

TABLE 2 OF § 89.102.—COR-RESPONDING TIER 3 AND TIER 4 POWER CATEGORIES

Tier 3 power categories	Tier 4 power categories
37≤kW<75*	19≤kW<56
37≤kW<75**, 75≤kW<130	56≤kW<130
130≤kW<225, 225≤kW<450, 450≤kW<560.	130≤kW≤560

* Applies only to use of engines rated between 37kW and 56kW by small volume equipment manufacturers.

** Includes only equipment that uses engines with a rated power greater than 56kw.

(iv) Manufacturers using allowances under this paragraph (i) must comply with the notification and reporting requirements specified in paragraph (i)(7) of this section.

(7) Notification and reporting. You must notify us of your intent to use the technical relief provisions of this paragraph (i) and send us an annual report to verify that you are not exceeding the allowances, as follows:

(i) Before the first year you intend to use the provisions of this section, send the Designated Compliance Officer and the Designated Enforcement Officer a written notice of your intent, including:

(A) Your company's name and address, and your parent company's name and address, if applicable.

(B) Whom to contact for more information.

(C) The calendar years in which you expect to use the exemption provisions of this section.

(D) The name and address of the company that produces the engines you will be using for the equipment exempted under this section.

(E) Your best estimate of the number of units in each power category you will produce under this section and whether you intend to comply under paragraph (d)(1) or (d)(2) of this section.

(F) The number of units in each power category you have sold in previous calendar years under paragraph (d) of this section.

(ii) For each year that you use the provisions of this section, send the Designated Compliance Officer and the Designated Enforcement Officer a written report by March 31 of the following year. Include in your report the total number of engines you sold in the preceding year for each power category, based on actual U.S.-directed production information. Also identify the percentages of U.S.-directed production that correspond to the number of units in each power category and the cumulative numbers and percentages of units for all the units you

have sold under this section for each power category. You may omit the percentage figures if you include in the report a statement that you will not be using the percent-of-production allowances in paragraph (d) of this section.

(8) *Recordkeeping.* Keep the following records of all equipment with exempted engines you produce under this paragraph (i) for at least five full years after the final year in which allowances are available for each power category:

(i) The model number, serial number, and the date of manufacture for each engine and piece of equipment.

(ii) The maximum power of each engine.

(iii) The total number or percentage of equipment with exempted engines, as described in paragraph (d) of this section and all documentation supporting your calculation.

(iv) The notifications and reports we require under paragraph (i)(7) of this section.

(9) *Equipment Labeling.* Any engine produced under this paragraph (i) must meet the labeling requirements of 40 CFR 89.110, but add the following statement instead of the compliance statement in 40 CFR 89.110 (b)(10): THIS ENGINE MEETS U.S. EPA EMISSION STANDARDS UNDER 40 CFR 89.102. SELLING OR INSTALLING THIS ENGINE FOR ANY PURPOSE OTHER THAN FOR THE EQUIPMENT FLEXIBILITY PROVISIONS OF 40 CFR 89.102 MAY BE A VIOLATION OF FEDERAL LAW SUBJECT TO CIVIL PENALTY.

(10) *Enforcement.* Producing more exempted engines or equipment than we allow under this paragraph (i) or installing engines that do not meet the applicable Tier 1 emission standards described in § 89.112 violates the prohibitions in § 89.1003(a)(1). You must give us the records we require under this paragraph (i) if we ask for them (see § 89.1003(a)(2)).

[FR Doc. E7-24976 Filed 12-21-07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2007-0309; FRL-8342-8]

Etoxazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of etoxazole in or

on cherry; hop, dried cones; and vegetable, cucurbit subgroup 9A. The Interregional Research Project No. 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 26, 2007. Objections and requests for hearings must be received on or before February 25, 2008, 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-2007-0309. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7610; e-mail address: jackson.sidney@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 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 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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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-2007-0309 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 February 25, 2008.

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-2007-0309, 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'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 June 27, 2007 (72 FR 35237) (FRL-8133-4), 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 6E7150) by the IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. 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 cherry at 0.70 parts per million (ppm), hops, dried cones, at 7.0 ppm, and melon subgroup 9A at 0.15 ppm. That notice referenced a summary of the petition prepared 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 current data supporting the petition, EPA has corrected the commodity definition and revised proposed tolerance levels as follows:

1. For commodity cherry, a revised tolerance at 1.0 ppm from 0.70 ppm; and

2. For the melon subgroup, the crop definition has been changed from "melon subgroup 9A" to "vegetable, cucurbit subgroup 9A" and the tolerance revised from 0.15 to 0.20 ppm.

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...." These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerance for residues of in or on cherry, sweet at 0.60 ppm, cherry, tart at 0.20 ppm, hop, dried cones, at 5.0 ppm, and vegetable, cucurbit subgroup 9A at 0.15 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 their 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. Specific information on the studies received and the nature of the adverse 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 can

be found at <http://www.regulations.gov>. The referenced document is available in the docket established by this action, which is described under Docket #: EPA-HQ-OPP-2007-0309 and is identified in that docket as PP 6E7150; Revised: Etoxazole in/on Cherries, Hops, and Melon Subgroup 9A; Health Effects Division (HED) Risk Assessment.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from 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) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC 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 risks by comparing aggregate 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 LOC by all applicable UFs. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

A summary of the toxicological endpoints for etoxazole used for human risk assessment can be found at <http://www.regulations.gov> in document PP#: 6E7150. Revised: Etoxazole in/on Cherries, Hops, and Melon Subgroup 9A. Health Effects Division (HED) Risk Assessment in docket ID number EPA-HQ-OPP-2007-0309.

C. Exposure Assessment

Dietary exposure from food and feed uses. In evaluating dietary exposure to etoxazole, EPA considered exposure under the petitioned-for tolerances as well as all existing etoxazole tolerances in (40 CFR 180.593 EPA assessed dietary exposures from etoxazole 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.

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. The EPA evaluated the suitability of the developmental toxicity study in rabbits in which the developmental NOAEL of 200 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, the EPA concluded that etoxazole is unlikely to pose an acute risk because these effects are minor in magnitude and were observed only at the limit dose (1000 mg/kg/day). Therefore, an acute dietary exposure assessment was not performed.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used DEEM-FCID, Version 2.03), which incorporates consumption data from United States Department of Agriculture's (USDA's) Continuing Surveys of Food Intakes by Individuals (CSFII), 1994–1996 and 1998. The 1994–96, 1998 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods “as consumed” (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. Consumption data are averaged for the entire U.S. population and within population subgroups for chronic exposure assessment.

An unrefined, chronic dietary exposure assessment was conducted for the general U.S. population and various population subgroups using EPA-calculated residues of concern (parent and metabolites) for livestock

commodities and tolerance-level residues for all other commodities. For all registered and proposed uses, 100% crop treated (CT) information was used, as well as DEEM 7.81 default processing factors for all commodities other than apple and grape (apple and grape residue data showed that there was no concentration in processed commodities; therefore, these default values were set to 1).

iii. *Cancer.* EPA classified etoxazole as “not likely to be carcinogenic to humans”. This decision was based on the lack of carcinogenicity in two studies in mice, lack of carcinogenicity in one study in rats, and the lack of hormonal and reproductive effects in special studies. Etoxazole is not a mutagen. Therefore, an exposure assessment related to cancer risk was not performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring 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 environmental fate characteristics of etoxazole. 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>.

The Agency conducted Tier 1 estimated drinking water concentrations (EDWCs) for etoxazole in assessing water exposure. Environmental fate data indicate that parent (etoxazole) has low mobility and relatively low persistence in soil. The major route of degradation based on the label use pattern will likely be aerobic soil degradation. Based on the aerobic soil metabolism study, Metabolite R–8 was found as a major degradate in 4 out of 5 soils tested, with a maximum of 38% of the applied dose. Metabolite R–8 is mobile and relatively persistent and could be available for runoff and leaching for periods of up to months. Metabolite R–13 was also found as a major degradate in 3 out of 5 soils tested, with a maximum of 30.0% (at 62 days) in an aerobic soil metabolism study. Based on submitted mobility data, Metabolite R–13 appears to be immobile. The Agency believes that metabolites R–8 and R–13 are likely to have similar toxicity to the parent; and, therefore, should be included in the drinking water assessment. Metabolites R–4 and R–7 were also found in aerobic soil dissipation studies, but less frequently. EPA concluded that the

inclusion of Metabolite R-8 should cover the exposure from R-4 and R-7. In summary, the Agency finds that for drinking water risk assessment, the residues of concern are parent, Metabolite R-8, and Metabolite R-13.

FQPA Index Reservoir Screening Tool (FIRST) and Screening Concentrations In Ground Water (SCI-GROW) models were used to calculate the chronic surface water and groundwater EDWCs (parent and metabolites), respectively. Drinking water was incorporated directly in the dietary assessment using the acute concentration for surface water generated by the FIRST model. Tier 1 EDWCs results for etoxazole and metabolites R-8 and R-13 show annual average surface water concentrations of 0.332 parts per billion (ppb), 0.913 ppb and 0.0285 ppb, respectively. Tier 1 EDWCs results for etoxazole and metabolites R-8 and R-13 show ground water concentrations of 0.00173ppb, 0.316 ppb and 0.000322 ppb, respectively.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the total sum of the annual average surface water concentrations for etoxazole and metabolites R-8 and R-13 of 1.27 ppb was used to assess the contribution to drinking 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 in or 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 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 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 ("10X") 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. This additional margin of safety is commonly referred to as the FQPA safety factor. 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 FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* No quantitative or qualitative evidence of increased susceptibility was seen following *in utero* exposure to rats or rabbits in developmental studies. Offspring toxicity was more severe (pup mortality) than maternal toxicity (increased liver and adrenal weights) at the same dose in the rat reproduction study.

Since there is qualitative evidence of increased susceptibility following exposure to etoxazole in the rat reproduction study, the EPA performed a Degree-of-Concern Analysis to:

i. Determine the LOC for the effects observed when considered in the context of all available toxicity data; and
ii. Identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment of this chemical. There is evidence of increased qualitative susceptibility in the rat reproduction study, but the concern is low since:

- The effects in pups are well-characterized with a clear NOAEL;
- The pup effects occur at the same dose as maternal toxicity; and,
- The doses selected for various risk assessment scenarios are lower than the doses that caused off spring toxicity.

Therefore, there are no residual uncertainties for pre-/post-natal toxicity in this study.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce

the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for etoxazole is complete for FQPA assessment.

ii. There is no indication that etoxazole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. No quantitative or qualitative evidence of increased susceptibility was seen following *in utero* exposure to rats or rabbits in developmental studies. Although there is qualitative evidence of increased susceptibility in the rat reproduction study, the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of etoxazole. The degree of concern for prenatal and/or postnatal toxicity is low.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessment utilizes EPA-calculated residues of concern (parent and metabolites) for livestock commodities; tolerance-level residues for other commodities; and 100% crop treated (CT) information for all proposed uses. By using these screening-level assumptions, actual exposures/risks will not be underestimated. The dietary drinking water assessment utilized modeling results which included conservative assumptions for the parent and all degradates of concern. Conservative assumptions were used in the water models. Therefore, the water exposure assessment will not underestimate the potential risks for infant and children.

v. There are no registered or proposed residential uses for etoxazole.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment was not performed because an endpoint of concern attributable to a single oral dose was not selected for any population subgroup (including infants

and children). No acute risk is expected from exposure to etoxazole.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to etoxazole from food and water will utilize 8.3% of the cPAD for children 1–2 years old, the most highly exposed population subgroup. There are no residential uses for etoxazole that result in chronic residential exposure to etoxazole. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short-term and intermediate-term risk.* Short-term and 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 or proposed 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. *Aggregate cancer risk for U.S. population.* A cancer aggregate risk assessment was not performed because etoxazole is not carcinogenic. Etoxazole is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to etoxazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression.

The following analytical enforcement methods have been validated: The gas chromatography/mass-selective detector (GC/MSD) method used to determine etoxazole residues in/on cherry matrices is a slightly modified version of a previously-validated method (Method RM–37HM). The validated limit of quantitation (LOQ) was 0.0037 ppm and the limit of detection (LOD) was 0.0012 ppm for etoxazole in/on cherries. The GC with nitrogen-phosphorus detector (NPD) method used to determine etoxazole residues in/on hop matrices is a modified version of a previously-validated method (Method RM–37). The validated LOQ was 0.2 ppm and the LOD was 0.1 ppm for etoxazole in/on dried hop cones. The nitrogen-phosphorus specific flame-ionization detector (NPD) method used to determine etoxazole residues in/on

cantaloupe matrices is a slightly modified version of a previously-validated method (Method RM–37). The validated LOQ was 0.0046 ppm and the LOD was 0.0015 ppm for etoxazole in/on cantaloupe.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, Fort Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

There are no established or proposed Codex, Canadian or Mexican maximum residue limits (MRLs) for etoxazole.

Therefore, tolerances are established for residues of the insecticide etoxazole, 2-(2,6-difluorophenyl)-4-[4-(1,1-dimethylethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole, in or on cherry at 1.0 ppm, hop, dried cones at 7.0 ppm, and vegetable, cucurbit subgroup 9A at 0.20 ppm.

VI. 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, 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) 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 tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This 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 6, 2000) do not apply to this rule. In addition, This 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: December 14, 2007.

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

§ 180.593 Etoazole; tolerances for residues.

(a) * * *

Commodity	Parts per million
Cherry	1.0
Hop, dried cones	7.0
Vegetable, cucurbit sub-group 9A	0.20

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2007-0545; FRL-8342-1]

Aspergillus Flavus AF36 on Corn; Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the *Aspergillus flavus* AF36 on corn when applied/used before corn tasseling occurs. Arizona Cotton Research and Protection Council submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting the temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of *Aspergillus flavus* AF36. The temporary tolerance exemption expires on December 31, 2011.

DATES: This regulation is effective December 26, 2007. Objections and requests for hearings must be received on or before February 25, 2008, 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-2007-0545. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8097; e-mail address: bacchus.shanaz@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 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 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in section 5 of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the regulations promulgated to carry out that provision of FIFRA (40 CFR part 172). 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?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this "**Federal Register**" document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

C. Can I File an Objection or Hearing Request?

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. 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-2007-0545 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 February 25, 2008.

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 your copies, identified by docket ID number EPA-HQ-OPP-2007-0545, by one of the following methods.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.