

Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must

submit a rule report, which includes a copy of the rule, 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: August 12, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.191 is amended by revising the entry for “Hops, dried cones” in the table in paragraph (a) as follows:

§ 180.191 Folpet; tolerances for residues.
(a) * * *

Commodity	Parts per million
* * * * *	*
Hop, dried cones	120
* * * * *	*

* * * * *
[FR Doc. 04–19036 Filed 8–24–04; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0212; FRL–7369–9]

Flumioxazin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flumioxazin in or on almond, garlic, grape, onion, peppermint, pistachio, shallot, spearmint, sugarcane, and tuberous/corm vegetables (Subgroup 1C). Valent U.S.A. Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 25, 2004. Objections and requests for hearings must be received on or before October 25, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket Identification (ID) number OPP–2004–0212. All documents in the docket are

listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 South Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: Miller.Joanne@epamail.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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather 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 person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at

<http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

II. Background and Statutory Findings

In the **Federal Register** of December 31, 2002 (67 FR 79918) (FRL-7285-6), and March 17, 2004 (69 FR 12683) (FRL-7346-8), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 1F6296 and 0F6171) by Valent U.S.A. Corporation, 1333 North California Boulevard, Suite 600, Walnut Creek, CA 94596-8025 and pesticide petitions (PP 3E6777, 3E6788 and 3E6779) by Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. The notices included a summary of the petitions prepared by Valent U.S.A. Corporation, the registrant, and IR-4. There were no comments received in response to the notices of filing.

The petitions requested that 40 CFR 180.568 be amended by establishing tolerances for residues of the herbicide flumioxazin, 2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propynyl)-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isoindole-1,3(2H)-dione, in or on the raw agricultural commodities grape at 0.02 parts per million (ppm), almonds at 0.02 ppm, pistachios at 0.02, almond, hulls at 0.70 ppm (1F6296), sugarcane at 0.20 ppm (0F6171), peppermint, tops; and spearmint, tops at 0.04 ppm (3E6777), onion, dry bulb; garlic, bulb; and shallot, bulb at 0.02 ppm (3E6788), vegetable, tuberous and corm subgroup 1C at 0.02 ppm (3E6779). The proposed tolerances were corrected to conform to the Food and Feed Commodity Vocabulary database (<http://www.epa.gov/pesticides/foodfeed/>) to read as follows: Grape at 0.02 ppm, almond (nutmeat) at 0.02 ppm, almond (hulls) at 0.70 ppm, pistachio at 0.02 ppm, onion (dry bulb) at 0.02 ppm, garlic (bulb) at 0.02 ppm, shallot (bulb) at 0.02 ppm, tuberous/corm vegetables (Subgroup 1C) at 0.02 ppm, sugarcane (cane) at 0.20 ppm, peppermint (tops) at 0.04 ppm, and spearmint (tops) at 0.04 ppm.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish tolerances (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. . . ."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for tolerances 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 on grape at 0.02 ppm, almond (nutmeat) at 0.02 ppm, almond (hulls) at 0.70 ppm, pistachio at 0.02 ppm, onion (dry bulb) at 0.02 ppm, garlic (bulb) at 0.02 ppm, shallot (bulb) at 0.02 ppm, tuberous/corm vegetables (Subgroup 1C) at 0.02 ppm, sugarcane (cane) at 0.20 ppm, peppermint (tops) at 0.04 ppm, and spearmint (tops) at 0.04 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered 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. The nature of the toxic effects caused by flumioxazin are discussed in a March 31, 2004 **Federal Register** document (69 FR 16823) (FRL-7351-2).

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: "Traditional UFs"; the "special FQPA safety factor"; and the "default FQPA safety factor." By the term "traditional uncertainty factor," EPA is referring to those additional UFs used prior to FQPA passage to account for database deficiencies. These traditional UFs have been incorporated by the FQPA into the additional safety factor (SF) for the protection of infants and children. The term "special FQPA SF" refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The "default FQPA SF" is the additional 10X SF that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional UF or a special FQPA SF).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional UFs deemed appropriate (RfD = NOAEL/UF). Where a special FQPA SF or the default FQPA SF is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of

exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC. The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a

probability risk is expressed would be to describe the risk as one in one hundred thousand (1 x 10⁻⁵), one in a million (1 x 10⁻⁶), or one in ten million (1 x 10⁻⁷). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to

cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for flumioxazin used for human risk assessment is shown in Table 1 of this unit:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FLUMIOXAZIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13–49 years of age)	NOAEL = 3 milligrams/kilogram (mg/kg)/day aRfD = 0.03 mg/kg/day	Special FQPA SF = 1 aPAD = aRfD ÷ FQPA SF = 0.03 mg/kg/day	Oral developmental and supplemental prenatal studies (rat) LOAEL = 10 mg/kg/day based on cardiovascular effects (especially ventricular septal defects in fetuses)
Acute dietary (General population including infants and children)	An endpoint attributable to a single dose (exposure) was not identified from the available studies, including the developmental toxicity studies in rats and rabbits.		
Chronic dietary (All populations)	NOAEL= 2 mg/kg/day UF = 100 cRfD = 0.02 mg/kg/day	Special FQPA SF = 1 cPAD = cRfD ÷ FQPA SF = 0.02 mg/kg/day	2-year chronic/carcinogenicity study (rat) LOAEL = 18 mg/kg/day based on increased chronic nephropathy in males and decreased hematological parameters in females (Hgb, MCV, MCH and MCHC)
Cancer (Oral, dermal, inhalation)	Not likely to be a carcinogen for humans based on the lack of carcinogenicity in a 2-year rat study, an 18-month mouse study and a battery of mutagenic studies.		

C. Exposure Assessment

1. Dietary exposure from food and feed uses. Tolerances have been established (40 CFR 180.568) for the residues of flumioxazin, in or on cotton, peanuts and soybean seed. No secondary residues are expected in meat, milk, poultry or eggs. Risk assessments were conducted by EPA to assess dietary exposures from flumioxazin in food as follows:

i. Acute exposure. Acute dietary 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.

In conducting the acute dietary risk assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute

exposure assessments: For the acute analyses, tolerance-level residues were assumed for all food commodities with current or proposed flumioxazin tolerances, and it was assumed that all of the crops included in the analysis were treated. Percent Crop Treated (PCT) and/or anticipated residues were not used in the acute risk assessment.

ii. Chronic exposure. In conducting the chronic dietary risk assessment, EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: For the chronic analyses, tolerance-level residues were assumed for all food commodities with current or proposed flumioxazin tolerances, and it was assumed that all of the crops included in the analysis were treated. PCT and/or anticipated residues were not used in the chronic risk assessment.

2. Dietary exposure from drinking water. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure

analysis and risk assessment for flumioxazin and its degradates (482-HA and APF) in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of flumioxazin and its degradates (482-HA and APF).

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in ground water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum

percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health LOC.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to flumioxazin they are further discussed in Unit III.E.

Based on the FIRST and SCI-GROW models, the EECs of flumioxazin and its degradates (482-HA and APF) for acute exposures are estimated to be a total of 34 parts per billion (ppb) for surface water and 48 ppb for ground water. The EECs for chronic exposures are estimated to be a total of 18 ppb for surface water and 48 ppb for ground water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Flumioxazin is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of

toxicity, EPA has not made a common mechanism of toxicity finding as to flumioxazin and any other substances. Flumioxazin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that flumioxazin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at <http://www.epa.gov/pesticides/cumulative/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold 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. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional SF value based on the use of traditional UFs and/or special FQPA SFs, as appropriate.

2. *Prenatal and postnatal sensitivity.* Although increased prenatal and postnatal quantitative susceptibility was seen in rats, it was concluded that there is low concern and no residual uncertainties for prenatal and/or postnatal toxicity because:

i. Developmental toxicity NOAELs/LOAELs are well characterized after oral and dermal exposure.

ii. Offspring toxicity NOAEL/LOAEL are well characterized.

iii. There is a well-defined dose-response curve for the cardiovascular effects seen following oral exposure (i.e. critical period).

iv. The endpoints of concern are used for overall risk assessments for appropriate route and population subgroups.

3. *Conclusion.* There is a complete toxicity database for flumioxazin and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the special 10X SF to protect infants and children should be removed. The FQPA factor is removed because developmental toxicity and offspring toxicity NOAELs/LOAELs are well characterized; there is a well-defined dose-response curve for the cardiovascular effects and the endpoints of concern are used for overall risk assessments are appropriate for the route of exposure and population subgroups.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the

aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in

drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to flumioxazin will occupy less than (<) 1% of the aPAD for females 13 to 49 years old. In addition,

there is potential for acute dietary exposure to flumioxazin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO FLUMIOXAZIN

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC/ (ppb)	Ground Water EEC/ (ppb)	Acute DWLOC/ (ppb)
Females (13–49 years)	0.03	<1	34	48	890

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to flumioxazin from food will utilize < 1% of the cPAD for the U.S. population, < 1% of the cPAD for all infant and children subpopulations.

There are no residential uses for flumioxazin that result in chronic residential exposure to flumioxazin. In addition, there is potential for chronic dietary exposure to flumioxazin in drinking water. After calculating DWLOCs and comparing them to the

EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FLUMIOXAZIN

Population Subgroup	cPAD (mg/kg/day)	% cPAD/ mg/kg/day/ (Food)	Surface Water EEC/ (ppb)	Ground Water EEC/ (ppb)	Chronic DWLOC/ (ppb)
U.S. population	0.02	<1	18	48	700
All infants (<1 year)	0.02	<1	18	48	200
Children (1–2 years)	0.02	2	18	48	200
Children (3–5 years)	0.02	2	18	48	200
Females (13–49 years)	0.02	<1	18	48	600

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

Flumioxazin is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

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

Flumioxazin is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

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, and to infants and children

from aggregate exposure to flumioxazin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

There are no Codex, Canadian or Mexican maximum residue limits established for flumioxazin on grape, almond, pistachio, onion, garlic, shallot, tuberous/corm vegetables (Subgroup 1C), sugarcane, peppermint, or spearmint.

V. Conclusion

Therefore, the tolerance is 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 grape at 0.02 ppm, almond (nutmeat) at 0.02 ppm, almond (hulls) at 0.70 ppm, pistachio at 0.02 ppm, onion (dry bulb) at 0.02 ppm, garlic (bulb) at 0.02 ppm, shallot (bulb) at 0.02 ppm, tuberous/corn vegetables (Subgroup 1C) at 0.02 ppm, sugarcane (cane) at 0.20 ppm, peppermint (tops) at 0.04 ppm, and spearmint (tops) at 0.04 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to

reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to “object” to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2004-0212 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 on or before October 25, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564-6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy

of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2004-0212, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop

an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: August 5, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.568 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.568 Flumioxazin; tolerances for residues.

(a) * * *

Commodity	Parts per million
Almond (hulls)	0.70
Almond (nutmeat)	0.02
* * *	* *
Garlic (bulb)	0.02
Grape	0.02
Onion (dry bulb)	0.02
* * *	* *
Peppermint (tops)	0.04
Pistachio	0.02
Shallot (bulb)	0.02
* * *	* *
Spearmint (tops)	0.04
Sugarcane (cane)	0.20
Tuberous/corm vegetables (Subgroup 1C)	0.02

* * * * *

[FR Doc. 04-19034 Filed 8-24-04; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2, 25, and 101

[IB Docket No. 97-95, FCC 03-296]

Allocation and Designation of Spectrum for Fixed-Satellite Services in the 37.5-38.5 GHz, 40.5-41.5 GHz and 48.2-50.2 GHz Frequency Bands; Allocation of Spectrum To Upgrade Fixed and Mobile Allocations in the 40.5-42.5 GHz Frequency Band; Allocation of Spectrum in the 46.9-47.0 GHz Frequency Band for Wireless Services; and Allocation of Spectrum in the 37.0-38.0 GHz and 40.0-40.5 GHz for Government Operations

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document is a summary of the Second Report and Order adopted by the Commission in this proceeding. The Commission modified the band plan for the 36.0-51.4 GHz band. Specifically, the Commission made various designation and allocation changes in the 37.0-42.0 GHz band to create contiguous spectrum for both fixed-satellite services and terrestrial fixed and mobile services (wireless services), which reflects decisions made at the 2000 and 2003 World Radiocommunication Conferences. The Commission finalized the satellite and terrestrial designations required by the Commission’s “soft-segmentation” approach and adopted service rules for satellite services, including gateway

definitions and power-flux density (PFD) limits.

DATES: Effective September 24, 2004.

FOR FURTHER INFORMATION CONTACT: David Strickland, Breck Blalock, or James Ball, Policy Division, International Bureau, (202) 418-1460.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission’s *Second Report and Order* in IB Docket No. 97-95, FCC No. 03-296, adopted November 17, 2003 and released on December 5, 2003. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY-A257), 445 12th Street, SW., Washington, DC 20554. The document is also available for download over the Internet at http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-03-296A1.pdf. The complete text may also be purchased from the Commission’s copy contractor, Qualex International, in person at 445 12th Street, SW., Room CY-B402, Washington, DC 20554, via telephone at (202) 863-2893, via facsimile at (202) 863-2898, or via e-mail at qualexint@aol.com.

Summary of Report and Order

On May 24, 2001, the Commission adopted a Further Notice of Proposed Rulemaking (66 FR 35399, July 5, 2001) in this proceeding to obtain comment on proposals to modify the band plan for the 36.0-51.4 GHz band. On December 5, 2003, the Commission released a Second Report and Order in this proceeding. In the Second Report and Order, the Commission made various designation and allocation changes in the 37.0-42.0 GHz band to create contiguous spectrum for both fixed-satellite services and terrestrial fixed and mobile services (wireless services), which reflects decisions made at the 2000 World Radiocommunication Conference (WRC-2000) in Istanbul, Turkey and the 2003 World Radiocommunication Conference (WRC-2003) in Geneva, Switzerland. The Commission finalized the satellite and terrestrial designations required by the Commission’s “soft segmentation” approach and adopted service rules for satellite services, including gateway definitions and power-flux density (PFD) limits. The Commission will address in separate service rulemakings additional service rules for satellite and terrestrial systems’ use of the designations we adopt in this item, including the precise conditions applied to the satellite PFD limits adopted in this Second Report and Order, and proposed rules to coordinate certain types of earth stations operating in the