EPA—APPROVED IOWA REGULATIONS—Continued

Iowa citation	Title	State effective date	EPA approval date	Comments
*	*	*	*	*
Chapter 22—Controlling Pollution				
567–22.1	Permits Required for New or Existing Stationary Sources.	7/17/02	3/7/03 and FR page citation	Subrules 22.1(2), 22.1(2) ''g,'' 22.1(2) ''i'' have a state effective date of 5/23/01.
*	*	*	*	*
567–22.3	Issuing Permits	4/24/02	3/7/03 and FR page citation	Subrule 22.3(6) is not SIP approved.
*	*	*	*	*
567–22.201	Eligibility for Voluntary Operating Permits	4/24/02	3/7/03 and FR page citation	
*	*	*	*	*
567–22.300	Operating Permit by Rule for Small Sources	4/24/02	3/7/03 and FR page citation	Subrule 22.300(7) ''c'' has a state effective date of 10/14/98.
*	*	*	*	*
Chapter 25—Measurement of Emissions				
567–25.1	Testing and Sampling of New and Existing Equipment.	4/24/02	3/7/03 and FR page citation	
*	*	*	*	*

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PART 70—[AMENDED]

1. The authority citation for part 70 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

2. Appendix A to part 70 is amended by adding under ''Iowa'' paragraph (e) to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

* * * * *

Iowa

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(e) The Iowa Department of Natural Resources submitted for program approval rules ''567–22.100,'' ''567–22.101,'' ''567–22.201,'' and ''567–22.300'' on April 25, 2002. The state effective date of these rules is April 24, 2002. These revisions to the Iowa program are approved effective May 6, 2003.

* * * * *

[FR Doc. 03–5310 Filed 3–6–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0345; FRL–7289–6]

Pyriproxyfen; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of pyriproxyfen in or on Brassica, head and stem, subgroup 5A, Brassica, leafy greens, subgroup 5B, vegetable, cucurbit group 9, olives and olive oil. Valent U.S.A. Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective March 7, 2003. Objections and requests for hearings, identified by docket ID number OPP–2002–0345, must be received on or before May 6, 2003.

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

FOR FURTHER INFORMATION CONTACT: Joseph M. Tavano, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6411; e-mail address: tavano.joseph@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:

- Industry (NAICS 111), Crop production.
- Industry (NAICS 112), Animal production.
- Industry (NAICS 311), Food manufacturing
- Industry (NAICS 32532), 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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2002–0345 The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

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

II. Background and Statutory Findings

In the **Federal Register** of May 29, 2002 (67 FR 37426–37432) (FRL–7178–3), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition PP 2F6385 by Valent U.S.A. Corporation, 1333 North California Blvd., Suite 600, P.O. Box 8025, Walnut Creek, CA 94596–8025. That notice included a summary of the petition prepared by Valent U.S.A. Corporation. the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.510 be amended by establishing a tolerance for residues of the insecticide, pyriproxyfen, 2-[1-methyl-2-(4-phenoxyphenoxy)ethoxypyridine, in or on Brassica leafy vegetables (Crop Group 5); vegetable, cucurbit (Crop Group 9); olive and olive, oil at 2.5, 0.1, 1.0, and 3.0 parts per million (ppm) respectively.

Based on the residue data submitted, EPA has determined that the following changes to the requested tolerances listed in this document are necessary. A lower tolerance of 2.0 ppm is required for olive, oil. Brassica vegetables are devided into two subgroups. A tolerance of 0.70 is required for Brassica, head and stem, subgroup 5A. A tolerance of 2.0 ppm is required for Brassica, leafy greens, subgroup 5B.

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for residues of pyriproxyfen on Brassica, head and stem, subgroup 5A; Brassica, leafy greens, subgroup 5B; Vegetable, cucurbit (Group 9); olive and olive, oil at 0.70, 2.0, 0.10, 1.0, and 2.0 ppm, respectively. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

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

TABLE 1.—TOXICITY PROFILE OF PYRIPROXYFEN TECHNICAL

Guideline No./Study Type	MRID No. (year)/ Classification /Doses	Results
870.3100 90-Day oral toxicity rodents— mouse	43210504 (1990) Acceptable/ guideline 0; 200; 1,000; 5,000; or 10,000 ppm M: 0, 28.2, 149.4, 838.1, or 2,034.5 milligram/kilogram/day (mg/kg/day) F: 0, 37.9, 196.5, 963.9, or 2,345.3 mg/kg/day	NOAEL = 149.4 mg/kg/day in males (M), 196.5 mg/kg/day in females (F) LOAEL = 838.1 mg/kg/day (M), 963.9 mg/kg/day (F) 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)
870.3100 90-Day oral toxicity rodents—rat	41321716 (1989) Acceptable/ guideline 0; 400; 2,000; 5,000; or 10,000 ppm M: 0, 23.49, 117.79, 309.05, or 641.81 mg/kg/day F: 0, 27.68, 141.28, 356.30, or 783.96 mg/kg/day	NOAEL = 23.49 mg/kg/day (M), 27.68 mg/kg/day (F) LOAEL = 117.79 mg/kg/day (M), 141.28 based on increased total cholesterol and phospholipids (M),decreased red blood cell, hematocrit, and hemoglobin counts, increased relative (to body) liver weight (M), and negative trend in red blood cell volume (F)
870.3150 90-Day oral toxicity non-rodents—dog	42178307 (1988) Acceptable/ guideline 0, 100, 300, or 1,000 mg/kg/day	NOAEL = 100 mg/kg/day (M) and (F) LOAEL = 300 mg/kg/day (M) and (F) based on increased absolute and relative (to body) liver weight (both sexes), and hepatocyte enlargement (F)
870.3200 21-Day dermal toxicity—rat	43994102 (1993) Acceptable/ guideline 0, 100, 300, or 1,000 mg/kg/day	NOAEL = 1,000 mg/kg/day (M) and (F) LOAEL = not established
870.3265 28-Day inhalation toxicity—rat	42178308 (1988) Supplementary 0, 269, 482, or 1,000 mg/meter cubed (m^3) 0, 0.269, 0.482, or 1.000 mg/liter (L)	NOAEL = 0.482 mg/L (M) and (F) LOAEL = 1.000 mg/L based on salivation (both sexes), sporadic decreased body weight (M), and increased lactate dehydrogenase (M)
870.3700a Prenatal developmental—rats (non-guideline)	44985002 (1988) Acceptable/ nonguideline 0, 100, 300, 500, or 1,000 mg/kg/day	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 highest dose tested (HDT)
870.3700a Prenatal developmental—rats (non-guideline)	44985001 (1988) Acceptable/ nonguideline 0, 30, 100, 300, or 500 mg/kg/day	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.
870.3700b Prenatal developmental—rabbit	41321720, 42178311, 43215401, 43215402, 43215403 (1989) Acceptable/guideline 0, 100, 300, or 1,000 mg/kg/day	Maternal NOAEL = 100 mg/kg/day Maternal LOAEL = 300 mg/kg/day based on premature delivery/abortions, soft stools, emaciation, lusterless fur, decreased activity, and bradypnea. Developmental NOAEL = 300 mg/kg/day Developmental LOAEL = 1,000 mg/kg/day based on decreased viable litters available for evaluation
870.3700a Prenatal developmental—rat	42178312 (1988) Acceptable/ guideline 0, 100, 300, or 1,000 mg/kg/day	Maternal NOAEL = 100 mg/kg/day Maternal LOAEL = 300 mg/kg/day based on decreased body weight, body weight gain, and food consumption and increased water consumption . Developmental NOAEL = 300 mg/kg/day Developmental LOAEL = 1,000 mg/kg/day based on increased incidence of skeletal variations at gestation day 21 and unspecified visceral variations at postnatal day (PND) 56.
870.3800 Reproduction and fertility effects— rat	42178313 (1991) Acceptable/ guideline 0; 200; 1,000; or 5,000 ppm M: 0, 18, 87, or 453 mg/kg/day F: 0, 20, 96, or 498 mg/kg/day	Parental/Systemic NOAEL = 87 mg/kg/day (M), 96 mg/kg/day (F) Parental/Systemic LOAEL = 453 mg/kg/day (M), 498 mg/kg/day (F) 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 (M), 498 mg/kg/day (F) Reproductive LOAEL = not established. Offspring NOAEL = 87 mg/kg/day (M), 96 mg/kg/day (F) Offspring LOAEL = 453 mg/kg/day (M), 498 mg/kg/day (F) based on decreased body weight on lactation days 14 and 21

TABLE 1.—TOXICITY PROFILE OF PYRIPROXYFEN TECHNICAL—Continued

Guideline No./Study Type	MRID No. (year)/ Classification /Doses	Results
870.4100b Chronic toxicity—dogs	42178309 (1991) Acceptable/ guideline 0, 30, 100, 300, or 1,000 mg/kg/day	NOAEL = 100 mg/kg/day (M) and (F) LOAEL = 300 mg/kg/day (M), 300 mg/kg/day (F) based on decreased body weight gain and increased relative liver weight (both sexes) and increased cholesterol and triglycerides and decreased red cell counts and hemoglobin in males
870.4300 Chronic/Carcinogenicity—rats	42178314, 43210501, 43210502, 43210503 (1991) Acceptable/ guideline 0, 120, 600, or 3,000 ppm M: 0, 5.42, 27.31, or 138.0 mg/kg/day F: 0, 7.04, 35.1, or 182.7 mg/kg/day	NOAEL = 138 mg/kg/day (M), 35.1 mg/kg/day (F) LOAEL = not established in males, 182.7 mg/kg/day (F) based on decreases in body weight gain No evidence of carcinogenicity
870.4200 Carcinogenicity—mice	42178310 (1991) Acceptable/ guideline 0, 120, 600, or 3,000 ppm M: 0, 16.8, 84.0, or 420 mg/kg/day F: 0, 21.9, 109.5, or 547 mg/kg/day	NOAEL = 84 mg/kg/day (M), 109.5 mg/kg/day (F) LOAEL = 420 mg/kg/day (M), 547 mg/kg/day (F) based on renal lesions (M) and (F) No evidence of carcinogenicity
870.5265 Gene mutation	44503506 (1995) Acceptable/ guideline	Non-mutagenic when tested up to 5,000 micrograms (mg)/plate or cytotoxic levels, in presence and absence of activation; in *S. typhimurium* strains TA98, TA100, TA1535, and TA1537; and in *E.coli* strain WP2uvra with 2-OH-PY (metabolite of pyriproxyfen).
870.5265 Gene mutation	44503507 (1993) Acceptable/ guideline	Non-mutagenic when tested up to 5,000 mg/plate or cytotoxic levels, in presence and absence of activation; in *S. typhimurium* strains TA98, TA100, TA1535, and TA1537; and in *E.coli* strain WP2uvra with 4'—OH-PY, 5″—OH-PYR, DPH-PYR, POPA, and PYPAC (metabolites of pyriproxyfen).
870.5265 Gene mutation	44503508 (1995) Acceptable/ guideline	Non-mutagenic when tested up to 5,000 mg/plate or cytotoxic levels, in presence and absence of activation; in *S. typhimurium* strains TA98, TA100, TA1535, and TA1537; and in *E.coli* strain WP2uvra with 2,5-OH-PY (metabolite of pyriproxyfen).
870.5265 Gene mutation	42178315 (1988) Acceptable/ guideline	Non-mutagenic when tested up to 5,000 mg/plate or cytotoxic levels, in presence and absence of activation; in *S. typhimurium* strains TA98, TA100, TA1535, TA1537, and TA1538; and in *E.coli* strain WP2uvra with 2-OH-PY (pyriproxyfen technical).
870.5300 Gene mutation	42178316 (1990) Acceptable/ guideline	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	41321722 (1989) Acceptable/ guideline	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	42178317 (1988) Acceptable/ guideline	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.
870.7485Metabolism and pharmacokinetics— rat	42178318 (1988) Acceptable/ guideline	Rats were orally dosed with ^{14}C-labeled pyriproxyfen at 2 or 1,000 mg/kg and at repeated oral doses (14 daily doses) of unlabeled pyriproxyfen at 2 mg/kg followed by administration of a single oral dose of labeled pyriproxyfen at 2 mg/kg. Most radioactivity was excreted in the feces (81–92%) and urine (5–12%) over a 7 day collection period. Expired air containing CO_2 was not detected. Tissue radioactivity levels were very low (less than 0.3%) except for fat. Examination of urine, feces, liver, kidney, bile, and blood metabolites yielded numerous (> 20) identified metabolites when compared to synthetic standards. The major biotransformation reactions of pyriproxyfen include: 1. Oxidation of the 4'— position of the terminal phenyl group. 2. Oxidation at the 5'—position of pyridine. 3. Cleavage of the ether linkage and conjugation of the resultant phenols with sulfuric acid.

B. Toxicological Endpoints

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

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factors (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

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

A summary of the toxicological endpoints for pyriproxyfen used for human risk assessment is shown in Table 2 of this unit:

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 LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary females 13–50 years old 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 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 Maternal NOAEL = 100 mg/kg/day	LOC for MOE = 100	Rat developmental toxicity study Maternal 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) (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 concerns (toxicity) were seen in either rats or rabbits.
Long-Term Dermal (6 months-lifetime) (Occupational/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
Short-, and Intermediate-Term Inhalation (1–30 days and 1–6 months) (Occupational/Residential)	None	None	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 concerns (toxicity) were seen in either rats or rabbits.
Long-Term Inhalation (6 months–lifetime) (Occupational/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

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 LOC for Risk Assessment	Study and Toxicological Effects
Cancer (oral, dermal, inhalation)	Cancer classification (''Group E'')	Risk Assessment not required	No evidence of carcinogenicity

[1] UF = uncertainty factor, FQPA SF = Food Quality Protection Act safety factor, NOAEL = no-observed-adverse-effect-level, LOAEL = lowest-observed-adverse-effect-level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, LOC = level of concern, MOE = margin of exposure

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.510) for the residues of pyriproxyfen, in or on a variety of raw agricultural commodities. 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 aRfD for females 13–50 years old and the general population, including infants and children, was not selected because an acute oral endpoint attributed to a single-dose exposure could not be identified in any of the toxicology data base, including maternal toxicity in the developmental toxicity studies. Thus, the risk from acute exposure is considered negligible.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), version 1.3 analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agricluture (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:

a. A tier 1 (assumptions: Tolerance level residues and 100 percent crop treated (PCT) was conducted.

b. The established tolerances of 40 CFR 180.510 and the new tolerances established in this document were included in the analysis.

c. Anticipated residues and PCT were not used in this analysis.

d. The processing factors applied were the DEEM default values.

For chronic dietary risk, EPA's level of concern is >100% cPAD. Dietary exposure estimates for representative population subgroups are presented in Table 3 of this unit. The results of the chronic analysis indicate that the estimated chronic dietary risk associated with the existing and EPA-recommended uses of pyriproxyfen is below EPA's level of concern.

TABLE 3.—SUMMARY OF RESULTS FROM CHRONIC DEEM™ ANALYSIS OF PYRIPROXYFEN

Subgroup	Exposure (mg/kg/day)	% cPAD
U.S. Population (total)	0.003836	1.1
All Infants (< 1 year old)	0.006852	2.0
Children 1–2 years old	0.013707	3.9
Children 3–5 years old	0.010107	2.9
Children 6–12 years old	0.005969	1.7
Youth 13–19 years old	0.003389	1.0
Adults 20–49 years old	0.002658	0.8
Females 13–49 years old	0.002702	0.8
Adults 50+ years old	0.002676	0.8

iii. *Cancer.* In accordance with the Agency's 1986 Guidelines for Carcinogenic Risk Assessment, the RfD/Peer Review Committee classified pyriproxyfen as a ''Group E'' chemical-negative for carcinogenicity to humans. This classification is based on the lack of evidence of carcinogenicity in mice and rats.

iv. *Anticipated residue and PCT information.* Anticipated residues and PCT information was not used in the Agency's assessment.

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 SCI-GROW, which predicts pesticide concentrations in groundwater. 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 the aggregate risk 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 EFED input guidance. Thus, the aerobic soil half-life in the modeling assessment was 27 days.

EPA determined that the residue of concern in water is pyriproxyfen per *se*. Drinking water estimates include surface water EDWCs based on the linked PRZM/EXAMS models and the SCI-GROW groundwater 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 active ingredient (ai)/acre (A), 3 times per year (citrus and stone fruit).

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 groundwater 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: Flea and tick control (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 for pet treatments), 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, due to the lack of toxicity observed in animal testing, no residential pet owner/homeowner handler risk of concern is expected.

Toddlers could potentially be exposed to pyriproxyfen residues on treated carpets, floors, furniture, and pets. There is potential for exposure expected for the following scenarios:

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). Due to the lack of toxicity observed in animal testing, the Agency did not select any short- or intermediate-term dermal endpoints and no dermal risk of concern for these durations is expected. 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 acute dietary risk of concern is expected.

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) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether 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*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. 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 pre/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 estimated environmental 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 EPA Office of Water are used to calculate DWLOCs: 2 L/70 kg (adult male), 2 L/60 kg (adult female), and 1 L/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 groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP 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 13–49 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. No acute dietary risk is expected.

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 1.1% of the cPAD for the U.S. population, 2.0% of the cPAD for all infant,s and 3.9% of the cPAD for children 1–2 years old. Pyriproxyfen is the active ingredient in many registered residential products for flea and tick control on pets and in the home for ant and roach control for indoor and outdoor applications. Based on the use pattern, the residential assessment was performed for toddlers since they are anticipated to have the higher chronic residential exposure to residues of pyriproxyfen. The total chronic food and residential aggregate MOEs range from 850 to 13,000. As these MOEs are greater than 100, the chronic aggregate risk does not exceed EPA's level of concern. 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 and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PYRIPROXYFEN

Population Subgroup	Aggegate MOE (Food + Residential)	Target MOE	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	9,200	100	0.40	0.006	12,000
All infants	1,000	100	0.40	0.006	3,200
Children 1–2 years old	860	100	0.40	0.006	3,100
Children 3–5 years old	940	100	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 26,000 for the U.S. population, 1,800 for all infants(<1 year old), and 1,600 for children (1–2 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 and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 5 of this unit:

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

Population Subgroup	Aggregate MOE (Food + Residential)	Target MOE	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. population	26,000	100	0.40	0.006	35,000
All infants (<1 year old	1,800	100	0.40	0.006	9,400
Children (1–2 years old)	1,600	100	0.40	0.006	9,400
Females (13–49 years old)	37,000	00	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 9,200 for the U.S. population, 650 for all infants (<1 year old, and 580 for children (1–2 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 and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 6 of this unit:

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO PYRIPROXYFEN

Population Subgroup	Aggregate MOE (Food + Residential)	Target MOE	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Inter-mediate-Term DWLOC (ppb)
U.S. population	9,200	100	0.40	0.006	12,000
All infants (<1 year old)	650	100	0.40	0.006	3,000
Children (1–2 years old)	580	100	0.40	0.006	3,000
Females (13–49 years old)	13,000	100	0.40	0.006	10,000

5. *Aggregate cancer risk for U.S. population*. 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 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 cabbage, cauliflower, mustard greens, cantaloupe, cucumber, summer squash, olive, okra, and sugar apple, 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 these 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 Pesticide Analytical Method (PAM) Vol. II (DP Barcode D257337, W. Donovan, 7/1/99). HED concludes that 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 Brassica leafy vegetables, cucurbit vegetables, olive, okra, sugar apple, cherimoya, atemoya, custard apple, ilama, soursop, birba, fig, avocado, papaya, star apple, black sapote, mango, sapodilla, canistel, and mamey sapote. As tolerances for residues of pyriproxyfen in livestock commodities are not required at this time, enforcement methodology for determining residues in livestock are not required.

MRM testing data have previously been provided (PP#6F04737, DP Barcode D228556, J. Garbus, 5/6/97) for pyriproxyfen. Pyriproxyfen was recovered from fortified apple and cotton samples through protocols A, C, D, E, and F. The results have been forwarded to FDA.

Adequate enforcement methodology (example—gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Francis Griffith, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: griffith.francis@epa.gov.

B. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) for residues of pyriproxyfen in/on any of the crops involved in the proposed new uses. 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)ethoxy]pyridine], in or on Brassica, head and stem, subgroup 5A; Brassica, leafy greens, subgroup 5B; vegetable, cucurbit, group 9; olive and olive, oil at 0.70, 2.0, 0.10, 1.0, and 2.0 ppm.respectively.

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0345 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 May 6, 2003.

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

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

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

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

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

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2002–0345, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account

uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

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

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: February 24, 2003.

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 371.

2. Section 180.510 is amended by alphabetically adding commodities to the table in paragraph (a)(1) to read as follows:

§ 180.510 Pyriproxyfen; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * *	* *
Brassica, head and stem, subgroup 5A	0.70
Brassica, leafy greens, subgroup 5B	2.0
* * *	* *
Olive	1.0
Olive, oil	2.0
* * *	* *
Vegetable, cucurbit, group 9	0.10
* * *	* *

* * * * *

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