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.

IX. 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 23, 2003.

Debra Edwards,

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), 346(a) and 371.

■ 2. Section 180.473 is revised to read as follows:

§ 180.473 Glufosinate ammonium; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-, monoammonium salt) and its metabolites, 2-acetamido-4-methylphosphinico-butanoic acid and 3-methylphosphinico-propionic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents, in or on the following food commodities:

Commodity	Parts per million
Almond, hulls	0.50
Apple	0.05
Banana	0.30
Banana, pulp	0.20
Bushberry subgroup 13B	0.15
Cattle, fat	0.40
Cattle, meat	0.15
Cattle, meat byproducts	6.0
Cotton, gin byproducts	15
Cotton, undelinted seed	4.0
Egg	0.15
Goat, fat	0.40
Goat, meat	0.15
Goat, meat byproducts	6.0
Grape	0.05
Hog, fat	0.40
Hog, meat	0.15
Hog, meat byproducts	6.0
Horse, fat	0.40
Horse, meat	0.15
Horse, meat byproducts	6.0
Juneberry	0.10
Lingonberry	0.10
Milk	0.15
Nut, tree, group 14	0.10
Potato	0.80
Potato, chips	1.60
Potato granules and flakes	2.00
Poultry, fat	0.15
Poultry, meat	0.15
Poultry, meat byproducts	0.60
Salal	0.10
Sheep, fat	0.40
Sheep, meat	0.15
Sheep, meat byproducts	6.0

(2) Tolerances are established for residues of the herbicide glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-, monoammonium salt) and its metabolites, 2-acetamido-4-methylphosphinico-butanoic acid and 3-methylphosphinico-propionic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents, in or on the following food commodities derived from transgenic canola, transgenic cotton, transgenic field corn, transgenic rice, transgenic soybean and transgenic sugar beet that are tolerant to glufosinate ammonium:

Commodity	Parts per million
Aspirated grain fractions	25.0
Beet, sugar, molasses	5.0
Beet, sugar, roots	0.9
Beet, sugar, tops (leaves)	1.5
Canola, meal	1.1
Canola, seed	0.4
Corn, field, forage	4.0
Corn, field, grain	0.2
Corn, field, stover	6.0
Cotton, gin byproducts	15
Cotton, undelinted seed	4.0
Rice, grain	1.0
Rice, hull	2.0
Rice, straw	2.0
Soybean	2.0
Soybean, hulls	5.0

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

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

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

[FR Doc. 03–24565 Filed 9–26–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0218; FRL–7318–2]

Quinoxyfen; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of quinoxyfen in or on sweet and tart cherry, grape, and hop, dried cones. Interregional Research Project Number (IR-4) requested these tolerances 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 29, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0218, must be received on or before November 28, 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: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9368; e-mail address: *Jamerson.Hoyt@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–2003–0218. 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 May 30, 2003 (68 FR 32497) (FRL–7295–7), 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 pesticide petitions (PP 1E6302 and 2E6474) by the Interregional Research Project Number (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902. That notice included a summary of the petitions prepared by Dow AgroSciences LCC, the registrant. The comment period ended June 30, 2003.

The petitions requested that 40 CFR 180 be amended by establishing tolerances for residues of the fungicide quinoxyfen, 5,7-dichloro-4-(4-fluorophenoxy)quinoline, in or on grape at 0.70 parts per million (ppm) (1E6302); hop, dried cones at 5 ppm (1E6302); and cherry at 0.4 ppm (2E6474).

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 quinoxyfen, 5,7-dichloro-4-(4-fluorophenoxy)quinoline in or on cherry, sweet at 0.30 ppm; cherry, tart at 0.30 ppm; grape at 0.60 ppm; and hop, dried cones at 3.0 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 quinoxyfen are discussed below and summarized 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.

The primary target organs affected by quinoxyfen are the liver and kidney. Liver effects were seen in rat and mouse subchronic and dog chronic studies. Subchronic effects in rats and mice included increased liver weights, hepatocellular hypertrophy and individual cell hepatocellular necrosis. These effects were noted at high doses and not observed in the chronic rat and mouse studies since they were performed at lower doses. Chronic effects in the dog included increased liver weights, increased alkaline phosphatase levels and increased incidences of slight microscopic hepatic lesions (increased bile in canaliculi and increased hepatocyte size). Kidney effects were noted only in the rat combined chronic/carcinogenicity study which resulted in an increased severity of chronic progressive glomerulonephropathy in the males. Rabbits were much more susceptible to the effects of quinoxyfen than any other species. Systemic effects observed in the rabbit developmental study included inanition, loss of body weight, perineal soiling, blood in the cage pan associated with urine, and abortions. Body weight decrements were noted in the rat and/or mouse subchronic, chronic and carcinogenicity studies and the rabbit developmental and rat reproduction studies. No effects were noted via the dermal route. No evidence of neurotoxicity or neuropathology was seen in any of the submitted studies, including the acute and subchronic neurotoxicity studies. There was no evidence of carcinogenic potential in either the rat chronic toxicity/carcinogenicity or mouse carcinogenicity studies and no concern for mutagenicity. There was no evidence of increased susceptibility in the oral rat or rabbit developmental studies. There was an increased quantitative susceptibility of young animals following pre/postnatal exposure to rats in the reproduction study. In this study, no maternal effects were observed up to the highest dose tested (100 milligrams/kilograms/day (mg/kg/day)); however, minimally reduced F_{1a} pup weights were noted at 100 mg/kg/day.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents (rat)	NOAEL = 10 mg/kg/day LOAEL = 100 mg/kg/day based on decreased body weight gain in females, increased liver weights in males and slight hepatocellular hypertrophy (centrilobular and midzonal; both sexes)
870.3100	90–Day oral toxicity rodents (mouse)	NOAEL = 100 mg/kg/day LOAEL = 500 mg/kg/day based on increased liver weights, individual cell hepatocellular necrosis and hepatocellular hypertrophy in both sexes
870.3150	90–Day oral toxicity in nonrodents (dog)	NOAEL = 100 mg/kg/day LOAEL = Not identified
870.3200	28–Day dermal toxicity (rat)	NOAEL = 1,000 mg/kg/day LOAEL = Not identified
870.3700	Prenatal developmental in rodents (rat)	Maternal NOAEL = 1,000 mg/kg/day LOAEL = Not identified Developmental NOAEL = 1,000 mg/kg/day LOAEL = Not identified
870.3700	Prenatal developmental in non-rodents (rabbit)	Maternal NOAEL = 80 mg/kg/day LOAEL = 200 mg/kg/day based on inanition, clinical signs, decreased body weights, body weight gains, and food consumption and on increased incidences of abortion Developmental NOAEL = 80 mg/kg/day LOAEL = 200 mg/kg/day based on increased incidences of abortion
870.3800	Reproduction and fertility effects (rat)	Parental/Systemic NOAEL = 100 mg/kg/day LOAEL = Not identified Reproductive NOAEL = 100 mg/kg/day LOAEL = Not identified Offspring NOAEL = 20 mg/kg/day LOAEL = 100 mg/kg/day based on a minimal decrease in F_{1a} pup weights
870.4100	Chronic toxicity rodents	See 870.4300

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

Guideline No.	Study Type	Results
870.4100	Chronic toxicity dogs	NOAEL = 20 mg/kg/day LOAEL = 200 mg/kg/day based on increased alkaline phosphatase, increased absolute and relative (to body) liver weights, and an increased incidence of very slight to slight microscopic hepatic lesions
870.4200	Carcinogenicity rats	See 870.4300
870.4200	Carcinogenicity mouse	NOAEL = 80 mg/kg/day LOAEL = 250 mg/kg/day based on decreased body weight gain in both sexes No evidence of carcinogenicity
870.4300	Combined chronic/carcinogenicity (rat)	NOAEL = 20 mg/kg/day LOAEL = 80 mg/kg/day based on increases in severity of chronic progressive glomerulonephropathy in the males and minimal decreases in body weight and body weight gain in the males and females No evidence of carcinogenicity
870.5100	Gene mutation (bacterial reverse mutation)	Negative for inducing reverse mutation in bacteria exposed to doses up to 5,000 μg/plate (-S9) and 1,000 μg/plate (+S9)
870.5300	Gene mutation (*In vitro* mammalian cell gene mutation)	Negative for inducing forward mutation in CHO (mammalian) cells treated up to 20 μg/ml (-S9) and 80 μg/ml (+S9)
870.5375	Cytogenetics (*In vitro* mammalian chromosome aberration (RL))	Negative up to 100 μg/ml (-S9 and +S9)
870.5395	Cytogenetics (mammalian micronucleus (mouse))	Negative up to 5,000 mg/kg
870.6200	Acute neurotoxicity screening battery (rat)	NOAEL = 2,000 mg/kg LOAEL = Not identified
870.6200	Subchronic neurotoxicity screening battery	NOAEL = 80 mg/kg/day LOAEL = Not identified

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

Guideline No.	Study Type	Results
870.7485	Metabolism and pharmacokinetics (rat)	Quinoline-labeled and phenyl-labeled quinoxyfen were rapidly absorbed with approximately 68-85% of the administered dose being eliminated within 24 hours. Overall recovery of the dosed radioactivity ranged from 83.5-96.2%. Sex, dose, and multiple dosing had little or no effect on the excretion profile at 48 hours post-dosing. Changing the position of the ^{14}C-label altered the pattern of excretion. The major route of elimination was through the urine in the phenyl-labeled test substance (44.9-48.7% of dose in urine and 38.2-39.8% of dose in feces) and through the feces in the quinoline-labeled test substance (65.8-78.3% of dose in feces and 13.4-19.7% of dose in urine). Biliary excretion increased its contribution to fecal radioactivity as the dose increased. Concentrations of radioactivity in the tissues were generally slightly lower in the males than females and in the low-dose compared to the high-dose group. The highest concentrations of radioactivity were found in the kidney, liver, ovaries, perirenal fat, GI tract and carcass. Maximum plasma concentration occurred between 0.5 and 1.5 hours, and elimination half-lives were <= 1 hour and 15-19 hours (10 mg/kg group) and 2-3 hours and 18-22 hours (500 mg/kg group). The presence of several radioactive components was determined in the unhydrolyzed urine (up to 12), fecal extracts (up to 8), and bile (up to 6). No differences in the metabolite profile were observed that were related to sex or multiple dosing. Increasing amounts of the parent compound were found in the feces with increasing dose. No other dose-related differences were observed. Identified metabolites accounted for 41.0-42.8% dose in the [Phenyl-U-^{14}C] XDE-795 treated group, and only 17.0-31.7% dose in the other treated groups. The [Phenyl-U-^{14}C] XDE-795 treated group had no urinary metabolites in common with the [2-Quinoline-^{14}C] XDE-795 treated groups suggesting cleavage of the parent molecule. An acid-labile conjugate of 4-fluorophenol was found in the urine of the [Phenyl-U-^{14}C] XDE-795 treated group (28.7-32.8% dose). 5,7-Dichloro-4-hydroxyquinoline was observed in the urine of the [2-Quinoline-^{14}C] XDE-795 treated groups in small quantities (0.7-1.7% dose). Thus, the identified metabolites in the urine followed diaryl-ether cleavage of the parent compound. Fluorophenyl-ring-OH-XDE-795 (two isomers) were found in the feces of all treated groups (5.4-10.6% dose). In the bile of the treated groups, two major metabolites were identified, a glucuronide and/or sulfate conjugate(s) of the two isomers of fluorophenyl ring-hydroxy-XDE-795 (9-19% dose) and an unidentified metabolite (13-21% dose).

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species 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 factor (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 quinoxyfen used for human risk assessment is shown in Table 2 of this unit:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13-50 years of age) and acute dietary (general population including infants and children)	Not applicable	Not applicable	There were no toxic effects attributable to a single dose. Therefore, an endpoint of concern was not identified to quantitate acute-dietary risk to the general population or to the subpopulation females 13-50 years old
Chronic dietary (all populations)	NOAEL= 20 mg/kg/day UF = 100 Chronic RfD = 0.20 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD/ FQPA SF = 0.20 mg/kg/day	Combined chronic toxicity/carcinogenicity study in rat LOAEL = 80 mg/kg/day, based upon increases in severity of chronic progressive glomerulonephropathy in the males and minimal decreases in body weight and body weight gain in both sexes
Cancer (oral, dermal, inhalation)	Classified as not likely to be carcinogenic to humans	Not applicable	No evidence of carcinogenicity in rats and mice

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Quinoxyfen is a new chemical and therefore, these are the first tolerances to be established for the residues of quinoxyfen. Risk assessments were conducted by EPA to assess dietary exposures from quinoxyfen in food as follows:

i. *Acute exposure*. Quantitative 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 one day or single exposure. There were no toxic effects attributable to a single dose. Therefore, an endpoint of concern was not identified to quantitate acute-dietary risk to the general population or to the subpopulation females 13–50 years old. As a result, no acute risk is expected from exposure to quinoxyfen and hence no quantitative acute dietary risk assessment was performed.

ii. *Chronic exposure*. In conducting this 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 USDA 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: An unrefined, Tier 1 chronic-dietary exposure assessment using tolerance-level residues and assuming 100% CT for all proposed commodities, and default DEEM Version 7.76 processing factors for all commodities.

iii. *Cancer*. Quinoxyfen has been classified as not likely to be carcinogenic to humans. Therefore, a quantitative risk assessment was not conducted to assess cancer risk.

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

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentrations in Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that

uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever 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) 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 quinoxyfen, they are further discussed in the aggregate risk sections see Unit E.

Based on the FIRST and SCI-GROW models, the EECs of quinoxyfen for chronic exposures are estimated to be 0.8 parts per billion (ppb) for surface water and 0.006 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). Quinoxyfen 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 quinoxyfen 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 quinoxyfen and any other substances and quinoxyfen 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 quinoxyfen 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 no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure in developmental studies. There is evidence of increased quantitative susceptibility (minimal decrease in F_{1a} pup weights) in the rat multi-generation reproduction study, but the concern is low since: (1) The effects in pups are well-characterized with a clear NOAEL; (2) the pup effects are minimal at the LOAEL and only noted in the first-generation offspring; and (3) the doses and endpoints selected for regulatory purposes would address the concerns of the pup effects noted in the rat reproduction study. Therefore, there are no residual uncertainties for prenatal/postnatal toxicity in this study.

3. *Conclusion*. There is a complete toxicity data base for quinoxyfen and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. There are no residual uncertainties for prenatal/postnatal toxicity. No additional safety factor is needed for data base uncertainties. No clinical sign of neurotoxicity or neuropathology was seen in the data base. A developmental neurotoxicity study is not required. Therefore, EPA determined that the 10X SF to protect infants and children should be reduced to 1X.

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 youth), 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 was not identified to quantitate acute-dietary risk to the general population or to the subpopulation females 13–50 years old. As a result, no acute risk is expected from exposure to quinoxyfen.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to quinoxyfen from food will utilize less than 1% of the cPAD for the U.S. population, 1% of the cPAD for all infants (< 1 year old) and 1% of the cPAD for children (1–2 years old), the children subpopulation at greatest exposure. There are no residential uses for quinoxyfen that result in chronic residential exposure to quinoxyfen. In addition, there is potential for chronic dietary exposure to quinoxyfen 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 QUINOXYFEN

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.20	<1%	0.8	0.006	7,000
All infants (<1 year old)	0.20	1%	0.8	0.006	2,000
Children (1-2 years old)	0.20	1%	0.8	0.006	2,000

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). Quinoxyfen 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 risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Quinoxyfen 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.* Quinoxyfen has been classified as not likely to be carcinogenic to humans. Therefore, quinoxyfen 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 quinoxyfen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

IR-4 has proposed a gas chromatography (GC) method with mass-selective detection (MSD) entitled *Determination of DE-795 Residues in Grape Wine, Must, and Pomace ERC95.26* (and its supplement S1) for the enforcement of proposed tolerances for residues of quinoxyfen in/on grapes, cherries, and hops. Method ERC 95.26 is classified as acceptable and conforms with the criteria of OPPTS Harmonized Guideline 860.1340. The petitioner has submitted a study which investigated the behavior of quinoxyfen through MRMs outlined in FDA's Pesticide Analytical Manual (PAM), Volume I, Appendix II. The study summary reported that depending on spike levels, certain MRM Protocols (D, E, and F) yielded partial (incomplete) to complete recoveries of quinoxyfen in grapes (non-fatty matrix) and ground beef (fatty matrix).

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

B. International Residue Limits

There are no Mexican, Canadian or Codex maximum residue limits established for quinoxyfen on sweet and tart cherries, grapes, or hops. Therefore, no compatibility problems exist for these tolerances.

V. Conclusion

Therefore, tolerances are established for quinoxyfen, 5,7-dichloro-4-(4-fluorophenoxy)quinoline in or on cherry, sweet at 0.30 ppm; cherry, tart at 0.30 ppm; grape at 0.60 ppm; and hop, dried cone at 3.0 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–2003–0218 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 28, 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–2003–0218, 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 23, 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 180.588 is added to subpart C to read as follows:

§ 180.588 Quinoxyfen; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide quinoxyfen, 5,7-dichloro-4-(4-fluorophenoxy)quinoline in or on the following raw agricultural commodities:

Commodity	Parts per million
Cherry, sweet	0.30
Cherry, tart	0.30
Hop, dried cones	3.0
Grape	0.60

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

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

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

[FR Doc. 03–24561 Filed 9–26–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0315; FRL–7328–6]

Sethoxydim; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of sethoxydim (2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on corn, sweet, forage; corn, sweet, stover; juneberry; lingonberry; pistachio; salal; and safflower and increases the tolerance on cattle, meat by products; corn, sweet, kernels plus cob with husk removed; goat, meat byproducts; hog, meat byproducts; horse, meat byproducts; milk; and sheep, meat byproducts. BASF Corporation requested the tolerances for corn, sweet, forage; corn, sweet, stover and the increase in tolerance for corn, sweet, kernels plus cob with husk removed; milk; and meat products under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). Interregional Project #4 (IR-4) requested the tolerances on juneberry, lingonberry, pistachio, salal, and safflower 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 29, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0315, must be received on or before November 28, 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: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@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. To determine whether you or your business may be affected by