(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0289; FRL–7324–8]

Etoxazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of etoxazole in or on cotton, pome fruits, strawberries, and imported tangerines. 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 September 26, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0289, must be received on or before November 25, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Daniel C. Kenny, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7546; e-mail address: *kenny.dan@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)
- Animal Production (NAICS 112)
- Food Manufacturing (NAICS 311)
- Pesticide Manufacturing (NAICS 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. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

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

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0289. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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.

2. *Electronic access.* 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 *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of August 13, 2003 (68 FR 48377) (FRL–7322–6), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 2F6420) by Valent U.S.A. Corporation, 1333 North California Blvd., Suite 600, Walnut Creek, CA 94596. That notice included a summary of the petition prepared by Valent U.S.A. Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide etoxazole, 2-(2,6-difluorophenyl)-4-[4-(1,1-dimethylethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole, in or on cottonseed at 0.05 parts per million (ppm); cotton, gin byproducts (gin trash) at 1.0 ppm, pome fruit (Crop Group 11) at 0.2 ppm, apple, wet pomace at 1.0 ppm, strawberry at 0.5 ppm, and oranges at 0.10 ppm (to support the importation of mandarin oranges into the U.S.). As residues in processed commodities fed to animals may be transferred to milk and edible tissue of ruminants, tolerances were also proposed for animal fat at 0.03 ppm and milk fat at 0.04 ppm.

Based on EPA's review, the petition was revised by the petitioner to propose tolerances for residues of etoxazole on cotton, undelinted seed at 0.05 ppm; cotton, gin byproducts at 1.0 ppm; fruit, pome, group 11 at 0.20 ppm; apple, wet pomace at 0.50 ppm; strawberry at 0.50 ppm; tangerine at 0.10 ppm; liver of cattle, goat, horse, and sheep at 0.01 ppm; fat of cattle, goat, horse, and sheep at 0.02 ppm; and milk, fat at 0.01 ppm. Although EPA requested a number of changes to the initial petition, the nature of the changes (i.e., clarification and correction of commodity terms and adjustments in tolerance levels) are not considered significant. Therefore, EPA is issuing this as a final action.

Section 408(b)(2)(A)(i) of the 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 the 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 the 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 the 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 the 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 the FFDCA, for tolerances for residues of etoxazole on cotton, undelinted seed at 0.05 ppm; cotton, gin byproducts at 1.0 ppm; fruit, pome, group 11 at 0.20 ppm; apple, wet pomace at 0.50 ppm; strawberry at 0.50 ppm; tangerine at 0.10 ppm; liver of cattle, goat, horse, and sheep at 0.01 ppm; fat of cattle, goat, horse, and sheep at 0.02 ppm; and milk, fat at 0.01 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by etoxazole are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents (rat)	NOAEL = 61.8/69.0 milligrams/kilogram/day (mg/kg/day) Male/Female (M/F) LOAEL = 183.7/204.8 mg/kg/day (M/F), based upon increases in hepatic enzyme levels, increased liver weights and centrilobular hepatocellular swelling in both sexes and liver enlargement in females only
870.3100	90–Day oral toxicity rodents (rat)	NOAEL = not determined LOAEL = 300.4/336.6 mg/kg/day (M/F), based upon clinical signs, clinical chemistry, increased liver weights, and histopathology
870.3100	90–Day oral toxicity rodents (mouse)	NOAEL = 213.6/250.5 mg/kg/day (M/F) LOAEL = 878.4/994.5 mg/kg/day (M/F), based upon periportal hepatocellular necrosis, increased alkaline phosphatase levels, accompanied by increased relative liver weight, liver enlargement, and centrilobular hepatocellular swelling
870.3150	90–Day oral toxicity in nonrodents (dog)	NOAEL = 5.33/5.42 mg/kg/day (M/F) LOAEL = 53.7/55.9 mg/kg/day (M/F), based upon clinical signs (vomiting foamy fluid and mucous stool), clinical chemistry, increased liver weights, and centrilobular swelling in the liver and acinar cell atrophy in the prostate
870.3200	21/28–Day dermal toxicity (rabbit)	NOAEL = 1,000 mg/kg/day (M/F) LOAEL = not determined. No systemic effects noted
870.3700	Prenatal developmental toxicity in rodents (rat)	Maternal NOAEL = 1,000 mg/kg/day LOAEL = not determined Developmental NOAEL = 1,000 mg/kg/day LOAEL = not determined
870.3700	Prenatal developmental toxicity in nonrodents (rabbit)	Maternal NOAEL = 200 mg/kg/day LOAEL = 1,000 mg/kg/day based upon liver enlargement and decreased body weight gains and food consumption Developmental NOAEL = 200 mg/kg/day LOAEL = 1,000 mg/kg/day based upon increased incidences of 27 presacral vertebrae and 27 presacral vertebrae with 13th ribs in the fetuses

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3800	Reproduction and fertility effects (rat)	Parental/Systemic NOAEL = 20 mg/kg/day LOAEL = 100 mg/kg/day (M/F), based upon increased liver weights in the P and F_1 males and increased adrenal weights in the P females Offspring/Systemic NOAEL = 20 mg/kg/day LOAEL = 100 mg/kg/day (M/F), based upon pup mortality Reproductive NOAEL = 100 mg/kg/day LOAEL = not determined
870.4300	Combined chronic toxicity/carcinogenicity rodents (rat)	NOAEL = 64 mg/kg/day (M/F) LOAEL = not determined Equivocal evidence of carcinogenicity
870.4300	2–Year feed/carcinogenic (rat)	NOAEL = 1.83/2.07 mg/kg/day (M/F) LOAEL = 187/216 (M/F), based upon effects on the incisors including abnormal amelogenesis No evidence of carcinogenicity
870.4100	Chronic toxicity nonrodents (dog)	NOAEL = 4.62/4.79 mg/kg/day (M/F) LOAEL = 23.5/23.8 mg/kg/day (M/F), based upon increased alkaline phosphatase activity, increased liver weights, liver enlargement (females), and incidences of centrilobular hepatocellular swelling in the liver
	78–Week carcinogenic mouse	NOAEL = 242/243 (M/F) LOAEL = 484/482 (M/F), based on a slight increase in the incidence of a fatty change in the centrilobular hepatocytes in males
870.4200	Carcinogenicity mouse	NOAEL = 241/243 mg/kg/day (M/F) LOAEL = not determined No evidence of carcinogenicity
Non-guideline	13–Week study: Effect on proliferative activity of testicular interstitial cells in rat	A toxic level of the test substance did not affect the proliferative activity of testicular interstitial cells
870.5100	Gene mutation - reverse gene mutation assay in bacteria	When tested up to cytotoxic levels, there was no evidence of induced mutant colonies over background
Non-guideline	Gene mutation - reverse gene mutation assay in bacteria	When tested up to cytotoxic levels, there was no evidence of induced mutant colonies over background
870.5300	Gene mutation - *in vitro* forward gene mutation assay in mouse lymphoma cells	When tested up to cytotoxic levels, mutagenic in the presence of S9 activation and equivocal for mutagenicity in the absence of S9 activation
870.5375	Cytogenetics - *in vitro* mammalian cytogenetics assay	When tested up to cytotoxic levels, not clastogenic in the presence or absence of S9 activation
870.5395	Bone marrow micronucleus assay	There was no significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow after any treatment time
870.5550	Unscheduled DNA synthesis (UDS) in primary rat hepatocytes/mammalian cell cultures	When tested up to cytotoxic levels, there was no evidence that UDS was induced by the test substance

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 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.

For dietary risk assessment (other than cancer) the Agency uses the UF to

calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factors (SF) is retained due to concerns unique to the FQPA, 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 FQPA 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 is expressed as 1×10^{-6} or one in a million). 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 etoxazole used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR ETOXAZOLE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13–50 years of age)	NOAEL = None mg/kg/day UF = Not applicable (N/A) Acute RfD = None	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = None	A dose and endpoint attributable to a single dose were not identified in the data base including the developmental toxicity studies
Acute dietary (general population including infants and children)	NOAEL = None mg/kg/day UF = N/A Acute RfD = None	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = None	A dose and endpoint attributable to a single dose were not identified in the data base including the developmental toxicity studies
Chronic dietary (all populations)	NOAEL = 4.62 mg/kg/day UF = 100 Chronic RfD = 0.046 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD ÷ FQPA SF = 0.046 mg/kg/day	Chronic oral toxicity study - dog LOAEL = 23.5 mg/kg/day based upon increased alkaline phosphatase activity, increased liver weights, liver enlargement (females), and incidences of centrilobular hepatocellular swelling in the liver
Short-term incidental oral (1–30 days)	NOAEL = 4.62 mg/kg/day	Residential LOC for MOE = 100 Occupational = NA	Chronic oral toxicity study - dog LOAEL = 23.5 mg/kg/day based upon increased alkaline phosphatase activity, increased liver weights, liver enlargement (females), and incidences of centrilobular hepatocellular swelling in the liver
Intermediate-term incidental oral (1–6 months)	NOAEL = 4.62 mg/kg/day	Residential LOC for MOE = 100 Occupational = NA	Chronic oral toxicity study - dog LOAEL = 23.5 mg/kg/day based upon increased alkaline phosphatase activity, increased liver weights, liver enlargement (females), and incidences of centrilobular hepatocellular swelling in the liver
Short-term dermal (1 to 30 days)	Dermal (or oral) study NOAEL = None	Residential LOC for MOE = N/A Occupational LOC for MOE = N/A	No hazard quantitation required for any duration. No systemic effects noted up to 1,000 mg/kg/day in the 28–day dermal rat study. There are no developmental or reproductive concerns
Intermediate-term dermal (1 to 6 months)	Dermal (or oral) study NOAEL = None	Residential LOC for MOE = N/A Occupational LOC for MOE = N/A	No hazard quantitation required for any duration. No systemic effects noted up to 1,000 mg/kg/day in the 28–day dermal rat study. There are no developmental or reproductive concerns

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR ETOXAZOLE FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Long-term dermal (>6 months)	Dermal (or oral) study NOAEL = None	Residential LOC for MOE = N/A Occupational LOC for MOE = N/A	No hazard quantitation required for any duration. No systemic effects noted up to 1,000 mg/kg/day in the 28-day dermal rat study. The weight-of-the-evidence from the 28–day, 90–day, 52–week interim chronic toxicity/carcinogenicity and the 2–year chronic toxicity/carcinogenicity rat studies shows that the systemic effects (mainly in the liver) occur around the same dose levels from short-term through long-term exposure without increasing in severity. Therefore, results of the 28–day dermal toxicity study can be applicable to long-term exposure
Short-term inhalation (1 to 30 days)	Oral study NOAEL = 4.62 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Chronic oral toxicity study - dog LOAEL = 23.5 mg/kg/day based upon increased alkaline phosphatase activity, increased liver weights, liver enlargement (females), and incidences of centrilobular hepatocellular swelling in the liver
Intermediate-term inhalation (1 to 6 months)	Oral study NOAEL = 4.62 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Chronic oral toxicity study - dog LOAEL = 23.5 mg/kg/day based upon increased alkaline phosphatase activity, increased liver weights, liver enlargement (females), and incidences of centrilobular hepatocellular swelling in the liver
Long-term inhalation (>6 months)	Oral study NOAEL = 4.62 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Chronic oral toxicity study - dog LOAEL = 23.5 mg/kg/day based upon increased alkaline phosphatase activity, increased liver weights, liver enlargement (females), and incidences of centrilobular hepatocellular swelling in the liver
Cancer (oral, dermal, inhalation)	Classified as ''not likely to be carcinogenic to humans''		

* The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. There are currently no food/feed uses or tolerances for etoxazole. 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 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 this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the 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. The general U.S. population and all population subgroups have exposure and risk estimates which are below EPA's LOC (i.e., the cPADs are all below 100%). The most highly exposed subgroup is children 1 to 2 years of age, which utilizes 5% of the cPAD.

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 First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/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 I model) before using PRZM/EXAMS (a Tier II model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes 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 coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever 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) from these models 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 Unit III.E.

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.''

EPA does not have, at this time, available data to determine whether etoxazole has a common mechanism of toxicity with other substances. 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 the 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 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.

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 UF 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 infant, 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 the model estimates of a pesticide's concentration in water (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 USEPA 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.* As stated above, 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, 3% of the cPAD for all infants less than 1–year old and 5% of the cPAD for children 1 to 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 Table 3 of this unit:

TABLE 3.—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	3	1.77	0.242	440
Children (1–2 years old)	0.046	5	1.77	0.242	440
Children (3–5 years old)	0.046	3	1.77	0.242	440
Children (6–12 years old)	0.046	1	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 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). 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 LOC.

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 (example—gas chromotography) 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

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

V. Conclusion

Therefore, the tolerances are established for residues of etoxazole, 2-(2,6-difluorophenyl)-4-[4-(1,1-dimethylethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole, in or on cotton, undelinted seed at 0.05 ppm; cotton, gin byproducts at 1.0 ppm; fruit, pome, group 11 at 0.20 ppm; apple, wet pomace at 0.50 ppm; strawberry at 0.50 ppm; tangerine at 0.10 ppm; liver of cattle, goat, horse, and sheep at 0.01 ppm; fat of cattle, goat, horse, and sheep at 0.02 ppm; and milk, fat at 0.01 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the 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 the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the 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 the 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–2003–0289 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 November 25, 2003.

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 (1900C), 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 Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *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 Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0289, 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 Unit I.B.1. 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 the 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 the 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 the 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: September 16, 2003.

James Jones,

Director, 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), 346(a) and 371.

■ 2. Section 180.593 is added to read as follows:

§ 180.593 Etoxazole; tolerances for residues.

(a) *General*. 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 the following raw agricultural commodities:

Commodity	Parts per million
Apple, wet pomace	0.50
Cattle, fat	0.02
Cattle, liver	0.01
Cotton, gin byproducts	1.0
Cotton, undelinted seed	0.05
Fruit, pome, group 11	0.20
Goat, fat	0.02
Goat, liver	0.01
Horse, fat	0.02
Horse, liver	0.01
Milk, fat	0.01
Sheep, fat	0.02
Sheep, liver	0.01
Strawberry	0.50
Tangerine[1]	0.10

[1]There are no U.S. registrations for use of etoxazole on tangerines as of September 26, 2003.

(b) *Section 18 emergency exemptions*. [Reserved]

(c) *Tolerances with regional registrations*. [Reserved]

(d) *Indirect and inadvertant residues*. [Reserved]

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