actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), or special consideration of environmental justice related issues 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 require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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 12612, entitled *Federalism* (52 FR 41685, October 30, 1987). This action 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 the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(n)(4). 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). In addition, since tolerances and exemptions that are established under FFDCA section 408(l)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

V. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: October 6, 1999.

James Jones,

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.

§ 180.368 [Amended]

2. In § 180.368, by amending paragraph (b) by changing the date for grass forage and grass hay from ''12/31/99'' to read ''12/31/01'' and by changing the date for spinach from ''5/15/00'' to read ''12/31/01''.

[FR Doc. 99–27399 Filed 10–20–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300917; FRL–6381–3]

RIN 2070–AB78

Pyriproxyfen; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of pyriproxyfen in or on citrus fruits, fruiting vegetables (except cucurbits), tree nuts, almond hulls, citrus oil and citrus pulp, dried. Valent USA Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective October 21, 1999. Objections and requests for hearings, identified by docket control number OPP–300917, must be received by EPA on or before December 20, 1999.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the ''SUPPLEMENTARY INFORMATION'' section. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300917 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joseph Tavano, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–6411; and e-mail address: tavano.joseph@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action

to a particular entity, consult the person listed in the ''FOR FURTHER INFORMATION CONTACT'' section.

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

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**--Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–300917. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of October 6, 1998 (63 FR 53656) (FRL–6033–8), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP 8F5022) for a tolerance by Valent USA Corporation, 1333 N. California Blvd., Walnut Creek, CA 94596. This notice included a summary of the petition prepared by Valent USA 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, in or on almond hulls at 2.0 parts per million (ppm) citrus fruits (crop group 10) at 0.3 ppm; fruiting vegetables (crop group 8) at 0.1 ppm; tree nuts (crop group 14) at 0.02 ppm; and in the processed commodities citrus oil at 20 ppm and dried citrus pulp at 1.5. Pyriproxyfen is a reduced risk pesticide and controls California red scale, black scale brown soft scale, citrus whitefly, citrus leafminer and citrus black fly on citrus; immature sweet potato/silverleaf whitefly on peppers and tomatoes; codling moth and navel orangeworm on walnuts and San Jose scale and peach twig borer on almonds.

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of 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), for a tolerance for residues of pyriproxyfen on almond hulls at 2.0 ppm; citrus fruits at 0.3 ppm; fruiting vegetables (except cucurbits) at 0.2 ppm; tree nuts at 0.02 ppm; and in the processed commodities citrus oil at 20 ppm and dried citrus pulp at 2.0 ppm. EPA's assessment of the dietary 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 this unit.

1. *Acute toxicity*. Acute toxicity studies with technical pyriproxyfen: Oral LD_{50} in the rat is >5,000 milligrams/kilograms (mg/kg) for males and females - Toxicity Category IV; dermal LD_{50} in the rabbit at >2, 000 mg/kg - Toxicity Category IV; inhalation LC_{50} in the rat is >1.3 mg/L (highest dose attainable) - Toxicity Category III; primary eye irritation in the rabbit (mild irritatant) - Toxicity Category III; primary dermal irritation in the rabbit (not an irritant: non-irritating to the skin under conditions of test))- Toxicity Category IV. Pyriproxyfen is not a sensitizer.

2. *Subchronic toxicity*— i. In the subchronic feeding study in rats, the no observed adversed effect level (NOAEL) was 27.68 mg/kg/day. The lowest oberved adversed effect level (LOAEL) was 141.28 mg/kg/day, based upon higher mean total cholesteral and phospholipids, decreased mean red blood cells (RBCs), hematocrit and hemoglobin counts and increased relative liver weight.

ii. In the subchronic feeding study in dogs, the NOAEL was 100 mg/kg/day and the LOAEL was 300 mg/kg/day. The effects were based on increased absolute and relative liver weight in males and hepatocellular hypertrophy in females. These findings were also observed at 1,000 mg/kg/day and may represent adaptive changes at both 300 mg/kg/day and the limit dose of 1,000 mg/kg/day.

iii. In a 21–day dermal study in rats, the NOAEL for systemic effects was >1,000 mg/kg/day (limit dose). The LOAEL for systemic effects was not established in this study. No dermal or systemic toxicity was observed at any dose tested.

3. *Chronic toxicity/carcinogenicity*—i. In a 1–year chronic feeding study in dogs, the NOAEL was 100 mg/kg/day. The LOAEL was 300 mg/kg/day based on decreased weight gain, increased absolute and relative liver weight, mild

anemia, increased cholesterol and triglycerides.

ii. In the oncogenicity study in mice, the NOAEL and LOAEL for systemic toxicity in males are 600 ppm and 3,000 ppm, respectively, based on renal lesions in males. The technical grade test material was given to male and female CD–1 mice in diet for 18 months at 0, 120, 600, or 3,000 ppm. No statistically significant increase in tumor incidence relative to controls were observed in either sex at any does up to 3,000 ppm highest dose tested (HDT).

iii. In the chronic feeding/ oncogenicity study in rats, the NOAEL (systemic) was 35.1 mg/kg/day and the LOAEL (systemic) was 182.7 mg/kg/day. The technical grade test material was administered to male and female Sprague-Dawley rats in diet for 24 months at 0, 120, 600, or 3,000 ppm. A decrease of 16.9% in body weight gain in females at 3,000 ppm (182.7 mg/kg/ day) was basis for the systemic LOAEL.

4. *Developmental toxicity* —i. In the developmental study in rabbits, the maternal NOAEL/LOAEL for maternal toxicity were 100 and 300 mg/kg/day based on premature delivery/abortions, soft stools, emaciation, decreased activity and bradypnea. The developmental NOAEL was determined to be 300 mg/kg/day and developmental LOAEL was determined to be undetermined; no dose related anomalies occurred in the four remaining litters studied at 1,000 mg/ kg/day.

ii. In the developmental study in rats, a maternal NOAEL/LOAEL were determined to be 100 mg/kg/day and 300 mg/kg/day, respectively. These findings were based on increased incidences in mortality and clinical signs at 1,000 mg/kg/day with decreased in food consumption, body weight, and body weight gain together with increases in water consumption at 300 and 1,000 mg/kg/day. The developmental NOAEL/LOAEL were 100 mg/kg/day and 300 mg/kg/day based on the increase of skeletal variations at 300 mg/kg/day and above.

5. *Reproductive toxicity*. In a 2–generation reproduction study in rats, the systemic NOAEL was 1,000 ppm (87 mg/kg/day). The LOAEL for systemic toxicity was 5,000 ppm (453 mg/kg/ day). Effects were based on decreased body weight, weight gain and food consumption in both sexes and both generations, and increased liver weights in both sexes associated with liver and kidney histopathology in males. The reproductive NOAEL was 5,000 ppm. A reproductive LOAEL was not established.

6. *Mutagenicity*. Studies on gene mutation and other genotoxic effects: In a Gene Mutation Assay (Ames Test)/ Reverse Mutation, finding were determined as negative for induction of gene mutation measured as the reversion to histine protrophy of five *S.typhimurium* strains and *E.Coli* WP2 uvra at doses from 10 to 5,000 µg/plate with and without S-9 activation. The highest does was insoluble. A Gene Mutation assay in Mammalian Cells was found to be negative for mutagencity in CHO (Chinese hamster ovary) V79 cells with and without metabolic activation up to cytotoxic doses (300 µg/milliliter (mL). In a Structural Chromosomal Aberration Assay *in vivo*, findings proved nonclastogenic in CHO cells both with and without S-9 activation up to cytotoxic doses (300 µg/mL). In other Genotoxicity Assays, an increase in unscheduled DNA synthesis was not induced both with and without activation in HeLa cells exposed up to insoluble doses ranging to 6.4 µg/mL (without activation) and 51.2 µg/mL (with activation).

7. *Metabolism*. The results of the metabolism studies are as follows: Acceptable 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 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: (i) Oxidation of the 4′ - position of the terminal phenyl group; (ii) Oxidation at the 5′ - position of pyridine; (iii) Cleavage of the ether linkage and conjugation of the resultant phenols with sulfuric acid.

8. *Neurotoxicity*. Neurotoxicity has not been observed in any of the acute, subchronic, chronic, developmental or reproductive studies performed with pyriproxyfen.

B. Toxicological Endpoints

1. *Acute toxicity*. An acute dietary dose and endpoint was not identified in the data base. The Agency concludes that there is a reasonable certainty of no harm from acute dietary exposure.

2. *Short-term and intermediate-term toxicity*. Doses and endpoints were not identified for short-term and intermediate-term dermal and inhalation exposure. The Agency concludes that there are reasonable certainties of no harm from these exposures.

3. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for pyriproxyfen, 2–[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine at 0.35 mg/kg/day. This RfD is based on a NOAEL of 35.1 mg/kg/day and an uncertainty factor (UF) of 100. The NOAEL was established from the combined chronic feeding/oncogenicity study in rats where the the LOAEL was 3,000 ppm, based on a 16.9% decrease in body weight gain in females when compared to controls.

The chronic Population Adjusted Dose (cPAD) is a modification of the chronic RfD to accommodate the FQPA Safety Factor. The cPAD is equal to the chronic RfD divided by the FQPA Safety Factor. The FQPA Safety Factor was reduced from 10x to 1x for the reasons explained below. Therefore, the cPAD is identical to the chronic RfD. Reducing 10x factor to 1x is supported by the following factors.

i. Developmental studies showed no increased sensitivity in fetuses as compared to maternal animals following *in utero* exposures in rats and rabbits.

ii. A 2–generation reproduction toxicity study in rats showed no increased sensitivity in pups as compared to adults.

iii. The toxicology data base is complete and there are no data gaps.

4. *Carcinogenicity*. Pyriproxyfen is classified as Category E: not carcinogenic in two acceptable animal studies.

C. Exposures and Risks

1. *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. In today's action, tolerances will be established for the residues of pyriproxyfen in or on the raw agricultural commodities almond hulls at 2.0 ppm citrus fruits at 0.3 ppm; fruiting vegetables (except cucurbits) at 0.2 ppm; tree nuts at 0.02 ppm; and in the processed commodities citrus oil at 20 ppm and dried citrus pulp at 2.0 ppm. Risk assessments were conducted by EPA to assess dietary exposures as follows:

i. *Acute exposure and risk*. 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. No acute dietary endpoint and dose was identified in the toxicology data base for

pyriproxyfen; therefore, the Agency concludes that there is a reasonable certainty of no harm from acute dietary exposure.

ii. *Chronic exposure and risk.* The Dietary Exposure Evaluation Model (DEEM) analysis for pyriproxyfen was performed in order to provide an estimate of the dietary exposure and associated risk resulting from the existing tolerances and the recommended tolerance levels for citrus fruits, fruiting vegetables (except cucurbits), and tree nuts. The DEEM analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–92 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity.

This chronic dietary exposure analysis from food sources was conducted using the chronic population adjusted dose (cPAD) of 0.35 mg/kg/day.

In conducting this chronic dietary risk assessment, EPA has made very conservative assumptions: 100% of all crops having pyriproxyfen tolerances will contain pyriproxyfen residues and those residues will be at the level of the established (or recommended) tolerance. Moreover, rather than making use of experimentally-determined processing factors, only DEEM default processing factors were used. This results in an overestimate of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment.

DEEM analysis including all the appropriate pyriproxyfen tolerances results in Total Exposures that are equivalent to the following percentages of the cPAD:

Subgroups	Total Exposure (mg/kg/day)	% cPAD
U.S. Population (48 contiguous states)	0.001411	0.4
Children (1–6 years)	0.003876	1.1
Non-hispanic other than black or white	0.001852	0.5
Hispanics	0.001592	0.5
Females (13+/nursing)	0.001660	0.5

The subgroups listed above are: (1) The U.S. population (48 contiguous states); (2) those for infants and children; and (3) the other subgroups for which the percentage of the cPAD occupied is greater than that occupied by the subgroup U.S. population (48 contiguous states).

2. *From drinking water* —i. *Acute exposure and risk.* Because no acute dietary endpoint was determined, the Agency concludes that there is a reasonable certainty of no harm from acute exposure from drinking water.

ii. *Chronic exposure and risk.* Following EPA's Interim Guidance for Conducting Drinking Water Exposure and Risk Assessments issued on October 15, 1998, the PRZM/EXAMS model and the SCI-GROW model were run to produce estimates of pyriproxyfen concentrations in surface and ground water, respectively. The primary use of these models is to provide a coarse screen for sorting out pesticides for which EPA has a high degree of confidence that the true levels of the pesticide in drinking water will be less than the human health drinking water levels of comparison (DWLOCs). A human health DWLOC is the concentration of a pesticide in drinking water which would result in unacceptable aggregate risk, after having already factored in all food exposures and other non-occupational exposures for which EPA has reliable data.

$DWLOC_{chronic}$ = chronic water exposure (mg/kg/day) x (body weight) / consumption (L) x 10^{-3} mg/µg where chronic water exposure (mg/kg/day) = [cPAD - (chronic food + residential exposure) (mg/kg/day)]

The $DWLOC_{chronic}$ is the concentration in drinking water as part of the aggregate chronic exposure that results in a negligible cancer risk. The Agency's default body weights and consumption values used to calculate DWLOCs are as follows: 70 kg/2L (adult male), 60 kg/2L (adult female), and 10 kg/1L (child).

The results are summarized in the following table:

DWLOC Values Calculated for Pyriproxyfen Based on a Chronic Scenario

Population Subgroup	Chronic Scenario[1]			
	cPAD mg/kg/day	DWLOC µg/L	SCI-GROW EEC in µg/L	PRZM-EXAMS[2] EEC in µg/L
U.S. Population	0.35	12,000	0.006	0.11
Children (1–6 yrs)	0.35	3,500	0.006	0.11

[1] DEEM TMRCs in mg/kg/day: U.S. Population = 0.001411, Children (1–6 years) = 0.003876. The average potential dose rate from residential use of pet collars is 0.00058 and 0.000081 mg/kg/day for children and U.S. population, respectively (see Table 4.1).
[2] Using the 1–year average EEC for pyriproxyfen in surface water calculated using the citrus fruit application rate.

For chronic (non-cancer) exposure to pyriproxyfen in surface and ground water, the drinking water levels of concern are 12,000 µg/L for U.S. Population and 3,500 µg/L for children (1–6 years). Estimated average concentrations of pyriproxyfen in surface and ground water are 0.11 parts per billion (ppb) and 0.006 ppb, respectively. The estimated average concentrations of pyriproxyfen in surface and ground water are less than EPA's level of concern for pyriproxyfen in drinking water as a contribution to chronic aggregate exposure. Therefore, taking into account present uses and uses proposed in this action, EPA concludes with reasonable certainty that residues of pyriproxyfen 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.

3. *From non-dietary exposure.* Pyriproxyfen is currently registered for use on residential non-food sites. Pyriproxyfen is the active ingredient in many registered residential (indoor, non-food) products for flea and tick control. Formulations include foggers, aerosol sprays, emulsifiable concentrates, and impregnated materials (pet collars).

i. *Acute exposure and risk.* Because no acute toxicological endpoint was determined, the Agency concludes that there is a reasonable certainty of no harm from acute exposure.

ii. *Chronic exposure and risk.* Chronic residential post-application exposure and risk assessments were conducted to estimate the potential risks from pet collar uses.

The risk assessment was conducted using the following assumptions: application rate of 0.58 mg ai/day (product label), average body weight for a 1 – 6 year old child of 10 kg, the active ingredient dissipates uniformly through 365 days (the label instruct to change collar once a year), 1% of the active ingredient is available for dermal and inhalation exposure per day (assumption from Draft EPA Standard Operating Procedures (SOPs) for Residential Exposure Assessments, December 18, 1998). The assessment also assumes an absorption rate of 100%. This is a conservative assumption since the dermal absorption was estimated to be 10%.

Residential Exposure and Risk Assessment Exposure & Risk Assessment for Homeowner Use of Pet Collars

Population Subgroup	Application Rate[1] mg/day	Average Potential Dose Rate[2] (mg/kg/day)	Chronic Term MOE[3]
Children	0.58	0.00058	61,000
Adults	0.58	0.000081	430,000

[1] Product label: Reg. No. 2382–149 (0.5% pyriproxyfen, ovisterilant pet collar). Application rate = 42 gm collar x 0.5% a.i./collar x 1,000 mg/1 gm x 1/365 days. Collar to be replaced once a year.

[2] Potential Dose Rate (PDR) = Application rate x fraction of ai available for exposure (1%) x absorption rate (100%) x 1/(10 or 71.8 kg bw for children or adults, respectively).

[3] Dermal and Inhalation NOAEL = 35.1 mg/kg/day; MOE = NOAEL/Exposure; Adequate MOE = 100.

The estimated chronic term MOE was 61,000 for children, and 430,000 for adults. The risk estimates indicate that potential risks from pet collar uses do not exceed the Agency's level of concern.

iii. *Short- and intermediate-term exposure and risk*. Toxicological endpoints of concern were not identified for short- and intermediate-term exposures.The Agency concludes that there is a reasonable certainty of no harm from short and intermediate exposure.

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

EPA does not have, at this time, available data to determine whether pyriproxyfen has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, pyriproxyfen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that pyriproxyfen has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk*. An acute dietary dose and endpoint was not identified. Thus the risk from acute aggregate exposure is considered to be negligible.

2. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has calculated that the maximum percentage of the cPAD that will be utilized by dietary (food) exposure to residues of pyriproxyfen is 1.1% for children (1 – 6 years). Chronic residential exposure to pyriproxyfen from pet collars is estimated to increase total pyriproxyfen exposure of infants and children only marginally. Despite the potential for dietary exposure to pyriproxyfen in drinking water, EPA does not expect the aggregate dietary exposure to exceed 100% of the cPAD.

EPA bases this determination on a comparison of estimated concentrations of pyriproxyfen in surface and ground water to levels of concern for pyriproxyfen in drinking water. The estimates of pyriproxyfen in surface and ground water are derived from water quality models that use conservative assumptions regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with the pesticide's uses, levels of concern in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impact of pyriproxyfen in food and drinking water as part of the aggregate chronic risk assessment process.

Taking into account the completeness and reliability of the toxicity data and this conservative exposure assessment, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from chronic aggregate exposure to pyriproxyfen residues.

3. *Short- and intermediate-term risk*. Due to the lack of significant toxicological effects observed, the risk from short and intermediate exposure is considered to be negligible.

Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

4. *Aggregate cancer risk for U.S. population*. Pyriproxyfen is classified as Category E: not carcinogenic in two acceptable animal studies.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*—i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of pyriproxyfen, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not

raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. In the rat developmental study, the developmental NOAEL was 100 mg/kg/day and the maternal NOAEL was 100 mg/kg/day. Therefore, there was no prenatal developmental toxicity in the presence of maternal toxicity. Similarly in rabbits, the prenatal developmental NOAEL was 300 mg/kg/day and the maternal NOAEL was 300 mg/kg/day. Therefore, prenatally exposed fetuses were not more sensitive to the effects of pyriproxyfen than maternal animals.

iii. *Reproductive toxicity study*. In the rat reproduction study, the parental NOAEL of 1,000 ppm was identical to the pup NOAEL of 1,000 ppm (and decreased body weight was seen in both pup and parental animals). This finding demonstrates that there are no extra sensitivities with respect to prenatal and postnatal toxicity between adult and infant animals.

iv. *Prenatal and postnatal sensitivity*. The oral perinatal and prenatal data demonstrated no indication of increased sensitivity of rats or rabbits to *in utero* and postnatal exposure to pyriproxyfen.

v. *Conclusion*. The 10x factor for infants and children (as required by FQPA) was reduced to 1x, since there was no special sensitivity for infants and children and the data base are complete. For chronic dietary risk assessment, a UF of 100 is adequate for protection from exposure to pyriproxyfen.

2. *Acute risk*. An acute dietary dose and endpoint was not identified. Thus the risk from acute aggregate exposure is considered to be negligible.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to pyriproxyfen from food will utilize 1.1% of the cPAD for infants and children. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to pyriproxyfen in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

4. *Short- or intermediate-term risk*. Short-term and intermediate-term dermal and inhalation risks are judged to be negligible due to the lack of significant toxicological effects observed.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to residues.

IV. Other Considerations

A. Metabolism in Plants and Animals

The nature of the residue in plants is understood. Acceptable metabolism studies using ^{14}C-labeled pyriproxyfen (phenyl and pyridyl rings) have been performed in/on apples, cotton and tomatoes. Metabolism of pyriproxyfen in apples proceeds through hydroxylation and cleavage of the phenoxy ether linkage. Primary metabolites formed are further metabolized to more polar products by oxidation or conjugation reactions. Similar metabolic pathways were observed for the metabolism of pyriproxyfen in cotton and tomatoes.

Accordingly, EPA has determined that there are no pyriproxyfen metabolites of toxicological or regulatory concern in plants. Thus, tolerances based on the parent only are appropriate.

1. *Poultry*. There are no poultry feed items associated with citrus, fruiting vegetables, or tree nuts. Therefore, no secondary residues are expected to occur in poultry eggs, fat, meat, and meat byproducts as a result of the proposed uses on citrus, fruiting vegetables, and tree nuts.

2. *Ruminants*. Valent submitted data from studies investigating the metabolism of (Ph-^{14}C uniformly ring labeled) and (Py-^{14}C in pyridine ring 2 and 6 positions) pyriproxyfen in lactating goats. Two goats were fed 10 ppm of Ph-^{14}C pyriproxyfen daily for 5 days, while two other goats were fed 10 ppm of Py-^{14}C pyriproxyfen daily for 5 days, with 1 control goat. Urine, feces and milk samples were obtained twice daily. After sacrifice at 6 hours after last dose, samples of blood, heart, kidneys, liver, loin muscle, rear leg muscle, omental and perirenal fat, gastrointestinal tract and contents were collected for ^{14}C analysis.

The majority (62–76%) of the ^{14}C-pyriproxyfen ingested by goats was excreted in urine and feces, with residue levels in feces being higher than in urine. Approximately 25 to 32% of the administered ^{14}C-pyriproxyfen was found in goat tissues, with the large majority located in the gastrointestinal tract. These studies show that metabolism of phenyl-^{14}C pyriproxyfen in goats proceeds through hydroxylation of the phenoxyphenyl and pyridyl rings, sulfation of the 4′- OH phenoxyphenyl moiety, and cleavage of the ether linkage. Metabolism of pyridyl-^{14}C pyriproxyfen in goats proceeds through hydroxylation of the phenoxyphenyl and pyridyl rings, sulfation of the 4′-OH phenoxyphenyl moiety, cleavage of the ether linkage and oxidation of the side chain. EPA concludes that the nature of the residue in ruminants is adequately understood.

EPA determined that the residues of concern in animals are pyriproxyfen and the free and sulfate forms of 4′-OH-PYR.

B. Analytical Enforcement Methodology

Residue analytical method RM-33P-2 (cotton) underwent validation in EPA laboratories and is suitable to gather residue data and to enforce tolerances.

For data collection and tolerance enforcement in fruits, Valent has proposed use of Method RM-33P-1-3, ''Determination of Pyriproxyfen and 4′-OH-Pyriproxyfen Residues in Apples, Pear, and Citrus Fruit.'' This method was successfully validated by an independent laboratory on the first try. The mean percent pyriproxyfen recoveries were 79.4 ± 1.6% and 84.9 ± 4.7% on apples and oranges, respectively. This method differs significantly from the method used to analyze cotton seed. Accordingly, method RM-33P-1-3 underwent validation in EPA laboratories and is suitable to gather residue data and to enforce tolerances. As described previously, this method also underwent successful radiovalidation using apple pomace samples. Thus, Valent has adequately demonstrated the extraction efficiency of this analytical method.

For data collection and tolerance enforcement in nutmeats, Valent has proposed use of Method RM-33N-2. This method is largely similar to Method RM-33P-1-3; thus, no independent laboratory validation was conducted for this method. However, method RM-33N-2 underwent validation in EPA laboratories and is suitable to gather residue data and to enforce tolerances. Method RM-33H was also validated in EPA laboratories and found suitable to gather residue data and enforce tolerances in almond hulls.

For data collection and tolerance enforcement in fruiting vegetables, Valent has proposed use of Method RM-33P-9. This method is largely similar to Method RM-33P-1-3; thus, no independent laboratory validation was conducted for this method. However, method RM-33P-9 underwent validation in EPA laboratories and is suitable to gather residue data and to enforce tolerances.

Valent submitted data from a study performed by Corning Hazleton Inc. describing the testing of pyriproxyfen through the Food and Drug Administration (FDA) Multiresidue

Methods Protocols A, C, D, E, and F found in the Pesticide Analytical Manual Volume I (PAM I), Appendix II. This study showed that pyriproxyfen was recovered from fortified apple and cotton samples through protocols A, C, D, E, and F. The metabolite PYPAC was tested with protocols A, B, C, and D. The multiresidue methods will serve as confirmatory methods for residues of pyriproxyfen. The multiresidue recovery data were sent to the FDA for inclusion in PAM I.

These methods may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

C. Magnitude of Residues

The submitted field trial data on citrus fruits are adequate. Geographic representation of field trials on grapefruit, lemons, and oranges conformed to OPPTS Series 860 guidelines and an adequate number of samples were analyzed. Residues of pyriproxyfen were <0.01–0.24 ppm in/on 52 samples of oranges, lemons, and grapefruits treated at 1x. The available data support the proposed tolerance of 0.3 ppm for residues of pyriproxyfen in/on citrus fruit.

The submitted field trial data on fruiting vegetables are adequate. Geographic representation of field trials on peppers and tomatoes conformed to OPPTS Series 860 guidelines and an adequate number of samples was analyzed. An adequate variety of commercially important peppers and tomatoes were included in the study. Residues of pyriproxyfen were <0.01–0.06 ppm in/on 46 samples of tomato and peppers treated at 1x; one sample bore pyriproxyfen residues at 0.105 ppm. The available data support a tolerance level of 0.20 ppm for residues of pyriproxyfen in/on fruiting vegetables.

Valent provided data from a total of 10 field trials in support of the tree nut group tolerance, 6 on almonds submitted with this petition, and 4 on walnuts that were previously reviewed. Valent requested that these data be used in lieu of the required 5 almond and 5 pecan field trials required for a tree nut group tolerance.

Due to the low toxicity of pyriproxyfen (no acute dietary, cancer, or short- or intermediate-term dermal or inhalation endpoints were identified), relatively high chronic RfD (0.35 mg/kg/day), removal of the FQPA safety factor, its low use rates, and the rapid incorporation of pyriproxyfen metabolites into the general carbon pool after metabolism, EPA is willing to agree to this modified data set for pyriproxyfen only. The Agency emphasizes that the general non-systemic nature of pyriproxyfen combined with the specific almond and walnut data showing that pyriproxyfen residues do not readily translocate from the nut shell into the nutmeat provide some confidence that finite pyriproxyfen residues should not be found in pecan nutmeat since almond shells are generally considered more porous than pecan shells.

The available data support the proposed tolerance of 2.0 ppm for residues of pyriproxyfen in/on almond hulls, and the proposed tolerance of 0.02 ppm for residues of pyriproxyfen in the tree nut crop group.

In conjunction with the residue study on oranges, Valent submitted data depicting residues of pyriproxyfen and 4′-OH-PYR in orange commodities processed from oranges bearing measurable residues.

The submitted orange processing study is adequate and indicates that residues of pyriproxyfen do not concentrate in juice, but concentrate by 74.6x in citrus oil and 6.4x in dried pulp. Based upon these concentration factors and the HAFT residues in/on oranges of 0.22 ppm, the proposed tolerances for pyriproxyfen residues in citrus oil and in dried pulp were 20.0 and 1.5 ppm, respectively. The citrus oil tolerance is appropriate; however, adverse effects disclosure (FIFRA section 6(a)(2)) data from California indicates that a citrus dried pulp tolerance of 2.0 ppm is needed.

Valent submitted data depicting the potential for concentration of pyriproxyfen residues in the processed commodities of tomatoes. This tomato processing study is adequate. Pyriproxyfen residues were 0.04 ppm in whole tomatoes, 0.02 ppm in paste, and <0.01 ppm in puree. As there was no concentration, separate tolerances for tomato paste and puree are not required.

There are no processed commodities associated with tree nuts and therefore no tolerances for processed commodities are required.

An adequate cattle feeding study has been previously reviewed and EPA concluded that tolerances would not be required for residues of pyriproxyfen in animal commodities provided that no additional uses on livestock feed items are proposed. The maximum theoretical dietary burden (MTDB) for beef and dairy cattle was calculated at 1.69 and 1.29 ppm, respectively, using estimated tolerances for almond hulls (2.0 ppm), apple wet pomace (0.8 ppm), dried citrus pulp (1.0 ppm), cottonseed (0.05 ppm) and cotton gin byproducts (2.0 ppm).

Based on the data submitted with the current petition, the calculated MTDB (Table 3.2) for beef and dairy cattle has increased slightly to 1.91 and 1.51 ppm, respectively, based on a more appropriate tolerance of 2.0 ppm for pyriproxyfen residues in dried citrus pulp. This adjustment does not significantly affect the maximum expected dietary burden of pyriproxyfen residues for livestock.

There are no poultry feed items associated with this petition. Therefore, no additional secondary residues are expected to occur in poultry eggs, fat, meat, and meat byproducts as a result of the proposed uses. In conjunction with the petition for use on cotton, EPA concluded that secondary residues in poultry and eggs are unlikely in light of the poultry metabolism study results.

Maximum Theoretical Dietary Burdens for Beef and Dairy Cattle.

Feed Item	Tolerance (ppm)	% Dry Matter[1]	Beef Cattle		Dairy Cattle	
			% of Diet	Burden, ppm	% of Diet	Burden, ppm
Apple pomace, wet	0.8[2]	40	40	0.80	20	0.40
Cotton gin byproducts	2.0[3]	90	20	0.44	20	0.44
Citrus, pulp	2.0	91	20	0.44	20	0.44
Almond hulls	2.0	90	10	0.22	10	0.22

Maximum Theoretical Dietary Burdens for Beef and Dairy Cattle.—Continued

Feed Item	Tolerance (ppm)	% Dry Matter[1]	Beef Cattle		Dairy Cattle	
			% of Diet	Burden, ppm	% of Diet	Burden, ppm
Cotton seed	0.05[3]	88	10	0.01	25	0.01
TOTAL			100	1.91	95	1.51

[1]From Residue Chemistry Test Guidelines (OPPTS 860.1000, Table 1).
[2]Based on apple residue data.
[3]Based on cotton residue data.

Typically, tolerances are required on all animal commodities having detectable residue levels at a 10x dosing rate or below. For the computed MTDB of 1.69 ppm in beef cattle, this would include the 3 and 9 ppm dosing levels. The only commodity having detectable pyriproxyfen residues at these levels was fat: 0.01 – 0.03 ppm. Since the MTDB calculation is based on a nutritionally unbalanced diet and includes contributions from some animal feed items that are used only regionally, EPA will not require the establishment of pyriproxyfen tolerances in fat at this time. However, should future new uses include additional animal feed items, tolerances on animal commodities will be needed.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican tolerances for pyriproxyfen residues in/on citrus fruits, fruiting vegetables, or the tree nut crop groups. Therefore, international harmonization is not an issue at this time.

E. Rotational Crop Restrictions

The Agency has determined that rotational crop studies are not required for uses of pesticides on the citrus fruits or tree nut crop groups. An adequate confined rotational crop study was conducted in support of the cotton tolerance previously issued. Based on a 30–day plantback interval and a treatment rate of 0.18 lb ai/A, no pyriproxyfen residues above 0.01 ppm were found in any of the following crop matrices: lettuce leaf; radish tops and roots; and wheat grain, forage, straw and chaff. Accordingly, EPA concludes that a 30–day plantback interval is needed for fruiting vegetables when treated with pyriproxyfen as directed.

V. Conclusion

Therefore, tolerances are established for residues of pyriproxyfen in citrus fruits, fruiting vegetables (except cucurbits), tree nuts, almond hulls, citrus oil and dried citrus pulp at 0.30, 0.20, 0.02, 2.0, 20, 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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–300917 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 December 20, 1999.

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 (1900), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

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, 401 M St., SW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources

and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A. of this preamble, you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. of this preamble. Mail your copies, identified by docket number OPP–300917, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. of this preamble. 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 5.1/6.1 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Regulatory Assessment Requirements

This final rule establishes tolerances 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). 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 prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), or special consideration of environmental justice related issues 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 require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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 12612, entitled *Federalism* (52 FR 41685, October 30, 1987). This action 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 the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(b)(4). 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). In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: September 23, 1999.

Peter Caulkins,

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), (346a) and 371.

2. In § 180.510, by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.510 Pyriproxyfen; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
Almond hulls	2.0
* * * *	*
Citrus fruits	0.3
Citrus oil	20
Citrus pulp, dried	2.0
* * * *	*
Fruiting vegetables (except cucurbits).	0.2
* * * *	*
Tree nuts	0.02
* * * *	*

* * * * *

[FR Doc. 99–27398 Filed 10–20–99; 8:45 am]

BILLING CODE 6560–50–F