

Commodity	Parts per million	Expiration/revocation date
Bermuda grass, forage	10	12/31/11
Bermuda grass, hay ...	25	12/31/11

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2008-0885; FRL-8810-3]

#### Flumioxazin; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of flumioxazin in or on vegetable, cucurbit, group 9; leaf petioles subgroup 4B; and hop, dried cones. This regulation additionally deletes the existing tolerances on almond and melon, subgroup 9A, as they will be superseded by inclusion in tree nut group 14 and cucurbit vegetable group 9, respectively. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective February 24, 2010. Objections and requests for hearings must be received on or before April 26, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0885. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m.

to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

#### FOR FURTHER INFORMATION CONTACT:

Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7390; e-mail address: [nollen.laura@epa.gov](mailto:nollen.laura@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

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

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

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

###### B. How Can I 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 cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/oppts> and select "Test Methods and Guidelines."

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

Under section 408(g) of FFDCA, 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-2008-0885 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before April 26, 2010.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2008-0885, by one of the following methods:

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

##### II. Petition for Tolerance

In the **Federal Register** of April 13, 2009 (74 FR 16866) (FRL-8396-6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7462) by IR-4, 500 College Rd. 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 vegetable, cucurbit, group 9 at 0.03 parts per million (ppm); leaf petioles, subgroup 4B at 0.02 ppm; and hop, dried cones at 0.07 ppm. The petition additionally requested that EPA revoke the existing tolerance on almonds, as a tolerance on nut, tree, group 14 has been established; and requested that EPA delete the existing tolerance for melon subgroup 9A,

because it will be replaced by the proposed tolerance for vegetable, cucurbit, group 9. That notice referenced a summary of the petition prepared on behalf of IR-4 by Valent U.S.A. Corporation, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance on hop, dried cones. 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 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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of flumioxazin on vegetable, cucurbit, group 9 at 0.03 ppm; leaf petioles subgroup 4B at 0.02 ppm; and hop, dried cones at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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.

Flumioxazin has mild or no acute toxicity when administered via the oral, dermal and inhalation routes of exposure. It has little or no toxicity with respect to eye or skin irritation and is not a dermal sensitizer. Subchronic and chronic toxicity studies demonstrated that the key toxic effects associated with flumioxazin include anemia and impacts on the liver and the cardiovascular system. Hematologic (hematopoietic) effects of anemia were noted in rats, including alterations in hemoglobin parameters. Increased absolute and relative liver weights and/or increased alkaline phosphatase values were observed in dogs.

There was no evidence (quantitative or qualitative) of susceptibility following *in-utero* oral exposure in rabbits. Developmental studies in the rat resulted in cardiovascular anomalies, including ventricular septal defects. In the two-generation reproduction study, systemic effects (clinical signs and mortality as well as a decrease in body weight/gain and food consumption) were noted in males and females; more severe offspring effects (decrease in the number of live born and decreased pup body weights) were noted at lower doses than that which resulted in parental effects.

None of the acute, subchronic, chronic, developmental or reproduction studies indicated an effect on the nervous systems. Based on the lack of evidence of carcinogenicity in mice and rats, flumioxazin is classified as "not likely to be carcinogenic to humans." Flumioxazin did not induce significant increases in any tumor type in either rats or mice under the conditions of the studies, and it did not induce any mutagenic activity in the required battery of mutagenicity studies.

Specific information on the studies received and the nature of the adverse effects caused by flumioxazin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document "Flumioxazin. Human Health Risk Assessment for the Proposed Aquatic Use and Proposed Food Uses on Cucurbit Vegetables, Leaf Petioles, and Hops," at pages 58-62 in docket ID number EPA-HQ-OPP-2008-0885.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk

assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a benchmark dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

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 greater than that 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 can be found at <http://www.regulations.gov> in the document "Flumioxazin. Human Health Risk Assessment for the Proposed Aquatic Use and Proposed Food Uses on Cucurbit Vegetables, Leaf Petioles, and Hops," at pages 26-28 in docket ID number EPA-HQ-OPP-2008-0885.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to flumioxazin, EPA considered exposure under the petitioned-for tolerances as well as all existing flumioxazin tolerances in 40 CFR 180.568. EPA assessed dietary exposures from flumioxazin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments

are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effect was identified for the general population. However, EPA identified potential acute effects (cardiovascular effects in offspring) for the population subgroup, females 13 to 49 years old.

In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance-level residues, Dietary Exposure Evaluation Model (DEEM) default processing factors for all processed commodities (with the exception of tomato, which used the empirical processing factor of 1x), and assumed 100 percent crop treated (PCT) for all proposed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used tolerance-level residues, DEEM default processing factors for all processed commodities (with the exception of tomato, which used the empirical processing factor of 1x), and assumed 100 PCT for all proposed commodities.

iii. *Cancer.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, EPA has classified flumioxazin as “not likely to be carcinogenic to humans.” Therefore, a quantitative exposure assessment to evaluate cancer risk is unnecessary.

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

2. *Dietary exposure from drinking water.* A hydrolysis study for flumioxazin indicates that flumioxazin forms the metabolite 482-HA, which can further hydrolyze into the metabolites APF and THPA. The rates of the two hydrolytic reactions are very pH dependent, but flumioxazin is not very stable at any likely environmental pH. Data also indicates that THPA and APF are likely to be very mobile. Although THPA can comprise a major portion of the total residue in water, it does not possess a phenyl ring and is thus considered significantly less toxic than flumioxazin, APF, and 482-HA. For this reason, THPA has not been included as

a residue of concern in drinking water. Therefore, the residues of concern in drinking water are flumioxazin and its 482-HA and APF degradates. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for flumioxazin and its degradates of concern in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of flumioxazin and its degradates of concern. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST) model, the estimated drinking water concentrations (EDWCs) of flumioxazin, 482-HA and APF for acute exposures are estimated to be 1.03 parts per billion (ppb), 6.87 ppb, and 26.46 ppb, respectively, for surface water. For chronic exposures for non-cancer assessments, the EDWCs of 482-HA and APF are estimated to be 4.84 ppb and 12.85 ppb, respectively, for surface water. 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 acute exposures and in both surface and ground water for chronic exposures.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The EDWC of 48 ppb (0.048 ppm), the total EDWC for flumioxazin residues in groundwater (including flumioxazin, 482-HA, and APF), was used to assess the contribution to drinking water for both the acute and chronic dietary risk assessments.

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 use in the following areas that could result in residential exposures: Walkways, parking lots and non-grassy areas around residential dwellings. EPA assessed residential exposure using the following assumptions: Short-term dermal and inhalation exposure to adult handlers resulting from the use of flumioxazin within residential settings. For the above use sites, no

postapplication exposure to adults or children from flumioxazin is expected.

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 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.* The prenatal and postnatal toxicology database for flumioxazin includes rat and rabbit prenatal developmental toxicity studies and a two-generation reproduction toxicity study in rats. There is no evidence of increased susceptibility following *in-utero* oral exposure in rabbits; however, there is evidence of increased quantitative susceptibility of rat fetuses to *in utero* exposure to flumioxazin in the oral and dermal developmental studies. In both studies, there was an increased incidence in fetal cardiovascular anomalies (including ventricular septal defects) in the absence of maternal toxicity. Additionally, quantitative susceptibility was observed in the two-

generation rat reproduction study, in which offspring effects (decrease in the number of live born and decreased pup body weights) were observed at lower doses than those which caused parental/systemic toxicity (red substance in vagina and increased mortality in females as well as decreases in male and female body weights, body weight gains and food consumption).

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. That decision is based on the following findings:

i. The toxicity database for flumioxazin is complete except for immunotoxicity, acute neurotoxicity, and subchronic neurotoxicity testing. Recent changes to 40 CFR part 158 make acute and subchronic neurotoxicity testing (OPPTS Guideline 870.6200), and immunotoxicity testing (OPPTS Guideline 870.7800) required for pesticide registration; however, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA.

The available data for flumioxazin do not show the potential for neurotoxic effects. In the subchronic and chronic toxicity studies, signs of anemia (a potential immunotoxic effect) were observed. In the rat, hematologic (hematopoietic) effects of anemia were noted, including alterations in hemoglobin parameters. Flumioxazin is a protoporphyrinogen oxidase (PPO) inhibitor, which inhibits the biosynthesis of chlorophyll in plants (giving flumioxazin its weed-control properties). In animals, PPO is responsible for one of the later steps in heme synthesis; therefore, the inhibition of PPO results in anemia. Although anemia can potentially be considered an immunotoxic effect, in this case it's likely the anemia is due to the inhibited heme formation (which can interfere with the porphyrin component of heme, a hematopoietic effect resulting in anemia), and the blood effects are not considered to be the result of potential immunotoxicity in this case. Thus, EPA has concluded that flumioxazin does not directly impact the nervous system or directly target the immune system. The Agency does not believe that conducting a functional immunotoxicity study will result in a NOAEL lower than the regulatory dose for risk assessment; therefore, an additional database uncertainty factor is not needed to account for potential immunotoxicity or neurotoxicity.

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 of increased quantitative susceptibility of the young following exposure to flumioxazin in the oral and dermal developmental toxicity studies in the rat and in the two-generation rat reproduction study; therefore, a degree of concern analysis was performed to determine the level of concern for the effects observed when considered in the context of all available toxicity data and to identify any residual concerns after establishing toxicity endpoints and traditional UFs to be used in the flumioxazin risk assessment. In considering the overall toxicity profile and the endpoints and doses selected for the flumioxazin risk assessment, EPA characterized the degree of concern for the susceptibility observed in the rat developmental and two-generation reproductive studies as low and determined that there are no residual uncertainties for prenatal and/or postnatal toxicity because:

a. The only missing toxicity data for flumioxazin are the newly required neurotoxicity and immunotoxicity studies; however, no additional UF is needed in the absence of these studies because there is no evidence to indicate that flumioxazin targets the nervous system or the immune system. Further, EPA has concluded that a developmental neurotoxicity study is not required.

b. There are clear NOAELs and LOAELs for the developmental and offspring effects noted in the rat developmental toxicity and two-generation reproductive toxicity studies, and the doses and endpoints have been selected from these studies for risk assessment for the relevant exposed populations, i.e., pregnant females and children (with the exception of the chronic dietary endpoint, for which a chronic study was chosen for endpoint selection).

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on conservative assumptions, including 100 PCT data 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. Postapplication exposure to children is not expected. 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to flumioxazin will occupy 9% of the aPAD for females 13 to 49 years old, the population subgroup where a potential acute risk was identified.

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 19% of the cPAD for children less than 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 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. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs of 2,400 or greater. As the aggregate MOEs for short-term exposure are greater than 100 (the LOC) for all exposure scenarios, short-term aggregate exposures to flumioxazin are not of concern to EPA.

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). Flumioxazin is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to flumioxazin through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

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

The following adequate enforcement methodology is available to enforce the tolerance expression: A gas chromatography/nitrogen-phosphorus detection (GC/NPD) method. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

There are no Codex, Canadian or Mexican maximum residue limits established for residues of flumioxazin on commodities associated with this petition.

##### C. Revisions to Petitioned-For Tolerances

Based on analysis of the residue field trial data supporting the petition, EPA revised the proposed tolerance on hop, dried cones from 0.07 ppm to 0.05 ppm. EPA revised this tolerance level based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data*. EPA has also revised the introductory text in § 180.568 to clarify in the tolerance expression: (1) That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of flumioxazin not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

#### 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 vegetable, cucurbit, group 9 at 0.03 ppm; leaf petioles subgroup 4B at 0.02 ppm; and hop, dried cones at 0.05 ppm.

#### VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this 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 section 408(d) of FFDCA, 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 final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined

that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 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) (Public Law 104-4).

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

#### VII. Congressional Review Act

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

#### List of Subjects in 40 CFR Part 180

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

Dated: February 1, 2010.

**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. Section 180.568 is amended in paragraph (a) by revising the introductory text, removing the entries for "Almond" and "Melon, subgroup 9A" from the table; and by alphabetically adding "Hop, dried cones"; "Leaf petioles subgroup 4B"; and "Vegetable, cucurbit, group 9" to the table to read as follows:

**§ 180.568 Flumioxazin; tolerances for residues.**

(a) \* \* \* 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
* * *	* *
Hop, dried cones .....	0.05
Leaf petioles subgroup 4B ...	0.02
* * *	* *
Vegetable, cucurbit, group 9	0.03
* * *	* *

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**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Subchapter R**

[EPA-HQ-OPPT-2007-0392; FRL-8798-9]

RIN 2070-AJ21

**Final Clarification for Chemical Identification Describing Activated Phosphors for TSCA Inventory Purposes**

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

**ACTION:** Final clarification.

**SUMMARY:** This is a clarification under which certain activated phosphors that are not on the Toxic Substances Control Act (TSCA) section 8(b) Chemical Substance Inventory (TSCA Inventory) will be considered to be new chemical substances under TSCA section 5, and thus will be subject to applicable notification requirements under TSCA section 5. In certain letters and other statements issued by EPA from 1978 to 2003, the Agency erroneously indicated that activated phosphors (otherwise known as doped phosphors) constitute mixtures of phosphors and dopants for purposes of the TSCA Inventory, and thus that they were not separately reportable as chemical substances under TSCA section 5(a) new chemical notification requirements. This clarification is necessary because EPA's statements in this area have not been consistent.

**DATES:** EPA's clarification is effective August 24, 2011.

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2007-0392. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

**FOR FURTHER INFORMATION CONTACT:** For general information contact: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

For technical information contact: David Schutz, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9262; e-mail address: [schutz.david@epa.gov](mailto:schutz.david@epa.gov).

**SUPPLEMENTARY INFORMATION:****I. Does this Action Apply to Me?**

You may be affected by this action if you are, or may in the future be, a manufacturer or importer of an activated phosphor that requires submission of a premanufacture notification (PMN) or

exemption request under TSCA section 5. Special procedures will apply to persons who manufactured these chemical substances after the publication of the Initial TSCA Inventory and before the effective date of this final chemical identification clarification document in the **Federal Register**. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers or importers (NAICS codes 325, 3251), e.g., anyone who manufactures or imports, or who plans to manufacture or import, an activated phosphor for a non-exempt commercial purpose.
- Electric lighting equipment manufacturing, electric lamp bulb and part manufacturing (NAICS codes 3351, 33511), e.g., anyone who manufactures or imports, or who plans to manufacture or import, lighting equipment containing an activated phosphor for a non-exempt commercial purpose.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

**II. Background****A. What Action is the Agency Taking?**

EPA is clarifying that certain previous EPA statements which indicated that activated phosphors are mixtures rather than chemical substances in their own right were erroneous, and that TSCA Inventory listing may be required for these materials. This action provides a clarification in the approach used for the chemical identification of activated (doped) phosphors for purposes of listing on the TSCA Inventory. This clarification was proposed in the **Federal Register** issue of January 16, 2008 (73 FR 2854) (FRL-8131-8) and a reopening of comments on the proposed clarification was announced in the **Federal Register** issue of May 2, 2008 (73 FR 24187) (FRL-8360-7).

An activated phosphor is a substance resulting from the chemical combination of a mixture of metal oxides, carbonates, phosphates or acid phosphates, chlorides, and/or fluorides, most frequently by sintering, along with a small amount of one or more dopants. Dopants can include such substances as