0.02 ppm. In the **Federal Register** of May 3, 2016 (81 FR 26471) (FRL–9944–87) establishing the Vegetable, brassica, head and stem, group 5–16, EPA indicated 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 Vegetable, brassica, head and stem, group 5–16 rather than head and stem brassica, subgroup 5A. EPA concludes it is reasonable to revise the petitioned-for tolerance so that they agree with the recent crop grouping revisions because (1) the new crop group includes the same commodities as the subgroup except two commodities are no longer in the group and (2) the representative commodities for the revised crop groups/subgroups have not changed.

Finally, the Agency is establishing tolerances for clover, forage and clover, hay with regional registrations in (c) since residue field trial data were only submitted to support registration in Idaho, Washington, and Oregon.

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-isoindole-1,3(2H)-dione, in or on 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-isoindole-1,3(2H)-dione, in or on, berry, low growing, subgroup 13–07G at 0.07 parts per million (ppm); caneberry, subgroup 13–07A at 0.5 ppm; citrus, group 10–10 at 0.02 ppm; fruit, pome, group 11 at 0.02 ppm; fruit, stone, group 12 at 0.02 ppm; nut, tree, group 14–12 at 0.02 ppm; onion, bulb subgroup 3–07A at 0.02 ppm; small fruit, vine climbing, except for fuzzy kiwifruit, subgroup 13–07F at 0.02 ppm; vegetable, brassica, head and stem, group 5–16 at 0.02 ppm; and vegetable, fruiting, group 8–10 at 0.02 ppm.

Additionally, EPA is establishing tolerances with regional registrations for clover, forage at 0.02 ppm and clover, hay at 0.15 ppm. Finally, the EPA is removing tolerances for Cabbage at 0.02 ppm; cabbage, Chinese, napa at 0.02 ppm; fruit, pome group 11 at 0.02 ppm; fruit, stone, group 12 at 0.02 ppm; garlic at 0.02 ppm; grape at 0.02 ppm; nut, tree

group 14 at 0.02 ppm; okra at 0.02 ppm; onion, bulb at 0.02 ppm; pistachio at 0.02 ppm; shallot bulb at 0.02 ppm; strawberry at 0.07 ppm and vegetable, fruiting group 8 at 0.02 ppm since these will be superseded by this action.

VI. Statutory and Executive Order Reviews

This action 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 tolerances 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 action 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (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 (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: December 6, 2016.

Daniel J. Rosenblatt,

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. Revise § 180.568 to read as follows:

§ 180.568 Flumioxazin; tolerances for residues.

(a) *General.* 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-isoindole-1,3(2H)-dione, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only flumioxazin.

Commodity	Parts per million
Alfalfa, forage	3.0
Alfalfa, hay	8.0
Almond, hulls	0.70

Commodity	Parts per million
Artichoke, globe	0.02
Asparagus	0.02
Berry, low growing, subgroup 13-07G	0.07
Bushberry subgroup 13-07B	0.02
Caneberry, subgroup 13-07A	0.50
Citrus, group 10-10	0.02
Citrus, oil	0.1
Corn, field, forage	0.02
Corn, field, grain	0.02
Corn, field, stover	0.02
Cotton, gin byproducts	0.60
Cotton, undelinted seed	0.02
Fish, freshwater	1.5
Fruit, pome, group 11-10	0.02
Fruit, small vine climbing, except for fuzzy kiwifruit, subgroup 13-07F	0.02
Fruit, stone, group 12-12	0.02
Grain, aspirated fractions	100
Hop, dried cones	0.05
Leaf petioles subgroup 4B	0.02
Nut, tree, group 14-12	0.02
Olive	0.02
Onion, bulb subgroup 3-07A	0.02
Pea and bean, dried shelled, except soybean, subgroup 6C	0.07
Peanut	0.02
Peppermint, tops	0.04
Pomegranate	0.02
Prickly pear, fruit	0.07
Prickly pear, pads	0.06
Rapeseed subgroup 20A	0.40
Soybean forage	0.03
Soybean hay	0.02
Soybean, seed	0.02
Spearmint, tops	0.04
Sugarcane, cane	0.20
Sunflower subgroup 20B	0.50
Vegetable, brassica, head and stem, group 5-16	0.02
Vegetable, cucurbit, group 9	0.03
Vegetable, fruiting, group 8-10	0.02
Vegetable, tuberous and corm, subgroup 1C	0.02
Wheat, forage	0.02
Wheat, grain	0.40
Wheat, hay	0.02
Wheat, straw	6.0

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

(c) *Tolerances with regional registrations.* 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-isoindole-1,3(2H)-dione, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only flumioxazin.

Commodity	Parts per million
Clover, forage	0.02
Clover, hay	0.15

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

[FR Doc. 2016–30467 Filed 12–16–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 59

RIN 937–AA04

Compliance With Title X Requirements by Project Recipients in Selecting Subrecipients

AGENCY: Office of Population Affairs, Office of the Secretary, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Department is amending the regulations that apply to Title X Project Grants for Family Planning Services. The final rule amends eligibility requirements to require that no recipient making subawards for the provision of services as part of its Title X project may prohibit an entity from participating for reasons other than its ability to provide Title X services.

DATES: This Rule is effective on January 18, 2017.

FOR FURTHER INFORMATION CONTACT: Susan B. Moskosky, MS, WHNP–BC, Office of Population Affairs (OPA), 200 Independence Avenue SW., Suite 716G, Washington, DC 20201; telephone (240) 453–2800; email: OPA_Resource@hhs.gov.

SUPPLEMENTARY INFORMATION: On September 7, 2016, The Department issued a proposed rule seeking comment on amending eligibility criteria under the Title X family planning services program so that no recipient making subawards for the provision of services as part of its Title X project may prohibit an entity from participating for reasons unrelated to its ability to provide Title X services effectively. 81 FR 61639. As reiterated below, the proposed rule set forth the need for the amendment and sought public input.

I. Background

A. Title X Background

As discussed in the Notice of Proposed Rule Making (NPRM), the Title X Family Planning Program, Public Health Service Act (PHSA) secs. 1001 *et seq.* [42 U.S.C. 300], was enacted in 1970 as part of the Public Health Service Act. Administered by the Office of Population Affairs (OPA) within the Office of the Assistant Secretary for Health (OASH), Title X is the only federal program focused solely on

providing family planning and related preventive services. In 2015, more than 4 million individuals received services through more than 3,900 Title X-funded health centers.¹

Title X serves women, men, and adolescents to enable individuals to determine freely the number and spacing of children. By law, services are provided to low-income individuals at no or reduced cost. Services provided through Title X-funded health centers assist in preventing unintended pregnancies and achieving pregnancies that result in positive birth outcomes. These services include contraceptive services, pregnancy testing and counseling, preconception health services, screening and treatment for sexually transmitted diseases (STD), HIV testing and referral for treatment, services to aid with achieving pregnancy, basic infertility services, and screening for cervical and breast cancer. By statute, Title X funds are not available to programs where abortion is a method of family planning (PHSA sec. 1008). Additionally, Title X implementing regulations require that all pregnancy options counseling shall be neutral and nondirective. 42 CFR 59.5(a)(5)(ii).

The Title X statute authorizes the Secretary “to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents).” PHSA sec. 1001(a). In addition, in awarding Title X grants and contracts, the Secretary must “take into account the number of patients to be served, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance.” PHSA sec. 1001(b). The statute also requires that local and regional entities “shall be assured the right to apply for direct grants and contracts.” PHSA sec. 1001(b). The statute delegates rulemaking authority to the Secretary to set the terms and conditions of these grants and contracts. PHSA sec. 1006. These regulations were last revised in 2000. 65 FR 41270 (July 3, 2000).

Title X regulations delineating the criteria used to decide which family planning projects to fund and in what amount, include, among other factors,

the extent to which family planning services are needed locally, the number of patients (and, in particular, low-income individuals) to be served, and the adequacy of the applicant’s facilities and staff. 42 CFR 59.7. Project recipients receive funds directly from the federal government following a competitive process. The project recipients may elect to provide Title X services directly, subaward funds to subrecipients, or both. The Department is responsible for monitoring and evaluating the project recipient’s performance and outcomes, and each project recipient that subawards to eligible subrecipients is responsible for monitoring the performance and outcomes of those subrecipients. The subrecipients must meet the same federal requirements as the project recipients, including being a public or private nonprofit entity, and adhering to all Title X and other applicable federal requirements. In the event of poor performance or noncompliance, a project recipient may take enforcement actions as described in the uniform grants rules at 45 CFR 75.371.

B. State Restrictions on Subrecipients

In the past several years, a number of states have taken actions to restrict participation by certain types of providers as subrecipients in the Title X program, for reasons other than the provider’s ability to provide Title X services. In at least several instances, this has led to disruption of services or reduction of services. Since 2011, 13 states have placed restrictions on or eliminated subawards with specific types of providers based on reasons other than their ability to provide Title X services. In several instances, these restrictions have interfered with the “capacity [of the applicant] to make rapid and effective use of [Title X federal] assistance.” PHSA sec. 1001(b). Moreover, states that restrict eligibility of subrecipients have caused limitations in the geographic distribution of services and decreased access to services through trusted providers.

States have restricted subrecipients from participating in the Title X program in several ways. Some states have employed a tiered approach to compete or distribute Title X funds, whereby entities such as comprehensive primary care providers, state health departments, or community health centers receive a preference in the distribution of Title X funds. This approach effectively excludes providers focused on reproductive health from receiving funds, even though they have been shown to provide higher quality services, such as preconception

¹ Fowler, C.I., Gable, J., Wang, J., & Lasater, B. (2016, August). Family Planning Annual Report: 2015 National Summary. Research Triangle Park, NC: RTI International.