



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0333; FRL-9984-01]

Flumioxazin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances with regional registrations for residues of flumioxazin in or on Grass, forage and Grass, hay. 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-2017-0333, 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 L. 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: RDFRNotices@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 FFDCFA 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-2017-0333 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-2017-0333, 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 October 23, 2017 (82 FR 49020) (FRL-9967-37), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E8565) by IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.568(c) be amended by establishing tolerances with regional registrations 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, including its metabolites and degradates, determined by measuring only flumioxazin, in or on Grass, forage at 0.4 parts per million (ppm) and Grass, hay 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>. This petition request is associated with an application to allow use of flumioxazin on grass in the States of Washington, Idaho, and Oregon. Although comments were submitted to the docket, none were relevant to the safety of the tolerances being established in this action.

Consistent with the authority in FFDCCA 408(d)(4)(A)(i), EPA is issuing a tolerance that varies from what the petitioner sought. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCCA 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 FFDCCA 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 FFDCCA 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 FFDCCA section 408(b)(2)(D), and the factors specified in FFDCCA 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 titled, “*SUBJECT: Flumioxazin. Human Health Risk Assessment for the Proposed New Uses on Grass (Seed Crop)*” at page 24 in docket ID number EPA-HQ-OPP-2017-0333.

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). One additional endpoint has since been identified, i.e., the selection of an adult oral endpoint for assessing the aggregate risks from short-term and intermediate-term oral exposure: an oral NOAEL of 3 mg/kg/day based on cardiovascular effects in fetuses seen at the LOAEL of 10 mg/kg/day in the rat developmental study was used, along with a 10X interspecies uncertainty factor, a 10X intraspecies uncertainty factor, and a 1X FQPA safety factor. Long-term exposures (greater than 6 months) are not expected based on the existing flumioxazin use pattern.

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 United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA; 2003-2008). As to residue levels

in food, EPA assumed tolerance-level residues, 100% 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 software which incorporates 2003–2008 food consumption data from USDA’s NHANES/WWEIA. As to residue levels in food, EPA incorporated tolerance-level residues and/or 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 PCT 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 hydrolysis and 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 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 400 ppb 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 141 ppb 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 grass, residential lawns, ornamentals, and aquatic weeds. EPA assessed residential exposure under 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 and oral post-application exposures and risks were assessed for adults and children. In addition, oral post-application exposures and risks were assessed specifically 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 website 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 the 10X FQPA database uncertainty factor (UF) for inhalation exposure and risk assessment due to the lack of an inhalation study. That decision is based on the following findings:

i. The toxicity database for flumioxazin is incomplete but sufficient for assessing the toxicity and characterizing the hazard of flumioxazin due to the absence of an acceptable inhalation study. Therefore, 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 acute and chronic dietary food exposure assessments were performed based on tolerance-level residues, default processing factors, and assuming 100 PCT. 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 post-application 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-term and intermediate-term risks.* Short-term and intermediate-term aggregate exposure takes into account short-term and intermediate-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 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 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 MOE of 200 for children less than 2 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/nitrogen-phosphorus detection (GC/NPD) method, Valent Method RM30-A-1), is available to enforce the tolerance expression. The reported method limits of quantitation and detection (LOQ and LOD) for flumioxazin in/on plant commodities are 0.02 and 0.01 ppm, respectively.

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 FFDC 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 a MRL for flumioxazin in/on grass, therefore there are no international harmonization issues.

C. Revisions to Petitioned-For Tolerances

EPA is establishing a tolerance for Grass, forage at 0.40 ppm, rather than 0.4 ppm, to be consistent with its practice to provide greater precision about the levels of residues that are permitted by a tolerance. This is intended to avoid the situation where residues may be higher than the tolerance level, but as a result of rounding would be considered non-violative. For example, Grass, forage tolerance proposed at 0.4 ppm was established at 0.40 ppm, to avoid an observed hypothetical tolerance at 0.44 ppm being rounded to 0.4 ppm.

V. Conclusion

Therefore, tolerances with regional registrations 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, including its metabolites and degradates determined by measuring only flumioxazin, in or on raw agricultural commodities, in or on Grass, forage at 0.40 ppm and Grass, hay at 0.05 ppm.

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); or Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). 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 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 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: September 21, 2018.

Michael L. Goodis,
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 commodities “Grass, forage” and “Grass, hay” to the table in paragraph (c) to read as follows:

§ 180.568 Flumioxazin; tolerances for residues.

* * * * *

(c) * * *

Commodity	Parts per million
* * *	* * * * *
Grass, forage	0.40
Grass, hay	0.05

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