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.

V. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and 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 the rule in the **Federal Register**. This 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 19, 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.

§ 180.910 [Amended]

■ 2. Section 180.910 is amended by removing, in the table, the following entries: Casein; fish meal; soy protein, isolated; and wheat, including flour, bran, and starch.

§ 180.920 [Amended]

■ 3. Section 180.920 is amended by removing, in the table, the following entry: Sodium caseinate.

§ 180.930 [Amended]

■ 4. Section 180.930 is amended by removing, in the table, the following entries: Rhodamine B; soy protein, isolated; and wheat shorts.

[FR Doc. 05–19056 Filed 9–22–05; 8:45 am]

BILLING 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0246; FRL–7737–8]

Pyriproxyfen; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyriproxyfen in or on grass, forage, fodder, and hay, group 17, forage; grass, forage, fodder, and hay, group 17, hay; vegetable, legume, group 6; onion, dry bulb; grape; strawberry; sapote, white; and citrus hybrids. Interregional Research Project Number 4 (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 23, 2005. Objections and requests for hearings must be received on or before November 22, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number OPP–2005–0246. 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: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–308–3194; e-mail address: *brothers.shaja@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.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of August 17, 2005 (70 FR 48413) (FRL–7732–1, EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 3E6596, 3E6750, 4E6866, 4E6865, and 3E6582) by IR-4, 681 US Highway #1 South, North Brunswick, NJ 08902–3390. The petitions requested that 40 CFR 180.510 be amended by establishing tolerances for residues of the insecticide pyriproxyfen, [2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine, in or on legume vegetables, crop subgroups 6a, 6b, and 6c at 0.2 part per million (ppm) (PP 3E6596); onion, dry bulb at 0.05 ppm (PP 3E6750); grape at 2.5 ppm, and raisin at 4.0 ppm (PP 4E6866); strawberry at 0.3 ppm (PP 4E6865); white sapote, and ugli fruit at 0.3 ppm (PP 3E6582). The petition for onion, dry bulb (PP 3E6750) was subsequently amended from 0.05 ppm to 0.15 ppm. The Agency has also determined a separate tolerance for raisin is not necessary. In addition, ugli fruit has been translated to citrus hybrids. No comments were recived on the notice of filing.

Additionally, in the **Federal Register** of December 22, 2004 (69 FR 76724) (FRL–7689–6), 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 4F6847) by Valent USA Corporation, 1600 Riviera Ave., Suite 200, Walnut Creek, California 94596–8025. The petition requested that 40 CFR 180.510 be amended by establishing tolerances for residues of the insecticide pyriproxyfen, [2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine], in or on grass forage and hay (crop group 17). The Agency has subsequently amended the petition to establish tolerances for grass, forage, fodder, and hay, group 17, forage at 0.70 ppm (previously requested at 0.5 ppm), and grass, forage, fodder, and hay, group 17, hay at 1.1 ppm (previously requested at 1.0 ppm). That notice included a summary of the petitions prepared by Valent USA Corporation], the registrant. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

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 *http://www.epa.gov/pesticides/health/human.htm*

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 these actions. 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 tolerances for residues of pyriproxyfen on vegetable, legume, group 6 at 0.20 ppm; onion, dry bulb at 0.15 ppm; grape at 2.5 ppm; strawberry at 0.30 ppm; white sapote at 0.30 ppm; citrus hybrids at 0.30 ppm; grass, forage, fodder, and hay, group 17, forage at 0.70 ppm; and grass, forage, fodder, and hay, group 17, hay at 1.1 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follow.

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. Specific information on the studies received and the nature of the toxic effects caused by pyriproxyfen as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies can be found at *http://www.epa.gov/fedrgstr/EPA-PEST/2003/May/Day-14/p12022.htm*.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, 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 of concern identified is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of

cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases.

A summary of the toxicological endpoints for pyriproxyfen used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PYRIPROXYFEN FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13–50 years of age) and general population	None	None	An appropriate endpoint attributable to a single oral dose was not available in the data base, including maternal toxicity in the developmental toxicity studies
Chronic dietary (all populations)	NOAEL = 35.1 mg/kg/day UF = 100 Chronic Reference Dose (cRfD) = 0.35 mg/kg/day	Special FQPA SF = 1X Chronic Population Adjusted Dose (cPAD) = cRfD Special FQPA SF = 0.35 mg/kg/day	Subchronic toxicity and chronic toxicity (feeding) - rat LOAEL = 141.28 mg/kg/day based on decreased body weight and clinical pathology results
Short-term incidental, oral (1 to 30 days) (Residential)	Oral Maternal NOAEL = 100 mg/kg/day	LOC for Margin of Exposure (MOE) = 100 (Residential)	Rat developmental toxicity study LOAEL = 300 mg/kg/day based on decreased body weight, body weight gain, and food consumption, and increased water consumption
Intermediate-term incidental, oral (1–6 months) (Residential)	Oral NOAEL = 35.1 mg/kg/day	LOC for MOE = 100 (Residential)	Subchronic toxicity and chronic toxicity (feeding) - rat (co-critical) LOAEL = 141.28 mg/kg/day based on decreased body weight and clinical pathology results
Short-term, and intermediate-term dermal (1–30 days and 1–6 months) (Occupational/Residential)	None	None	Based on the systemic toxicity NOAEL of 1,000 mg/kg/day (limit dose) in the 21-day dermal toxicity study in rats, quantification of dermal risks is not required. In addition, no developmental concern (toxicity) were seen in either rats or rabbits
Long-term dermal (6 months to lifetime) (Occupational/Residential)	Dermal (or oral) study NOAEL = 35.1 mg/kg/day	LOC for MOE = 100 (Residential)	Subchronic toxicity and chronic toxicity (feeding) - rat(co-critical) LOAEL = 141.28 mg/kg/day based on decreased body weight and clinical pathology results
Short-term, and intermediate-term dermal (1 to 30 days and 1–6 months)(Residential)	None	None	28-day inhalation toxicity - rats. Based on the absence of significant toxicity at the LOAEL of 1.0 mg/L (limit dose), the quantification of inhalation risks is not required. In addition, no developmental concern (toxicity) were seen in either rats or rabbits
Long-term dermal (6 months to lifetime) (Occupational/Residential)	Dermal oral study NOAEL = 35.1 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Subchronic and chronic toxicity (feeding) - rat (co-critial) LOAEL = 141.28 mg/kg/day based on decreased body weight and clinical pathology results
Cancer (oral, dermal, inhalation)	Cancer classification (“Group E”)	None	No evidence of carcinogenicity

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.510) for the residues of pyriproxyfen, in or on the following raw agricultural commodities: Acerola at 0.10 part per million (ppm); almond, hulls at 2.0 ppm; apple, wet pomace at 0.8 ppm; atemoya at 0.20 ppm; avocado at 1.0 ppm; biriba at 0.20 ppm; black sapote at 1.0 ppm; brassica, head and stem, subgroup at 5A at 0.70 ppm; brassica, leafy greens, subgroup 5B at 2.0 ppm; bushberry subgroup 13B at 1.0 ppm; canistel at 1.0 ppm; cherimoya at 0.20 ppm; citrus, oil at 20 ppm; citrus, dried pulp at 2.0 ppm; cotton, gin byproducts at 2.0 ppm; cotton, undelinted seed at 0.05 ppm; custard apple at 0.20 ppm; feijoa at 0.10 ppm; fig at 0.30 ppm; fig, dried at 1.0 ppm; fruit, citrus at 0.3 ppm; fruit, pome at 0.2 ppm; fruit, stone, group 12 at 1.0 ppm; guava at 0.10 ppm; ilama at 0.20 ppm; jaboticaba at 0.10 ppm; juneberry at 1.0 ppm; lingonberry at 1.0 ppm; logan at 0.30 ppm; lychee at 0.30 ppm;

mamey sapote at 1.0 ppm; mango at 1.0 ppm; okra at 0.02 ppm; olive at 1.0 ppm; olive, oil at 2.0 ppm; papaya at 1.0 ppm; passionfruit at 0.10 ppm; pistachio at 0.02 ppm; pulasan at 0.30 ppm; rambutan at 0.30 ppm; salal at 1.0 ppm; sapodilla at 1.0 ppm; soursop at 0.20 ppm; spanish lime at 0.30 ppm; star apple at 1.0 ppm; starfruit at 0.10 ppm; sugar apple at 0.20 ppm; tree nut at 0.02 ppm; vegetable, cucurbit, group 9 at 0.10 ppm; vegetable, fruiting, group 8 at 0.2 ppm; walnut at 0.02 ppm; and wax jambu at 0.10 ppm. Risk assessments were conducted by EPA to assess dietary exposures from pyriproxyfen in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. No such effects were identified in the toxicological studies for pyriproxyfen, therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure 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 U.S. Department of Agriculture (USDA) 1994–1996, and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The Tier 1 chronic analysis assumed 100% crop treated, DEEM™ 7.81 default processing factors and tolerance-level residues for all commodities. Percent crop treatedand/or anticipated residues were not used.

iii. *Cancer*. The Agency classified pyriproxyfen as a ''Group E'' chemical, no evidence for carcinogenicity to humans, based on the absence of evidence of carcinogenicity in male and female rats as well as in male and female mice. Therefore, a cancer risk assessment was not performed.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for pyriproxyfen 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 pyriproxyfen. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on EPA's Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and, Screening Concentration in Ground Water (SCI-GROW) models, the Estimated Environmental Concentrations (EECs) of pyriproxyfen for ground water exposures are estimated to be 0.006 parts per billion (ppb) (acute and chronic). Surface water exposures are estimated to be 2.15 ppb (peak concentration), and 0.40 ppb (long term average).

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model DEEM™/FCID using long-term average concentrations for surface water (0.40 ppb) to access the contribution to drinking water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Pyriproxyfen is currently registered for use on the following residential non-dietary sites: Residential products for flea and tick control (home environment and pet treatments), and ant and roach control (indoor and outdoor applications). Formulations include carpet powders, foggers, aerosol sprays, liquids (shampoos, sprays and pipettes for pet treatments), granules, bait (indoor and outdoor), and impregnated materials (pet collars). Adults and toddlers could potentially be exposed to pyriproxyfen residues on treated carpets, floors, upholstery, and pets; however, since the Agency did not select any short-term dermal or inhalation endpoints, only a post-application residential assessment was conducted. Toddlers are anticipated to have higher exposures than adults from treated home environments and pets due to their behavior patterns. The risk assessment was conducted using the following residential exposure assumptions:

i. *Hand-to-mouth*: Short-term, intermediate term, and long-term hand-to-mouth exposures to toddlers from treated carpets, flooring (note the efficacy of carpet powders is approximately 365 days).

ii. *Hand-to-mouth*: Short-term and intermediate-term hand-to-mouth exposures to toddlers from petting treated animals (shampoos, sprays, spot-on treatments and collars). Long-term hand-to-mouth exposures to toddlers from petting treated animals (pet collars; note efficacy of pet collars up to 365 days).

iii. *Dermal*: Long-term dermal exposures from treated carpets, flooring, and pets (note that treated furniture is included in the carpet/flooring assessment).

iv. *Ingestion of granules or bait by toddlers (acute, episodic event*).

v. *Combined short-term and intermediate-term hand-to-mouth exposures (toddlers)*:

- Treated carpet (powder application) and treated pet (collar/pet shampoo/pet spray).
- Treated carpet (spray application) and treated pet (collar/pet shampoo/pet spray).
- Treated home environment (fogger application) and treated pet (collar/pet shampoo/pet spray).

vi. *Combined long-term hand-to-mouth and dermal exposures* (toddlers):

- Dermal exposure from pet hugging.
- Dermal contact with treated carpet.
- Hand-to-mouth exposures from treated carpets.
- Hand-to-mouth exposures from treated pets.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the Federal Food, Drug, and Cosmetic Act (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 pyriproxyfen and any other substances and pyriproxyfen does not appear to produce a toxic metabolite produced by other substances. EPA has also evaluated comments submitted that suggested there might be a common mechanism among pyriproxyfen and other named pesticides that cause brain effects. EPA concluded that the evidence did not support a finding of common mechanism for pyriproxyfen and the named pesticides. For the purposes of this tolerance action, therefore, EPA has not assumed that pyriproxyfen has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements

released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. Based on the available data, there is no quantitative and qualitative evidence of increased susceptibility observed following *in utero* pyriproxyfen exposure to rats and rabbits or following prenatal/postnatal exposure in the 2-generation reproduction study.

3. *Conclusion*. There is a complete toxicity data base for pyriproxyfen and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined the 10X safety factor for infants and children should be reduced to 1X. The FQPA safety factor was reduced:

i. Due to the lack of evidence of prenatal or postnatal extra sensitivity, or increased susceptibility in developmental studies (rats and rabbits), and reproduction studies (rats).

ii. The lack of quantitative or qualitative evidence of increased susceptibility for rats and rabbits identified in the guideline prenatal developmental toxicity studies.

iii. The lack of evidence of quantitative or qualitative increased susceptibility in the two non-guideline studies that evaluated perinatal and prenatal development.

iv. Offspring toxicity (decreased body weight on pups during lactation days 14 to 21) in the reproduction toxicity study occurred only in the presence of decreases in body weight in parental animals at the same dose level (i.e., comparable toxicity in adults and offspring).

E. Aggregate Risks and Determination of Safety

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against estimated environmental concentrations (EECs). The DWLOC values are not regulatory standards for drinking water, but 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 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). 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 DWOCs, EPA concluded with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposures 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 changes. When new uses are added EPA reassesses the potential impacts of residues of the pesticide in drinking water as a part of the aggregate assessment process.

More recently the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface water and ground water EECs are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic estimate of exposure because actual body weights and water consumption from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in developing drinking water modeling inputs.

1. *Acute risk*. An acute aggregate exposure analysis was not conducted since no acute doses or endpoints were selected for the general U.S. population (including infants and children) or the females 13–50 years old population subgroup.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to pyriproxyfen from food and water will utilize 3.2% of the cPAD for the U.S. population, 4.4% of the cPAD for all infants <1 year old, 9.9% of the cPAD for children 1–2 years old, and 2.4% of the cPAD for females 13–49 years old.

Chronic aggregate exposure takes into account chronic residential exposure plus chronic exposure to food and water. Pyriproxyfen is currently registered for use that could result in chronic residential exposure and the Agency has determined that it is appropriate to aggregate chronic food, water, and residential exposures for pyriproxyfen.

Using the exposure assumptions described in this unit for chronic exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs of 3,200 for the U.S. population; 820 for all infants <1 year old; 560 for children 1–2 years old; and 4,700 for females 13–49 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PYRIPROXYFEN

Population/Subgroup	cPAD/mg/kg/day	%cPAD/(Food)	Target MOE	Aggregate MOE (food + water + residential)
U.S. population	0.35	3.2	100	3200
All infants (<1 year old)	0.35	4.4	100	820
Children (1–2 years old)	0.35	9.9	100	560
Females (13–49 years old)	0.35	2.4	100	4700

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).

Pyriproxyfen is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for pyriproxyfen.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs of 9,000 for the U.S. population; 1,600 for all infants <1 year old; 1,200 for children 1–2 years old; and 1,3000 for females 13–49 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses.

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).

Pyriproxyfen is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for pyriproxyfen.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs of 3,200 for the U.S. population; 560 for all infants <1 year old, 430 for children 1–2 years old, and 4,700 for females 13–49 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses.

5. *Aggregate cancer risk for U.S. population*. A cancer aggregate risk assessment was not performed since pyriproxyfen has not been classified as a potential carcinogen.

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 pyriproxyfen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

In conjunction with the crop field trial studies, the petitioner submitted adequate concurrent recovery data for a gas chromatography/nitrogen-phosphorus detector (GC/NPD) method (RM-33P-1-3a or 9.66 V 1) used to determine residues of pyriproxyfen in/on the subject crops. The method has undergone an adequate radiovalidation, independent laboratory validation (ILV) trial, petition method validation (PMV) trial, and has been forwarded to the Food and Drug Administration (FDA) for inclusion in PAM Vol. II. The GC/NPD method RM-33P-1-3a is adequate for enforcement of the recommended tolerance levels for residues of pyriproxyfen per se in/on the subject crops.

B. International Residue Limits

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

C. Response to Comments

Several comments were received from a private citizen on objecting to pesticide body load, IR-4 profiteering, animal testing, establishing tolerances, pesticide residues, and pesticide exemptions.

The Agency has received these same comments from this commenter of numerous previous occasions. Refer to the **Federal Register** of June 30, 2005 (70 FR 37686) (FRL–7718–3), January 7, 2005 (70 FR 1349) (FRL–7691–4), and October 29, 2004 (69 FR 63083) (FRL–7681–9) for the Agency's response to these objections.

V. Conclusion

Therefore, tolerances are established for residues of pyriproxyfen, [2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine], in or on vegetable, legume, group 6 at 0.20 ppm; onion, dry bulb at 0.15 ppm; grape at 2.5 ppm; strawberry at 0.30 ppm; white sapote at 0.30 ppm; citrus hybrids at 0.30 ppm; grass, forage,fodder, and hay, group 17, forage at 0.70 ppm; and grass, forage, fodder, and hay, group 17, hay at 1.1 ppm.

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0246 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 22, 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 issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

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

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0246, 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.''''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 19, 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 180.510 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.510 Pyriproxyfen; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Citrus hybrids	0.30
* * * * *	
Grape	2.5
Grass, forage, fodder, and hay, group 17, forage	0.70
Grass, forage, fodder, and hay, group 17, hay	1.1
* * * * *	
Onion, dry bulb	0.15
* * * * *	
Strawberry	0.30
* * * * *	
Vegetable, legume, group 6	0.20
* * * * *	
White sapote	0.30
* * * * *	

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0133; FRL–7738–7]

Fenpropathrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenpropathrin in or on bushberry subgroup 13B; lingonberry; juneberry; salal; pea, succulent; and vegetable, fruiting, group 8. Interregional Research Project Number 4 (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 23, 2005. Objections and requests for hearings must be received on or before November 22, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0133. 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: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather 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