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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0109; FRL–7305–9]

Pyriproxyfen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of pyriproxyfen in or on atemoya, biriba, cherimoya, custard apple, ilama, soursop, and sugar apple at 0.20 parts per million (ppm); avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla and star apple at 1.0 ppm; okra at 0.02 ppm; fig at 0.30 ppm; and fig, dried at 1.0 ppm. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective May 14, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0109, must be received on or before July 14, 2003.

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

FOR FURTHER INFORMATION CONTACT: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–9368; e-mail address: *jamerson.hoyt@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111)
- Animal Production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

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

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0109. 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 March 7, 2003 (68 FR 11093) (FRL–7289–8), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of pesticide petitions (PP) 2E6416, 2E6425, 2E6428, and 2E6436) by IR-4, 681 US Highway #1 South, North Brunswick, NJ 08902–3390. That notice included a summary of the petitions 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 tolerances for residues of the insecticide pyriproxyfen, 2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine, in or on atemoya, biriba, cherimoya, custard apple, ilama, soursop, and sugar apple at 0.20 ppm (PP 2E6416); avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla and star apple at 1.0 ppm (PP 2E6428); okra at 0.02 ppm (PP 2E6436); fig at 0.30 ppm (PP 2E6425); and fig, dried at 1.0 ppm (2E6425).

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for tolerances for residues of pyriproxyfen on atemoya, biriba, cherimoya, custard apple, ilama, soursop, and sugar apple at 0.20 ppm (PP 2E6416); avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla and star apple at 1.0 ppm (PP 2E6428); okra at 0.02 ppm (PP 2E6436); fig at 0.30 ppm (PP 2E6425); and fig, dried at 1.0 ppm (2E6425). EPA's assessment of exposures and risks associated with establishing the tolerances 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 no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed as well as the nature of the toxic effects caused by pyriproxyfen are discussed in Unit III.A. of the **Federal Registers** of June 5, 2001 (66 FR 30065) (FRL–6782–5), August 28, 2002 (67 FR 55150) (FRL–7195–7), and March 7, 2003 (68 FR 10972) (FRL–7289–6).

B. Toxicological Endpoints

The dose at which 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 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 (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for pyriproxyfen used for human risk assessment is shown in Unit III.B. of the **Federal Register** of March 7, 2003 (68 FR 10972).

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. There are no significant livestock feed items associated this action, thus the proposed uses will not result in the transfer of 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 one day or single exposure. An acute dietary exposure analysis was not conducted since no acute doses or toxicological 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 EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID®) which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic dietary exposure assessment was performed using published and proposed tolerance levels, DEEM® default processing factors, and 100% crop treated (PCT) assumptions for all commodities. Some of the crops (atemoya, custard apple, ilama, birba, sapodilla, black and white sapote, star apple, and ugli fruit) considered in this risk assessment are not included in the present version of DEEM-FCID® due to their low consumption. In these cases, the DEEM-FCID® program underestimates the exposure to pyriproxyfen residues from these crops; however, because the consumption levels of these crops is so low (on a national basis), inclusion of these crops in a future version of DEEM-FCID® would likely make no difference in the overall predicted exposures to pyriproxyfen residues.

iii. *Cancer.* Pyriproxyfen was classified by the EPA (June, 1995) as a ''Group E'' chemical - no evidence of 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 FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of

pesticide concentrations in an index reservoir. The screening concentration in ground water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier I model) before using PRZM/EXAMS (a Tier II model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. FIRST and PRZM/EXAMS incorporate an index reservoir environment, and a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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 percent reference dose (%RfD) or percent population adjusted dose (%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 sections in Unit III.E.

EPA determined that the residue 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 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 per acre, applied 3 times per year. (The registered use for citrus). Based on the PRZM/EXAMS and SCI-GROW models the EECs of pyriproxyfen for acute exposures are estimated to be 2.15 parts per billion (ppb) for surface water and 0.006 ppb for ground water. The EECs for chronic exposures are estimated to be 0.40 ppb for surface water and 0.006 ppb for ground water.

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

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).

The risk assessment was conducted using the following residential exposure assumptions: 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 identify any short-term dermal or inhalation endpoints. Because no short-term dermal or inhalation endpoints could be identified, EPA expects no short-term dermal or inhalation risks from exposure to pyriproxyfen. There is also a potential for non-dietary oral exposures (hand-to-mouth exposures) and dermal exposure following applications around the home and on pets for flea and tick control (carpet powder and pet shampoo). Short- and intermediate-term non-dietary oral and long-term dermal exposure assessments were included for toddlers since EPA selected toxicology endpoints for these exposures and toddlers are expected to have higher exposures than adults from treated home environments and pets due to their behavior patterns. Although EPA did not select a long-term non-dietary oral endpoint for pyriproxyfen, EPA used the chronic endpoint for the chronic (long-term) aggregate risk assessment.

Toddlers could potentially be exposed to pyriproxyfen residues on treated carpets, floors, furniture, and pets as follows: (i). Hand-to-Mouth: Short-, intermediate, and long-term hand-to-mouth exposures by toddlers from treated carpets, flooring (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; efficacy of pet collars up to 395 days); (iii). Dermal: Long-term dermal exposures from treated carpets, flooring, and pets. (iv). Ingestion of granules or bait by toddlers (acute, episodic event): For the granular ingestion scenario, 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 I 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. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to pyriproxyfen and any other substances and pyriproxyfen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that pyriproxyfen has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, *see* the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common

mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of 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/post natal 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 2 non-guideline studies that evaluated perinatal and prenatal development, there was no evidence of quantitative or qualitative increased susceptibility. In 1–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 milligrams/kilogram/day (mg/kg/day) = cPAD − (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by EPAs Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

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

1. *Acute risk*. 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; therefore, acute dietary risk is not expected.

2. *Chronic aggregate risk*. Using the exposure assumptions described in this unit for chronic (long-term) exposure, EPA has concluded that exposure to pyriproxyfen from food will utilize 1.1% of the cPAD for the U.S. population, 2% of the cPAD for all infants, less than 1 year old and 3.9% of the cPAD for children 1 to 2 years old, the subpopulation at greatest exposure. Pyriproxyfen is an active ingredient in pesticide products registered for residential use. Based on the use patterns, the residential risk assessment was performed for toddlers since they are anticipated to have the higher chronic residential exposure to residues of pyriproxyfen. EPA considered background chronic-dietary exposure (food + water), long-term, residential non-dietary oral exposures (hand-to-mouth exposures by toddlers following applications around the home and on pets for flea and tick control-carpet powder and pet shampoo), and long-term dermal exposure to toddlers. The total chronic food and residential aggregate MOEs were calculated. 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 chronic exposure to exceed the Agency's level of concern, as shown in Table 1 of this unit:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) 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	9,200	100	0.4	0.006	12,000
All infants < 1 year	1,000	100	0.4	0.006	3,200
Children 1–2 years	860	100	0.4	0.006	3,100
Children 3–5 years	940	100	0.4	0.006	3,100
Females 13–49 years	13,000	100	0.4	0.006	10,000

3. *Short-term aggregate 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. EPA considered background chronic-dietary exposure (food + water) and short-term, residential non-dietary oral exposures (hand-to-mouth exposures by toddlers following applications around the home and on pets for flea and tick control-carpet powder and pet shampoo).

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 for toddlers ranging from 1,600 for children 1 to 2 years old to 1,800 for children less than 1 year 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 and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 2 of this unit:

TABLE 2.—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)	Sh ort-Term DWLOC (ppb)
All infants (<1 year)	1,800	100	0.4	0.006	9,400
Children 1–2 years	1,600	100	0.4	0.006	9,400
Children 3–5 years	1,700	100	0.4	0.006	9,400

4. *Intermediate-term aggregate 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. EPA considered background chronic-dietary exposure (food + water) and intermediate-term, residential non-dietary oral exposures (hand-to-mouth exposures by toddlers following applications around the home and on pets for flea and tick control-carpet powder and pet shampoo).

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 for toddlers ranging from 580 for children 1 to 2 years old to 650 for infants less than 1 year 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 and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 3 of this Unit:

TABLE 3.—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)	Inter-mediate-Term DWLOC (ppb)
All infants < 1 year	650	100	0.4	0.006	3,000
Children 1–2 years	580	100	0.4	0.006	2,900
Children 3–5 years	620	100	0.4	0.006	2,900

5. *Aggregate cancer risk for U.S. population.* There is no evidence of carcinogenicity to humans based on carcinogenicity studies in male and female rats and mice. The Agency concludes that pesticidal uses of

pyriproxyfen are not likely to pose a carcinogenic hazard to humans.

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

Adequate enforcement methodology (gas chromotography/nitrogen phosphorous detector method (RM-33P-1-3a)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits established for residues of pyriproxyfen in or on the subject food commodities.

V. Conclusion

Therefore, the tolerance is established for residues of pyriproxyfen, [2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine], in or on atemoya, biriba, cherimoya, custard apple, ilama, soursop, and sugar apple at 0.20 parts per million (ppm); avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla and star apple at 1.0 ppm; okra at 0.02 ppm; fig at 0.30 ppm; and fig, dried at 1.0 ppm.

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0109 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 July 14, 2003.

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

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

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

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

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

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0109, 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 104–13, 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: May 6, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

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

§ 180.510 Pyriproxyfen: tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Atemoya	0.20
Avocado	1.0
Biriba	0.20
Black sapote	1.0
* * *	* *
Canistel	1.0
Cherimoya	0.20
* * *	* *
Custard apple	0.20
* * *	* *
Fig	0.30
Fig, dried	1.0
* * *	* *
Ilama	0.20
* * *	* *
Mamey sapote	1.0
Mango	1.0
* * *	* *
Okra	0.02
* * *	* *
Papaya	1.0
* * *	* *
Sapodilla	1.0
* * *	* *
Soursop	0.20
* * *	* *
Star apple	1.0
* * *	* *
Sugar apple	0.20
* * *	* *

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