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: February 7, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.364 is amended by alphabetically adding the commodity ''Alfalfa, seed'' to the table in paragraph (a) to read as follows:

§ 180.364 Glyphosate; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Alfalfa, seed	0.5
* * *	* *

* * * * *

[FR Doc. 05–2983 Filed 2–15–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0324; FRL–7694–4]

Quizalofop-ethyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of quizalofop (2-[4-(6-chloroquinoxalin-2-yl oxy)phenoxy]propanoic acid) and quizalofop ethyl (ethyl-2-[4-(6-chloroquinoxalin-2-yl oxy)phenoxy]propanoate, all expressed as quizalofop ethyl in or on bean, dry; bean, succulent; beet, sugar, roots; beet, sugar, tops; cowpea, forage; cowpea, hay; peas, dry; pea, field, hay; pea, field, vines; and pea, succulent. Also a tolerance for the combined residues of quizalofop-p-ethyl ester (ethyl (R)-(2-(4-((6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoate) and its acid metabolite quizalofop-p (R-(2-(4-((6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoic acid)), and the S enantiomers of both the ester and the acid, all expressed as quizalofop-p-ethyl ester is established for beet, sugar, molasses. E. I. DuPont de Nemours and Company 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 February 16, 2005. Objections and requests for hearings must be received on or before April 18, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number OPP–2004–0324. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: James A. 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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American

Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of August 25, 2004 (69 FR 52256) (FRL–7372–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F4268) by E. I. DuPont de Nemours and Company, Laurel Run, Wilmington, DE 19880–0038. The petition requested that 40 CFR 180.441(a)(1) be amended by establishing a tolerance for residues of the herbicide quizalofop (2-[4-(6-chloroquinoxalin-2-yl oxy)phenoxy]propanoic acid) and quizalofop ethyl (ethyl-2-[4-(6-chloroquinqaxalin-2-yl oxy)phenoxy]propanoate), all expressed as quizalofop ethyl (DuPont Assure II) in or on the raw agricultural commodities, dry beans at 0.4 parts per million (ppm); dry bean straw at 3.0 ppm; succulent beans at 0.25 ppm; succulent bean forage at 3.0 ppm; dry peas at 0.25; dry pea straw at 3.0 ppm; succulent peas at 0.3 ppm; succulent pea forage at 3.0 ppm; sugar beet root at 0.1 ppm; sugar beet top at 0.5 ppm; and § 180.441(a)(3) by establishing a permanent tolerance for sugar beet molasses at 0.2 ppm. These proposed tolerances replace the time-limited tolerances listed in § 180.441(a)(4). That notice included a summary of the petition prepared by E.I. Dupont de Nemours and Company, the registrant. There was one comment received in response to this notice of filing. The commenter objected to all approvals of this chemical. The commenter further opposed all exemptions, waivers, residues on food and in soil/water or any plant. The commenter also objected to testing on cows, rabbits, and dogs and to the residues in milk. This comment will be further discussed in Unit V. of this document.

During the course of the review it was determined that the commodity listing in the notice of filing was not consistent with current terminology. Therefore, these corrections are being made at this time. The proposed commodity language for 40 CFR 180.441(a)(1) is beans, dry at 0.4 ppm; bean, succulent at 0.25 ppm; beet, sugar, roots at 0.1 ppm; beet, sugar, tops at 0.5 ppm; cowpea, forage at 3.0 ppm; cowpea, hay at 3.0 ppm; pea, dry at 0.25 ppm; pea, field, hay at 3.0 ppm; pea, field vines at 3.0 ppm; and pea, succulent at 0.3 ppm. The commodities dry bean straw, succulent bean forage, dry pea straw, and succulent pea forage are replaced by the commodities cowpea, hay; cowpea, forage; pea. field, hay; and pea, field, vines; respectively. Similarly, the proposed commodity language for § 180.441(a)(3) is beet, sugar, molasses. These tolerances replace the time-limited tolerances listed in § 180.441(a)(4).

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues of quizalofop (2-[4-(6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoic acid) and quizalofop ethyl (ethyl-2-[4-(6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoate), all expressed as quizalofop-ethyl in or on the agricultural commodities beans, dry at 0.4 ppm; bean, succulent at 0.25 ppm; beet, sugar, roots at 0.1 ppm; beet, sugar, tops at 0.5 ppm; cowpea, forage at 3.0 ppm; cowpea, hay at 3.0 ppm; pea, dry at 0.25 ppm; pea, field, hay at 3.0 ppm; pea, field vines at 3.0 ppm; and pea, succulent at 0.3 ppm and quizalofop-p-ethyl ester (ethyl (R)-(2-(4-((6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoate) and its acid metabolite quizalofop-p (R-(2-(4-((6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoic acid)), and the S enantiomers of both the ester and the acid, all expressed as quizalofop-p-ethyl ester in or on the commodity beet, sugar, molasses at 0.2 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 quizalofop-ethyl as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of June 16, 1998 (63 FR 32753) (FRL–5793–5).

B. Toxicological Endpoints

The dose at which 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.

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

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

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} =point of departure/exposures) is calculated.

A summary of the toxicological endpoints for quizalofop-ethyl used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of June 16, 1998 (63 FR 32753) (FRL–5793–5).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.441) for the combined residues of quizalofop-ethyl, quizalofop-p-ethyl and associated metabolites, in or on a variety of raw agricultural commodities. Tolerances are established under § 180.441(a)(2) for quizalofop, quizalofop-ethyl, and quizalofop methyl (methyl 2-[4-(6-oxy)phenoxy]propanoate) all expressed as quizalofop-ethyl in or on meat, fat, and meat by products of cattle, goat, hog, horse, poultry, and sheep; milk and milk fat; and egg. Risk assessments were conducted by EPA to assess dietary exposures from quizalofop ethyl 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. There were no effects observed in the toxicology data base that could be attributable to a single dose (exposure). Therefore an acute dietary exposure analysis was not performed.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model (DEEM™) software with the Food Commodity Intake Database (FCID), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Tolerance level residues, DEEM™ default factors, and 100% crop treated. Data on percent of the crop treated or anticipated residues were not used.

iii. *Cancer.* EPA concluded that the pesticidal use of quizalofop-ethyl is not classifiable as to human carcinogenicity. Therefore, a quantitative cancer exposure assessment was not performed. Refer to Unit II.B.4. in the **Federal Register** of June 16, 1998 (63 FR 32753) (FRL–5793–5) for a detailed discussion.

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

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporates an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop (PC) area factor as an adjustment to account for the maximum PC coverage within a watershed or drainage basin.

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

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental

concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to quizalofop-ethyl, they are further discussed in Unit III.E.

Based on the GENEEC and SCI-GROW models, the EECs of quizalofop-ethyl for chronic exposures are estimated to be 8.08 ppb for surface water and 0.15 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).

Quizalofop-ethyl is not registered for use on any sites that would result in residential exposure.

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to quizalofop-ethyl and any other substances and quizalofop-ethyl 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 quizalofop-ethyl 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 OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety (MOS) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. The histopathology data for F2 weanlings in the 2-generation reproductive toxicity study suggested an increased sensitivity to the offspring. In that study, an increase in the incidence of eosinophilic changes in the liver were noted in the F2 weanlings, and the offspring no observed effect level (NOEL) was less than the parental systemic NOEL. However, the significance of these observations in the 2-generation reproductive toxicity study is rendered questionable due to: (i) The changes in the weanling liver were not well characterized; (ii) the biological significance of this endpoint was not known; (iii) the precise dose of test substance to 21-day old weanlings cannot be determined with any accuracy, but it is likely to exceed that of the adults; (iv) this endpoint (eosinophilic changes), in adults, would not be considered appropriate for use in regulation of a chemical because of the questionable biological significance of this effect; and, (v) previous toxicological studies show the liver as the target organ in rats. No particular significance to the offspring is attributed to the liver effects. Developmental toxicity studies showed no increased sensitivity in pups as compared to maternal animals following *in utero* exposures to rats and rabbits.

3. *Conclusion*. There is a complete toxicity data base for quizalofop-ethyl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The impact of quizalofop-ethyl on the nervous system has not been specifically evaluated in neurotoxicity studies. A developmental neurotoxicity study is not required for quizalofop-ethyl based on the following: (i) Quizalofop-ethyl does not appear to be a neurotoxic chemical; (ii) no-treatment-related effects on brain weight or histopathology (non-perfused) of the nervous system was observed in studies that measured these endpoints; (iii) no evidence of developmental anomalites of the fetal nervous system were observed in either rats or rabbits, at maternally toxic oral doses up to 300 and 600 mg/kg/day, respectively, and; (iv) no evidence of an effect on functional development was observed in a postnatal segment of the developmental toxicity study in rats. EPA determined that the 10X SF to protect infants and children should be removed. The FQPA factor is removed because the toxicology data base is complete; a developmental neurotoxicity study is not required; developmental toxicity studies showed no increased sensitivity in fetuses as compared to maternal animals following *in utero* exposures in rats and rabbits; and a 2-generation reproduction study showed no increased sensitivity in pups as compared to adults.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure milligrams/kilogram/day (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 EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be

taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Quizalofop-ethyl is not expected to pose an acute risk because no toxicological endpoints attributable to a single exposure (dose) were identified in the toxicology data base.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to quizalofop-ethyl from food will utilize 3.0% of the cPAD for the U.S. population, 3.4% of the cPAD for all infants (< 1 year old), and 9.6% of the cPAD for children 1–2 years old. There are no residential uses for quizalofop-ethyl that result in chronic residential exposure to quizalofop-ethyl. In addition, there is potential for chronic dietary exposure to quizalofop-ethyl in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 1.

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

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.009	3.0	8.08	0.15	306
All infants (<1 year old)	0.009	3.4	8.08	0.15	87
Children (1–2 years old)	0.009	9.6	8.08	0.15	81
Females (13–49 years old)	0.009	2.2	8.08	0.15	264
Youth (13–19 years old)	0.009	2.8	8.08	0.15	262
Adults (20–49 year old)	0.009	1.9	8.08	0.15	308

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).

Quizalofop-ethyl 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).

Quizalofop-ethyl 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*. Quizalofop-ethyl is classified as ''not classifiable as to human cancer potential.'' The Agency believes that any cancer risk posed by quizalofop-ethyl is negligible and there is reasonable certainty that no harm will result form exposure to residue of quizalofop-ethyl. Refer to the **Federal Register** of June 16, 1998 (63 FR 32753) (FRL–5793–5) for a detailed discussion.

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 quizalofop-ethyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate analytical methodology (high pressure liquid chromatography (HPLC) using either an ultraviolet or fluorescence detector is available for enforcement purposes in Vol II of the Food and Drug Administration (FDA) Pesticide Analytical Method (PAM II, Method I).

B. International Residue Limits

Since there are no Mexican or Canadian Maximum Residue Levels, compatibility is not a problem at this time. Compatibility cannot be achieved with the Canadian negligible residue type limit of 0.1 ppm, since data supporting United States use patterns had findings of real residues above 0.1 ppm.

C. Conditions

There are no conditions of registration for establishment of tolerances on the commodities bean, dry; bean, succulent; cowpea, forage; cowpea, hay; beet, sugar, molasses; beet, sugar, roots; beet, sugar, tops; pea, dry; pea, field, hay; pea, field, vines; and pea, succulent.

V. Comment

One comment was received in response to the notice of filing. The commenter objected to all approvals of any kind for this pesticide and objected to all exemptions, waivers, residues on food, milk, or on soil/water or any plants. The commenter also objected to animal testing on cows, rabbits, or dogs, because animal testing constitutes animal abuse and stated that it should be stopped. The commenter also stated that more modern less abusive methods should be used.

The comment contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from the aggregate exposure to quizalofop-ethyl, including all anticipated dietary exposure and all other exposures for which there is reliable information.

OPPTS Harmonized Guideline--Health Effects Guidelines (Series 870) recommend that dog or rabbit be used for various acute, subchronic, and longer term chronic, carcinogenic, developmental, and reproductive studies. Residue Chemistry Guidelines (Series 860) recommend that a cow be used for certain feeding studies. Information derived from these tests indicate the presence of possible hazards or residues from exposure to the test substance. Currently, there are no *in vitro* studies that can address the questions that these studies answer. The Agency is currently working with the Interagency Coordinating Committee on the Validation or Alternate Methods to investigate alternative *in vitro* methods.

VI. Conclusion

Therefore, permanent tolerances are established for combined residues of quizalofop (2-[4-(6-chloroquinoxalin-2-yl)oxy)phenoxy)-propanoic acid) and quizalofop ethyl (ethyl-2-[4-(6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoate), all expressed as quizalofop ethyl in or on bean, dry at 0.4 ppm; bean, succulent at 0.25; beet, sugar, roots at 0.1 ppm; beet, sugar, tops at 0.5 ppm; cowpea, forage at 3.0 ppm; cowpea, hay at 3.0 ppm; pea, dry at 0.25 ppm; pea, field, hay at 3.0 ppm; pea, field, vines at 3.0 ppm; and pea, succulent at 0.3 ppm (40 CFR 180.441(a)(1)). Also, 40 CFR 180.441(a)(3) is amended by establishing a permanent tolerance for the combined residues of quizalofop-p-ethyl ester (ethyl (R)-(2-(4-((6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoate)) and its acid metabolite quizalofop-p R-(2-(4-((6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoic acid), and the S enantiomers of both the ester and the acid, all expressed as quizalofop-p-ethyl ester is established for beet, sugar, molasses at 0.2 ppm. These tolerances replace the ones listed in 40 CFR 180.441(a)(4).

VII. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0324 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 April 18, 2005.

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

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

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0324, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VIII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to*

Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

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: February 7, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.441 is amended by adding alphabetically the following commodities to the table in paragraph (a)(1) and (a)(3) to read as follows:

§ 180.441 Quizalofop-ethyl; tolerances for residues.

(a)(1) * * *

Commodity	Parts per million
Bean, dry	0.4
Bean, succulent	0.25
Beet, sugar, roots	0.1
Beet, sugar, tops	0.5
Cowpea, forage	3.0
Cowpea, hay	3.0
Pea, dry	0.25
Pea, field, hay	3.0
Pea, field, vines	3.0≤
Pea, succulent	0.3
* * * * *	

* * * * *

(3) * * *

Commodity	Parts per million
Beet, sugar, molasses	0.2 ppm
* * * * *	

* * * * *

[FR Doc. 05–2982 Filed 2–15–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0026; FRL–7697–9]

Syrups, Hydrolyzed Starch, Hydrogenated; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of syrups, hydrolyzed starch, hydrogenated (CAS Reg. No. 68425–17–2) when used as an inert ingredient in pesticide products. Grain Processing Corporation and SPI Polyols submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of syrups, hydrolyzed starch, hydrogenated.

DATES: This regulation is effective February 16, 2005. Objections and requests for hearings must be received on or before April 18, 2005.

ADDRESSES : To submit a written objection or hearing request follow the detailed instructions as provided in Unit XI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a