

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 technical correction does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, this technical correction 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.

**V. 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: July 8, 2005.

**Betty Shackelford,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR part 180 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 § 180.920, by revising the entry for 2-Propanamine, compound with  $\alpha$ -phosphono- $\omega$ -butoxypoly (oxy-1,2-ethanediyl) (2:1), in the table, to read as follows:

**§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
* * * * *	* * * * *	* * * * *
2-Propanamine, compound with $\alpha$ -phosphono- $\omega$ -butoxypoly (oxy-1,2-ethanediyl) (2:1). (CAS No. 431040-31-2).	Not more than 15% in the formulated product.	Surfactant
* * * * *	* * * * *	* * * * *

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-2005-0170; FRL-7723-3]

**Etoxazole; Pesticide Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of etoxazole in or on grapes and tree nuts, including pistachios. 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 July 20, 2005. Objections and requests for hearings must be received on or before September 19, 2005.

**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-2005-0170. 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 S. 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:** Kable Davis, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 306-0415; e-mail address: [davis.kable@epa.gov](mailto:davis.kable@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; farmers; 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/>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm/>.

**II. Background and Statutory Findings**

In the **Federal Register** of September 26, 2003 (68 FR 55485) (FRL-7324-8), 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 3F6739) by Valent U.S.A. Corporation, 1600 Riviera

Avenue, Suite 200, P.O. Box 8025, Walnut Creek, CA 94596. The petition requested that 40 CFR 180.593 be amended by establishing a tolerance for residues of the insecticide etoxazole, [2-(2, 6-difluorophenyl)-4-[4-(1, 1-dimethylethyl)-2-ethoxyphenyl]-4, 5-dihydrooxazole], in or on grapes at 0.50 parts per million (ppm), raisins at 1.5 ppm, tree nuts (Crop Group 14), including pistachios at 0.01 ppm, and almond, hulls at 2.0 ppm. That notice included a summary of the petition prepared by Valent U.S.A. Corporation, the registrant. A comment was received from a private citizen who challenged the value of using animal testing for evaluating pesticide toxicity. This commenter's objections have been addressed in prior rulemaking documents in the *Federal Register* of October 29, 2004 (69 FR 63083) (FRL-7681-9).

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. . . ."

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 of November 26, 1997 (62 FR 62961) (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 a tolerance for residues of etoxazole on grapes at 0.50 ppm, raisins at 1.5 ppm, tree nuts (Crop Group 14), including pistachios at 0.01 ppm, and almond, hulls at 2.0 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 etoxazole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of September 26, 2003 (68 FR 55485) (FRL-7324-1).

*B. Toxicological Endpoints*

The dose at which 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 LOAEL of concern are identified 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 uncertainty factors (UF);" the "special FQPA safety factor;" and, the "default FQPA safety factor." By the term "traditional UF," 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 for the protection of infants and children. The term "special FQPA safety factor" 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 safety factor" is the additional 10X safety factor 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 safety factor).

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 safety factor or the default FQPA safety factor 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 safety factor.

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 ( $1 \times 10^{-5}$ ), one in a million ( $1 \times 10^{-6}$ ), or one in ten million ( $1 \times 10^{-7}$ ). 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 ( $MOE_{cancer} = \text{point of departure}/\text{exposures}$ ) is calculated.

A summary of the toxicological endpoints for etoxazole used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of September 26, 2003 (68 FR 55485) (FRL-7324-8).

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.593) for the residues of etoxazole in or on a variety

of raw agricultural commodities. The tolerances include: Apple, wet pomace 0.50 ppm, cattle fat 0.02 ppm, cattle liver 0.01 ppm, cotton gin byproducts 1.0 ppm, cotton undelinted seed 0.05 ppm, pome fruit (group 11) 0.20 ppm, goat fat 0.02 ppm, goat liver 0.01 ppm, horse fat 0.02 ppm, horse liver 0.01 ppm, milk fat 0.01 ppm, sheep fat 0.02 ppm, sheep liver 0.01 ppm, strawberry 0.50 ppm, tangerine 0.10 ppm. Risk assessments were conducted by EPA to assess dietary exposures from etoxazole 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. An endpoint of concern attributable to a single oral dose was not selected for either the general U.S. population (including infants and children) or the females 13–50 years old population subgroup for etoxazole; therefore, an acute dietary exposure analysis was not performed. EPA evaluated the suitability of the developmental toxicity study in rabbits in which the developmental NOAEL of 200 milligram/kilogram/day (mg/kg/day) is based upon increased incidences of 27 presacral vertebrae and 27 presacral vertebrae with 13th ribs (skeletal variations) in the fetuses at the LOAEL of 1,000 mg/kg/day (limit dose). Although these developmental effects may be attributed to a single dose, EPA concluded that these effects are minor in magnitude and were observed only at the limit dose (1,000 mg/kg/day).

Therefore, quantitation of the acute risk was not performed.

ii. *Chronic exposure.* In conducting the chronic 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 chronic exposure assessments: The assessment assumed that 100% of the proposed crops were treated and that all treated crops and livestock had residues of concern at the tolerance level.

iii. *Cancer.* EPA has determined that etoxazole is not likely to be a human carcinogen and EPA therefore, does not expect it to pose a cancer risk. As a result, a quantitative cancer dietary exposure analysis was not performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for etoxazole 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 etoxazole.

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 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 levels of concern.

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 etoxazole they are further discussed in the aggregate risk sections in this Unit.

Based on the FIRST and SCI-GROW models, the EECs of etoxazole for chronic exposures are estimated to be 1.77 parts per billion (ppb) for surface water and 0.242 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).

Etoxazole 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 the 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 etoxazole and any other substances and etoxazole 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 etoxazole 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 website 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 data base 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 UFs (safety) 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 safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

#### 2. Prenatal and postnatal sensitivity.

There is qualitative evidence of increased susceptibility following exposure to etoxazole in the rat reproduction study. Therefore, EPA performed a Degree of Concern Analysis to determine the LOC for the effects observed when considered in the context of all available toxicity data, and to identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of this chemical. If residual uncertainties are identified, EPA examines whether these residual uncertainties can be addressed by a special FQPA safety factor and, if so, the size of the factor needed. In performing the Degree of Concern Analysis, EPA noted that the effects in the pups in the rat reproduction study are well-characterized with a clear NOAEL. In addition, the pup effects occur at the same dose as maternal toxicity. Furthermore, the doses selected for various risk assessment scenarios are lower than the doses that caused off spring toxicity. There are no residual uncertainties for prenatal/postnatal toxicity in this study. Therefore, although there is evidence of increased qualitative susceptibility in the rat reproduction study, the concern is low. For the reasons stated above, EPA has concluded that there is low concern for prenatal and/or postnatal toxicity resulting from exposure to etoxazole.

3. *Conclusion.* There is a complete toxicity data base for etoxazole and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be removed. The FQPA factor is removed for the following reasons. The toxicological data base is complete for FQPA assessment and there is low concern for prenatal and/or postnatal toxicity resulting from exposure to etoxazole. The chronic dietary food exposure assessment assumed that 100% of the proposed crops were treated and that all treated crops and livestock had residues of concern at the tolerance level. By using these screening-level assumptions, actual exposures/risks will not be underestimated. In addition, the dietary drinking water assessment utilized modeling results which

included conservative assumptions for the parent and all degradates of concern. Since conservative assumptions were used in the water models where environmental fate data are lacking, the water exposure assessment will not underestimate the potential risks for infants, and children. Finally, there are no registered or proposed residential uses for etoxazole.

#### 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.* An endpoint of concern attributable to a single oral dose was not identified in the hazard data base for either the general U.S. population (including infants and children) or the females 13–50 years old population subgroup. Therefore, no acute risk is expected.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to etoxazole from food will utilize 1% of the cPAD for the U.S. population, 4% of the cPAD for all infants (<1 year old), and 8% of the cPAD for children 1–2 years old. There are no residential uses for etoxazole that result in chronic residential exposure to

etoxazole. In addition, there is potential for chronic dietary exposure to etoxazole 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 the following Table 1:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON- CANCER) EXPOSURE TO ETOXAZOLE

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.046	1	1.77	0.242	1,600
All infants<1 year old)	0.046	4	1.77	0.242	440
Children (1–2 years old)	0.046	8	1.77	0.242	420
Children (3–5 years old)	0.046	5	1.77	0.242	440
Children (6–12 years old)	0.046	2	1.77	0.242	450
Youth (13–19 years old)	0.046	1	1.77	0.242	1,400
Adults (20–49 years old)	0.046	1	1.77	0.242	1,600
Females (13–49 years old)	0.046	1	1.77	0.242	1,400
Adults (50+ years old)	0.046	1	1.77	0.242	1,600

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).

Etoxazole 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 level of concern.

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

Etoxazole 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 level of concern.

5. *Aggregate cancer risk for U.S. population.* Etoxazole has been classified as a "not likely human carcinogen." Therefore, etoxazole is not expected to pose a cancer risk.

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, and to infants and children from aggregate exposure to etoxazole residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography/mass-selective detector or nitrogen/phosphorus detector) 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](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

No Codex, Canadian or Mexican maximum residue limits have been established for residues of etoxazole.

#### V. Conclusion

Therefore, the tolerance is established for residues of etoxazole, [2-(2, 6-difluorophenyl)-4-[4-(1, 1-dimethylethyl)-2-ethoxyphenyl]-4, 5-dihydrooxazole], in or on grapes at 0.50 ppm, raisins at 1.5 ppm, tree nuts (Crop Group 14), including pistachios at 0.01 ppm, and almond, hulls at 2.0 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–2005–0170 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 September 19, 2005.

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., NW., 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-2005-0170, 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](mailto: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: July 12, 2005.

**Lois Ann 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 180.593 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

**§ 180.593 Etoazole; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Almond, hulls .....	2.0
Grape .....	0.50 ppm
Grape, raisin .....	1.5 ppm
Nut, tree, group 14 .....	0.01 ppm
Pistachio .....	0.01 ppm

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 300**

[FRL-7939-7]

**National Oil and Hazardous Substance Pollution Contingency Plan; National Priorities List**

**AGENCY:** Environmental Protection Agency.

**ACTION:** Direct Final Notice of Deletion of the Mallard Bay Landing Bulk Plant Superfund Site from the National Priorities List.

**SUMMARY:** The Environmental Protection Agency (EPA) Region 6 is publishing a Direct Final Notice of Deletion of the Mallard Bay Landing Bulk Plant Superfund Site (Site), located northeast of Grand Chenier in Cameron Parish, Louisiana, from the National Priorities List (NPL). The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final deletion is being published by EPA with the concurrence of the State of Louisiana, through the Louisiana Department of Environmental Quality (LDEQ), because EPA has determined that all appropriate response actions under CERCLA have been completed and, therefore, further

remedial action pursuant to CERCLA is not appropriate.

**DATES:** This Direct Final Notice of Deletion will be effective September 19, 2005, unless EPA receives adverse comments by August 19, 2005. If adverse comments are received, EPA will publish a timely withdrawal of the direct final deletion in the **Federal Register** informing the public that the deletion will not take effect.

**ADDRESSES:** Comments may be mailed to: Beverly Negri, Community Involvement Coordinator, U.S. EPA Region 6 (6SF-LP), 1445 Ross Avenue, Dallas, TX 75202-2733, (214) 665-8157 or 1-800-533-3508 (*negri.beverly@epa.gov*).

*Information Repositories:*

Comprehensive information about the Site is available for viewing and copying at the Site information repositories located at: U.S. EPA Region 6 Library, 12th Floor, 1445 Ross Avenue, Suite 12D13, Dallas, Texas 75202-2733, (214) 665-6427, Monday through Friday 7:30 a.m. to 4:30 p.m.; Vermilion Parish Library, 605 McMurtry Street, Gueydan, Louisiana 70542-4140, (337) 536-6781, Monday through Friday 10 a.m. to 5 p.m., Saturday 9 a.m. to 12 p.m.; Louisiana Department of Environmental Quality, Public Records Center, 602 North Fifth Street, Baton Rouge, LA 70802, (225) 219-3168, Monday through Friday 8 a.m. to 4:30 p.m.

**FOR FURTHER INFORMATION CONTACT:** Michael A. Hebert, Remedial Project Manager (RPM), U.S. EPA Region 6 (6SF-LP), 1445 Ross Avenue, Dallas, TX 75202-2733, (214) 665-8315 or 1-800-533-3508 (*hebert.michael@epa.gov*).

**SUPPLEMENTARY INFORMATION:**

**Table of Contents**

- I. Introduction
- II. NPL Deletion Criteria
- III. Deletion Procedures
- IV. Basis for Site Deletion
- V. Deletion Action

**I. Introduction**

The EPA Region 6 office is publishing this Direct Final Notice of Deletion of the Mallard Bay Landing Bulk Plant Superfund Site from the NPL.

The EPA identifies sites that appear to present a significant risk to public health or the environment and maintains the NPL as the list of those sites. As described in section 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for remedial actions if conditions at a deleted site warrant such action.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication of a notice of intent to delete. This action will be effective September 19, 2005, unless EPA receives adverse comments by August 19, 2005, on this document. If adverse comments are received within the 30-day public comment period on this document, EPA will publish a timely withdrawal of this direct final notice of deletion before the effective date of the deletion and the deletion will not take effect. The EPA will, as appropriate, prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.