VIII. Submission to Congress and the Comptroller General

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: July 3, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346(a) and 374.

2. Section 180.371 is amended as follows:

i. By alphabetically adding entries for the commodities ''grape,'' ''pear,'' and ''pistachio'' and revising the entry for ''potatoes, seed treatment'' to read ''potato'' to the table in paragraph (a) as set forth below.

ii. By adding text and a table to paragraph (c):

§ 180.371 Thiophanate-methyl; tolerances for residues.

(a) *General.* Thiophanate-methyl and its metabolite (methyl 2-benzimidazoyl carbamate (MBC)), expressed as thiophanate-methyl

Commodity	Parts per million
* * *	* *
Grape	5.0
* * *	* *
Pear	3.0
* * *	* *
Pistachio	0.1
* * *	* *
Potato	0.1
* * *	* *

* * * * *

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for the residues of thiophanate-methyl and its metabolite (methyl 2-benzimidazolyl carbamate (MBC)), expressed as thiophanate-methyl in or on the following raw agricultural commodity:

Commodity	Parts per million
Canola	0.1

* * * * *

[FR Doc. 02–21678 Filed 8–27–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0215; FRL–7195–7]

Pyriproxyfen; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the residues of pyriproxyfen in or on acerola at 0.10 part per million (ppm), bushberry subgroup at 1.0 ppm, feijoa at 0.10 ppm, fruit, stone, group at 1.0 ppm, guava at 0.10 ppm, jaboticaba at 0.10 ppm, juneberry at 1.0 ppm, lingonberry at 1.0 ppm, longan at 0.30 ppm, lychee at 0.30 ppm, passionfruit at 0.10 ppm, pulasan at 0.30 ppm, rambutan at 0.30 ppm, salal at 1.0 ppm, spanish lime at 0.30 ppm, starfruit at 0.10 ppm, and wax jambu at 0.10 ppm. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective August 28, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0215, must be received on or before October 28, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0215 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; 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 affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the**Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/

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

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–0215. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of June 5, 2002 (67 FR 38660) (FRL–7177–4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170), announcing the filing of pesticide petitions (PP 1E6272, 1E6285, and 2E6353) by IR–4, Technology Centre of New Jersey, Rutgers University, 681 U.S. Highway No. 1 South, North Brunswick, NJ 08902–3390. This notice included a summary of the petitions prepared by Valent USA Corporation, the registrant. There were no comments received in response to the notice of filing.

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)ethoxypyridine, in or on acerola at 0.10 ppm, bushberry subgroup at 1.0 ppm, feijoa at 0.10 ppm, fruit, stone, group at 1.0 ppm, guava at 0.10 ppm, jaboticaba at 0.10 ppm, juneberry at 1.0 ppm, lingonberry at 1.0 ppm, longan at 0.30 ppm, lychee at 0.30 ppm, passionfruit at 0.10 ppm, pulasan at 0.30 ppm, rambutan at 0.30 ppm, salal at 1.0 ppm, spanish lime at 0.30 ppm, starfruit at 0.10 ppm, and wax jambu at 0.10 ppm.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) 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) 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 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), 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), for tolerances for residues of acerola at 0.10 ppm, bushberry subgroup at 1.0 ppm, feijoa at 0.10 ppm, fruit, stone, group at 1.0 ppm, guava at 0.10 ppm, jaboticaba at 0.10 ppm, juneberry at 1.0 ppm, lingonberry at 1.0 ppm, longan at 0.30 ppm, lychee at 0.30 ppm, passionfruit at 0.10 ppm, pulasan at 0.30 ppm, rambutan at 0.30 ppm, salal at 1.0 ppm, spanish lime at 0.30 ppm, starfruit at 0.10 ppm, and wax jambu at 0.10 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. The nature of the toxic effects caused by pyriproxyfen is discussed in Unit III.A. of the Final Rule on Pyriproxyfen Pesticide Tolerance published in the **Federal Register** of June 5, 2001 (66 FR 30065) (FRL–6782–5). Additionally, toxicological studies to the toxicological profile for pyriproxyfen are shown below in Table 1:

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents-mouse	NOAEL = 149.4 mg/kg/day in males, 196.5 mg/kg/day in females LOAEL = 838.1 mg/kg/day in males, 963.9 mg/kg/day in females based on pathological changes in the kidney, increased absolute and relative (to body) liver weight, decreased red blood cell parameters (both sexes) and decreased body weight gain (M)
870.3265	28-Day inhalation toxicity-rat	NOAEL = 0.482 mg/L (males and females) LOAEL = 1.000 mg/L based on salivation (both sexes), sporadic decreased body weight (M), and increased lactate dehydrogenase (M)

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

Guideline No.	Study Type	Results
Non-guideline	Special study prenatal developmental in rodents-rats	Parental NOAEL = 100 mg/kg/day Parental LOAEL = 300 mg/kg/day based on clinical signs, decreased body weight gains, increased water consumption (both sexes) and increased food consumption, changes in organ weights, and gross pathological changes (M) Developmental NOAEL = 1,000 mg/kg/day (HDT)
Non-guideline	Special study prenatal developmental in rodents-rats	Maternal NOAEL = 100 mg/kg/day Maternal LOAEL = 300 mg/kg/day based on clinical signs, decreased body weight gains, and decreased food consumption Developmental NOAEL = 100 mg/kg/day Developmental LOAEL = 300 mg/kg/day based on decreased body weight and increased incidence of dilation of the renal pelvis
870.3800	Reproduction and fertility effects-rat	Parental/systemic NOAEL = 87 mg/kg/day in males, 96 mg/kg/day in females Parental/systemic LOAEL = 453 mg/kg/day in males, 498 mg/kg/day in females based on decreased body weight, body weight gain, and food consumption (both sexes) and increased liver weight (both sexes) and histopathological lesions of liver and kidneys (M) Reproductive NOAEL ≥453 mg/kg/day in males, 498 mg/kg/day in females Reproductive LOAEL = not established Offspring NOAEL = 87 mg/kg/day in males, 96 mg/kg/day in females Offspring LOAEL = 453 mg/kg/day in males, 498 mg/kg/day in females based on decreased body weight on lactation days 14 and 21
870.4300	Carcinogenicity mice	NOAEL = 84 mg/kg/day in males, 109.5 mg/kg/day in females LOAEL = 420 mg/kg/day in males. 547 mg/kg/day in females based on renal lesions in males and females No evidence of carcinogenicity
870.5265	Gene mutation	Non-mutagenic when tested up to 5,000 μg/plate or cytotoxic levels, in presence and absence of activation, in *S. typhimurium* strains TA98, TA100, TA1535 and TA1537 and *E.coli* strain WP2uvra with 2-OH-PY (metabolite of pyriproxyfen)
870.5265	Gene mutation	Non-mutagenic when tested up to 5,000 μg/plate or cytotoxic levels, in presence and absence of activation, in *S. typhimurium* strains TA98, TA100, TA1535 and TA1537 and *E.coli* strain WP2uvra with 4'-OH-PY, 5''-OH-PYR, DPH-PYR, POPA, and PYPAC (metabolites of pyriproxyfen)
870.5265	Gene mutation	Non-mutagenic when tested up to 5,000 μg/plate or cytotoxic levels, in presence and absence of activation, in *S. typhimurium* strains TA98, TA100, TA1535 and TA1537 and *E.coli* strain WP2uvra with 2,5-OH-PY (metabolite of pyriproxyfen)
870.5265	Gene mutation	Non-mutagenic when tested up to 5,000 μg/plate or cytotoxic levels, in presence and absence of activation, in *S. typhimurium* strains TA98, TA100, TA1535, TA1537, and TA1538 and *E.coli* strain WP2uvra with 2-OH-PY (pyriproxyfen technical)
870.5265	Gene mutation	Non-mutagenic at the HGPRT locus in Chinese hamster lung V79 cells tested up to cytotoxic concentrations or limit of solubility, in presence and absence of activation
870.5375	Chromosome aberration	Did not induce structural chromosome aberration in Chinese hamster ovary (CHO) cell cultures in the absence or presence of activation
870.5550	Unscheduled DNA synthesis	There was no evidence that unscheduled DNA synthesis, as determined by radioactive tracer procedures (nuclear silver grain counts) was induced in HeLa cells exposed up to cytotoxic levels, both in the presence or absence of S-9

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the

variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA 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 is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, margin of error (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 pyriproxyfen used for human risk assessment is shown in the following Table 2:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13-50 years old and general population)	None	None	There were no effects observed in oral toxicity studies including developmental toxicity studies in rats and rabbits that could be attributable to a single dose (acute) exposure. Therefore, a dose and endpoint was not selected for this risk assessment.
Chronic dietary (all populations)	NOAEL= 35.1 mg/kg/day UF = 100 Chronic RfD = 0.35 mg/kg/day	FQPA SF = 1X cPAD = cRfD/FQPA SF = 0.35 mg/kg/day	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 incidental, oral (1-30 days) Residential	Oral NOAEL = 100 mg/kg/day	LOC for MOE = 100	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	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-, and intermediate-term dermal (1-30 days and 1-6 months) (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 were not performed. In addition, no developmental concerns (toxicity) were seen in either rats or rabbits.
Long-term dermal (6 months-lifetime) (Residential)	Oral NOAEL= 35.1 mg/kg/day (dermal absorption rate = 30%)	LOC for MOE = 100	Subchronic and chronic toxicity (feeding) - rat (co-critical) LOAEL = 141.28 mg/kg/day based decreased body weight and clinical pathology results

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Short-, and intermediate-term inhalation (1-30 days and 1-6 months) (Residential)	None	None	Based on the absence of significant toxicity at the LOAEL of 1.0 mg/L (limit dose) in the 28-day inhalation study, the quantification of inhalation risks is not required. In addition, no developmental concerns (toxicity) were seen in either rats or rabbits.
Long-term inhalation (6 months-lifetime) (Residential)	Oral study NOAEL = 35.1 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100	Subchronic and chronic toxicity (feeding) - rat (co-critical) 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

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.510) for the residues of pyriproxyfen, in or on a variety of raw agricultural commodities: Almond hulls at 2.0 ppm; apple, pomace, wet at 0.8 ppm; citrus fruits at 0.3 ppm; citrus oil at 20 ppm; citrus pulp, dried at 2.0 ppm; cotton, gin byproducts at 2.0 ppm; cottonseed at 0.05 ppm; fruiting vegetables (except cucurbits) at 0.2 ppm; pistachio at 0.02 ppm; pome fruits at 0.2 ppm; tree nuts at 0.02 ppm; and walnuts at 0.02 ppm). Section 18s have been established for bean, succulent at 0.10 ppm, and stone fruits at 0.1 ppm, and are currently set to expire on June 30, 2003, and December 31, 2002, respectively. There are no livestock feed items associated with stone fruits, guava, lychee, blueberry, or the related crops, thus the proposed uses will not result in the transfer of any additional pyriproxyfen residues to livestock. Risk assessments were conducted by EPA to assess dietary exposures from pyriproxyfen in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. An acute dietary 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.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment, the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 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 chronic dietary exposure was performed using published and proposed tolerance levels, DEEM™ default processing factors, and 100% crop treated (CT) assumptions for all commodities.

iii. *Cancer.* Pyriproxyfen was classified by EPA (June 1995) as a ''Group E'' chemical-negative for carcinogenicity to humans-based on the absence of carcinogenicity in mice and rats.

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.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentrations in Ground Water (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 incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address

total aggregate exposure to pyriproxyfen, they are further discussed in Unit III.E.

Pyriproxyfen is relatively long-lived in soil and water, with variable half-lives of approximately 2 weeks to 2 months. Pyriproxyfen is immobile, as indicated by the relative mobility scheme in Dragun (1998) for five soils and one sediment. The registrant determined the half-lives, 6.8 and 9 days, respectively, for the phenyl-label and pyridyl-label portions of pyriproxyfen. Since there is only one value, the longest half-life (9 days) was multiplied by 3 using the Agency's input guidance. Thus, the aerobic soil half-life in the modeling assessment was 27 days.

EPA determined that the residues of concern in water is pyriproxyfen per se. Drinking water estimates include surface water EECs based on the linked PRZM/EXAMS models and the SCI-GROW ground water regression model, which was developed from studies with different hydrology and study conditions. Both models assumed a maximum seasonal application rate of 0.11 lb ai/A, 3 times per year (citrus).

Based on the PRZM/EXAMS model the EECs of pyriproxyfen for surface water was estimated to be 2.15 parts per billion (ppb) for the peak concentration and 0.40 ppb for the long term average. Based on the SCI-GROW model, the EECs of pyriproxyfen for ground water was estimated to be 0.006 ppb for both the acute and chronic exposure.

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 sites for flea and tick control products (home environment and pet treatments) as well as products for ant and roach control (indoor and outdoor applications). Formulations include carpet powders, foggers, aerosol sprays, liquids (shampoos, sprays, and pipettes), granules, bait (indoor and outdoor), and impregnated materials (pet collars).

There is a potential for short-term dermal and inhalation exposures to pet owners and homeowners who apply products containing pyriproxyfen (handlers); however, EPA did not select short-term dermal or inhalation endpoints. Therefore, no residential pet owner/homeowner handler assessment is included. However, a post-application toddler residential assessment is included since toddlers are anticipated to have higher exposures than adults from treated home environments and pets due to their behavior patterns.

Toddlers could potentially be exposed to pyriproxyfen residues on treated carpets, floors, furniture, and pets. Therefore, risk assessment was conducted using the following residential exposure assumptions:

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

ii. Hand-to-mouth: Short- and intermediate-term hand-to-mouth exposures by toddlers from petting treated animals (shampoos, sprays, spot-on treatments and collars). Long-term hand-to-mouth exposures by toddlers from petting treated animals (pet collars; note efficacy of pet collars up to 395 days).

iii. Dermal: Long-term dermal exposures from treated carpets, flooring, and pets (note that treated furniture is included in the carpet/flooring assessment). Since the Agency did not select any short- or intermediate-term dermal endpoints, no dermal assessment for these durations is included. A long-term dermal assessment is included, since EPA selected a long-term dermal endpoint.

iv. Ingestion of granules or bait by toddlers (acute, episodic event). For the granular ingestion scenario, it should be noted that the Agency believes that if a toddler were to be exposed to a pellet/granular formulation (i.e., ant bait), the event is most likely to be ''episodic,'' that is, a one time occurrence and not likely to be repeated. It is not likely that a toddler would repeatedly locate and ingest very small, sand colored granules. For pyriproxyfen, EPA did not select an acute dietary endpoint, since an appropriate endpoint could not be attributed to a single oral dose; therefore, no granular assessment was performed.

Exposure and risk estimates from post-application exposure to indoor crack and crevice treatments are not presented in this assessment as indoor broadcast treatments (i.e., carpet powders and sprays) are anticipated to have a higher exposure potential. Additionally, the Agency acknowledges that pet owners could retreat the home environment and/or the pet near the end of the efficacy period identified on the product labels. However, there are no chemical-specific residue data for pyriproxyfen to determine the dissipation rate of residues or whether residues may be additive upon retreatment. Therefore, a Tier 1 assessment was performed based on day 0 residues without accounting for daily residue dissipation. EPA anticipates that this assessment is protective as pyriproxyfen residues would be expected to dissipate from day 0 residue values.

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

EPA does not have, at this time, available data to determine whether pyriproxyfen has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, pyriproxyfen 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 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1.*In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. 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 that the 10X safety factor to protect infants and children should be reduced to 1X because there was no evidence of prenatal or postnatal extra sensitivity or increased susceptibility in developmental studies in rats and rabbits, and in reproduction studies in rats. Likewise, there was no quantitative or qualitative evidence of increased susceptibility to rat or rabbit fetuses identified in the guideline prenatal developmental toxicity studies for rats and rabbits. Additionally, in the two non-guideline studies that evaluated perinatal and prenatal development, there was no evidence of quantitative or qualitative increased susceptibility. In one study, when pregnant rats were treated from gestation day 17 to lactation day 20, the resulting toxicity was comparable between adults (clinical signs, decreased body weight gain and food consumption) and offspring (decreased body weight and dilation of the renal pelvis) at the same dose. In the other study, when rats were exposed to pyriproxyfen prior to and in the early stages of pregnancy, no developmental toxicity was seen at the limit dose. Lastly, in the reproduction toxicity study, offspring toxicity (decreased body weight on pups during lactation days 14 to 21) 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

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/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*. An acute dietary RfD for females 13-50 and the general U.S. population, including infants and children, was not selected because an acute oral endpoint attributable to a single-dose exposure could not be identified in the toxicology data base, including maternal toxicity in the developmental toxicity studies.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to pyriproxyfen from food will utilize 1.0% of the cPAD for the U.S. population, 2.0% of the cPAD for all infants, and 2.7% of the cPAD for children 1-6 years old. Based on the use pattern, chronic residential exposure to residues of pyriproxyfen is not expected. In addition, there is potential for chronic dietary exposure to pyriproxyfen 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 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PYRIPROXYFEN

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.35	1.0	0.40	0.006	12,000
All infants	0.35	2.0	0.40	0.006	3,200
Children (1-6 years old)	0.35	2.7	0.40	0.006	3,100
Females (13-50 years old)	0.35	0.7	0.40	0.006	10,000

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

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 and residential exposures aggregated result in aggregate MOEs of 29,000 for the U.S. population, 1,800 for all infants (<1 year old), and 1,700 for children (1-6 years old). These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic

exposure of pyriproxyfen in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO PYRIPROXYFEN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. population	29,000	100	0.40	0.006	35,000
All infants (<1 year old)	1,800	100	0.40	0.006	9,500
Children (1-6 years old)	1,700	100	0.40	0.006	9,400
Females (13-50 years old)	41,000	100	0.40	0.006	30,000

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 and residential exposures aggregated result in aggregate MOEs of 10,000 for the U.S. population, 650 for all infants (<1 year old), and 620 for children (1-6 years old). These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of pyriproxyfen in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 5:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO PYRIPROXYFEN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb)
U.S. population	10,000	100	0.40	0.006	12,000
All infants (<1 year old)	650	100	0.40	0.006	3,000
Children (1-6 years old)	620	100	0.40	0.006	3,000
Females (13-50 years old)	14,000	100	0.4	0.006	10,000

5. *Aggregate cancer risk for U.S. population*. The chronic toxicity of pyriproxyfen is based on the assessment of a combination (co-critical) of the 90–day rat feeding study and the 2–year rat feeding study. There was no evidence of carcinogenicity in a 78–week mouse feeding study and a 2–year rat feeding study. Pyriproxyfen was classified as a ''Group E'' chemical (no evidence of carcinogenicity to humans) by the Agency on June 22, 1995, based on the absence of evidence of carcinogenicity in male and female rats as well as in male and female mice.

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 residue studies on guava, lychee, and blueberry, the petitioner submitted adequate concurrent recovery data for a gas chromatography/nitrogen-phosphorous detector (GC/NPD) method (RM-33P-1-3a) used to determine residues of pyriproxyfen in/on guava, lychee, and blueberry. 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 Pesticide Analytical Method (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 guava, lychee, blueberry, and the related crops.

Adequate enforcement methodology (e.g., chromotography) is available to enforce the tolerance expression. The method may be requested from: Francis Griffith, Analytical Chemistry Branch, Environmental Science Center, Environmental Protection Agency, 701 Mapes Road, Fort George G. Mead, MD 20755–5350; telephone number (410) 305–2905; griffith.francis@epa.gov.

B. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits for residues of pyriproxyfen in/on guava, lychee, blueberry, or the related crops; therefore, international harmonization is not an issue at this time.

V. Conclusion

Therefore, the tolerances are established for residues of pyriproxyfen, 2-[1-methyl-2-(4-phenoxyphenoxy)ethoxypyridine, in or on acerola at 0.10 ppm, bushberry subgroup at 1.0 ppm, feijoa at 0.10 ppm, fruit, stone, group at 1.0 ppm, guava at 0.10 ppm, jaboticaba at 0.10 ppm, juneberry at 1.0 ppm, lingonberry at 1.0 ppm, longan at 0.30 ppm, lychee at 0.30 ppm, passionfruit at 0.10 ppm, pulasan at 0.30 ppm, rambutan at 0.30 ppm, salal at 1.0 ppm, spanish lime at 0.30 ppm, starfruit at 0.10 ppm, and wax jambu at 0.10 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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–2002–0215 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 October 28, 2002.

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

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

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

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

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

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP–2002–0215, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) 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 FFDCA section 408(d), 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 FFDCA section 408(n)(4). 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. Submission to Congress and the Comptroller General

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: August 15, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346(a) and 374.

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
Acerola	0.10
* * * * *	
Bushberry subgroup	1.0
* * * * *	
Feijoa	0.10
* * * * *	
Fruit, stone, group	1.0
* * * * *	
Guava	0.10
Jaboticaba	0.10
Juneberry	1.0
Lingonberry	1.0
Logan	0.30
Lychee	0.30
Passionfruit	0.10
* * * * *	
Pulasan	0.30
Rambutan	0.30
Salal	1.0
Spanish lime	0.30
Starfruit	0.10

Commodity	Parts per million
* * * * *	
Wax jambu	0.10

* * * * *

[FR Doc. 02–21756 Filed 8–27–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 281

[FRL–7268–9]

South Carolina; Final Approval of State Underground Storage Tank Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final determination on the State of South Carolina's application for final approval.

SUMMARY: The State of South Carolina has applied for final approval of its underground storage tank program for petroleum and hazardous substances under subtitle I of the Resource Conservation and Recovery Act (RCRA). The EPA has reviewed the State of South Carolina's application and has reached a final determination that South Carolina's underground storage tank program for petroleum and hazardous substances satisfies all of the requirements necessary to qualify for final approval. Thus, EPA is granting final approval to the State of South Carolina to operate its underground storage tank program for petroleum and hazardous substances.

EFFECTIVE DATE: Final approval for the State of South Carolina's underground storage tank program shall be effective on September 27, 2002.

FOR FURTHER INFORMATION CONTACT: Mr. John K. Mason, Chief, Underground Storage Tank Section, U.S. EPA, Region 4, Sam Nunn Federal Center, 61 Forsyth Street SW., Atlanta, Georgia 30303, phone number: (404) 562–9441.

SUPPLEMENTARY INFORMATION:

A. Background

Section 9004 of RCRA authorizes EPA to approve State underground storage tank programs to operate in the State in lieu of the Federal underground storage tank (UST) program. To qualify for final authorization, a State's program must: (1) be ''no less stringent'' than the Federal program for the seven elements set forth at RCRA section 9004(a)(1) through (7); and (2) provide for adequate enforcement of compliance with UST standards of RCRA section 9004(a). Note that RCRA sections 9005 (on information-gathering) and 9006 (on Federal enforcement) by their terms apply even in States with programs approved by EPA under RCRA section 9004. Thus, EPA retains its authority under RCRA sections 9005 and 9006, 42 U.S.C. 6991d and 6991e, and other applicable statutory and regulatory provisions to undertake inspections and enforcement actions in approved States. With respect to such an enforcement action, EPA will rely on Federal sanctions, Federal inspection authorities, and Federal procedures rather than the State authorized analogues to these provisions.

On January 7, 1999, the State of South Carolina submitted an official application to obtain final program approval to administer the underground storage tank program for petroleum and hazardous substances. On January 29, 2002, EPA published a tentative decision announcing its intent to grant South Carolina final approval. Further background on the tentative decision to grant approval appears at 67 FR 4225, January 29, 2002.

Along with the tentative determination, EPA announced the availability of the application for public comment and the date of a public hearing on the application. EPA requested advance notice for testimony and reserved the right to cancel the public hearing for lack of public interest. Since there was no public request, the public hearing was cancelled. No public comments were received regarding EPA's approval of South Carolina's underground storage tank program.

The State of South Carolina is not approved to operate the underground storage tank program in Indian Country within the State's borders.

B. Decision

I conclude that the State of South Carolina's application for final program approval meets all of the statutory and regulatory requirements established by subtitle I of RCRA. Accordingly, South Carolina is granted final approval to operate its underground storage tank program for petroleum and hazardous substances. The State of South Carolina now has responsibility for managing all regulated underground storage tank facilities within its borders and carrying out all aspects of the underground storage tank program except with regard to Indian Country, where the EPA will retain regulatory authority. South Carolina also has primary enforcement responsibility, although EPA retains the right to conduct enforcement actions under section 9006 of RCRA.

C. Administrative Requirements

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for