proposal would expand the permissible attachments and enclosures beyond those contemplated in the Domestic Mail Classification Schedule (DMCS), and would be beyond the authority of the Postal Service to adopt. The Postal Service respectfully disagrees. Under DMCS 544.2, Bound Printed Matter may contain attachments and enclosures ''as specified by the Postal Service.'' The comment appears to suggest that this discretion is limited by the additional phrase ''and as described in subsections a and e of section 523.1,'' which concerns order forms with books and sound recordings. Under the reading apparently favored by the commenter, the permissible attachments and enclosures under DMCS 544.2 would be limited to these order forms in accordance with standards prescribed by the Postal Service. In contrast, the Postal Service believes that the two parts of section 544.2 should be read independently. That is, the permissible attachments and enclosures include the order forms described in 523.1, and, in addition to that, any other attachment and enclosure specified by the Postal Service. Nevertheless, the Postal Service agrees with the commenter that the permissible attachments and enclosures should not be without limits. Indeed, as explained above, the Postal Service believes that the amount of nonprint attachments and enclosures should be relatively small in comparison to the qualifying Bound Printed Matter, and rejected requests that the ratio be increased beyond the standard proposed.

After full consideration of the comments received and for the reasons discussed above, the Postal Service adopts, without revisions, the proposed changes in the Domestic Mail Manual, which is incorporated by reference in the Code of Federal Regulations (see 39 CFR part 111).

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

PART 111—[AMENDED]

1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 3001–3011, 3201–3219, 3403–3406, 3621, 3626, 5001.

2. Revise Domestic Mail Manual E712.1.2, as follows:

Domestic Mail Manual

* * * * *

E ELIGIBILITY

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E712 Bound Printed Matter

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1.0 BASIC STANDARDS

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1.2 Enclosures and Attachments

(Revise 1.2 to add new standards for attachments and enclosures as follows:)

In addition to the basic standards in E710, BPM may have the following attachments and enclosures:

a. Any printed matter mailable as Standard Mail.

b. Nonprint attachments and enclosures. The combined weight of all nonprint attachments and enclosures in the mailpiece must be less than or equal to 25 percent of the weight of the Bound Printed Matter in the mailpiece. The individual cost of each nonprint attachment or enclosure must be less than or equal to the cost of a ''low cost'' item as defined in E670.5.11. In addition, the combined cost of all nonprint attachments and enclosures must not exceed two times the cost of a ''low cost'' item as defined in E670.5.11.

* * * * *

This change will be published in a future issue of the Domestic Mail Manual. An appropriate amendment to 39 CFR 111.3 to reflect these changes will be published.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 01–13973 Filed 6–4–01; 8:45 am]

BILLING CODE 7710–12–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301131; FRL–6782–5]

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 pistachio. The Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective June 5, 2001. Objections and requests for hearings, identified by docket control number OPP–301131, must be received by EPA on or before August 6, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI.. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301131 in the subject line on the first page of your response.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up

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

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301131. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of April 4, 2001 (66 FR 17883) (FRL–6772–4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP 0E6081) for tolerance by IR-4, Technology Center of New Jersey, Rutgers, The State University of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. This notice included a summary of the petition prepared by Valent U.S.A. Corporation, 1333 North California Blvd., P.O. Box 8025, Walnut Creek, CA 94596–8025, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.510 be amended by establishing a tolerance for residues of the insecticide pyriproxyfen, 2-[1-methyl-2-(4-phenoxyphenoxy)ethoxypyridine, in or on pistachio at 0.02 part per million (ppm).

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of 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 pistachio at 0.2 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

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

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	Subchronic feeding in rats (13 weeks)	NOAEL = 23.49 mg/kg/day in males 27.68 mg/kg/day in females LOAEL = 117.79 milligram/kilogram/day (mg/kg/day) in males and 141.28 mg/kg/day in females based on higher mean total cholesterol and phospholipids; decreased mean red blood cells, hematocrit and hemoglobin counts and increased liver weight.
870.3150	Subchronic oral toxicity in dogs (13 weeks)	NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day 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.
870.3200	21-Day dermal toxicity (rat)	NOAEL = >1,000 mg/kg/day There was no dermal or systemic toxicity at the 1,000 mg/kg/day dose, highest dose tested (HDT).

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

Guideline No.	Study Type	Results
870.3700a	Prenatal developmental (rat)	Maternal NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day based on increased incidences in mortality and clinical signs at 1,000 mg/kg/day with decreases in food consumption, body weight, and body weight gain together with increases in water consumption at 300 and 1,000 mg/kg/day. Developmental NOAEL = 300 mg/kg/day LOAEL = 1,000 mg/kg/day based on increased incidences of skeletal variations and unspecified visceral variations at 1,000 mg/kg/day.
870.3700b	Prenatal developmental (rabbit)	Maternal NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day based on based on premature delivery/abortions, soft stools, emaciation, decreased activity and bradypnea. Developmental NOAEL = 300 mg/kg/day LOAEL = 1,000 mg/kg/day. There were no effects observed in the 4 litters examined.
870.3800	Reproduction and fertility effects (rat)	Parental/systemic NOAEL = 76 mg/kg/day in males and 87 mg/kg/day in females LOAEL = 386 mg/kg/day and males 442mg/kg/day in females based on decreased body weight, weight gain and food consumption in both sexes and both generations. Increased liver weight in both sexes of the F_1 generation and liver and kidney histopathology in F_1 males. Reproductive NOAEL = 386 mg/kg/day in males and 442 mg/kg/day in females (highest dose tested). Offspring NOAEL = 97 mg/kg/day in males and 105 mg/kg/day in females LOAEL = 519 mg/kg/day in males and 554 mg/kg/day in females based on decreased pup body weight on lactation.
870.3800	Perinatal and postnatal study of pyriproxyfen orally administered to rats	Maternal NOAEL: 100 mg/kg/day Maternal LOAEL: 300 mg/kg/day based on increased clinical signs, decreased body weight gains, and decreased food consumption Pup NOAEL: 100 mg/kg/day Pup LOAEL: 300 mg/kg/day based on decreased body weight and increased incidence of dilation of the renal pelvis. At 500 mg/kg/day, there was an increase in pup mortality during lactation Pup Reproductive, Developmental, and Learning NOAEL: 500 mg/kg/day LOAEL: ≥500 mg/kg/day
870.3800	Non-guideline study of rats orally exposed prior to and in the early stages of pregnancy	Parental NOAEL = 100 mg/kg/day Parental LOAEL = 300 mg/kg/day based on increased clinical signs, decreased body weight gains, and increased water consumption in both sexes, and increased food consumption, changes in organ weights, and gross pathological findings in the males only. Developmental NOAEL = 1,000 mg/kg/day Developmental LOAEL = 1,000 mg/kg/day
870.4300	Chronic toxicity/oncogenicity (rat)	NOAEL = 35.1 mg/kg/day (females) LOAEL = 182.7 mg/kg/day (females) based on decrease in body weight gain in females at 182.70 mg/kg/day. There was no evidence of carcinogenic response.
870.4100	1-Year chronic feeding (dog)	NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day based on decreased weight gain, increased absolute and relative liver weight, mild anemia, increased cholesterol and triglycerides in both sexes and slight anemia in males.
870.4200	Carcinogenicity mice	NOAEL = 84 mg/kg/day in males and 109 mg/kg/day in females LOAEL = 320 mg/kg/day in males and 547 mg/kg/day in females based on renal lesions in both sexes. No statistically significant increase in tumor incidence relative to controls were observed in either sex at any dose up to the highest dose tested.
870.5100	Gene Mutation Assay (Ames Test) Reverse Mutation	Negative for induction of gene mutation measured as the reversion to histidine protrophy of 5 *S. typhimurium* strains and *E. coli* WP2 uvra at doses from 10 to 5,000 μg/plated with and withour S-9 activation.
870.5300	Gene Mutation	Negative for induction of gene mutation in Chinese hamster V79 cells with and without metabolic activation up to cytotoxic doses.

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

Guideline No.	Study Type	Results
870.5380	Structural ChromosomalAbberation *In vivo*	Nonclastogenic in Chinese hamster ovary cells both with and without S-9 activation up to cytotoxic doses.
870.5550	Unscheduled DNA Synthesis	Did not induce an increase in unscheduled DNA synthesis 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.
870.7485	Metabolism	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: 1. Oxidation of the 4' - position of the terminal phenyl group; 2. Oxidation at the 5' - position of pyridine; 3. Cleavage of the ether linkage and conjugation of the resultant phenols with sulfuric acid.
870.7600	Dermal penetration	

B. Toxicological Endpoints

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

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

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for pyriproxyfen used for human risk assessment is shown in the following Table 2:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary all populations	Not applicable	Not applicable	No effects that could be attributed to a single exposure were observed in oral toxicity studies.
Chronic dietary all populations	NOAEL= 35.1 mg/kg/day UF = 100 Chronic RfD = 0.35 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD ÷FQPA SF =0.35 mg/kg/day	2-Year chronic feeding study in rats LOAEL = 182.7 mg/kg/day based on a decrease in body weight gains in females.

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Short-term dermal and inhalation (1 to 7 days) (residential)	Not applicable Absorption rate = not more than 10%	Not applicable	21-Day dermal toxicity study lack of dermal or systemic toxicity at the limit-dose of 1,000 mg/kg/day.
Intermediate-term dermal and inhalation (1 week to several months) (residential)	Not applicable Absorption rate = not more than 10%	Not applicable	21-Day dermal toxicity study Lack of dermal or systemic toxicity at the limit-dose of 1,000 mg/kg/day.
Long-term dermal and inhalation (several months to lifetime) (residential)	35.1 mg/kg/day	LOC for MOE = 100 (residential)	Chronic toxicity/carcinogenicity in rats LOAEL = 182.7 mg/kg/day based on decreased weight gain in female rats.
Cancer (oral, dermal, inhalation)	''Group E'' human carcinogen	Not applicable	There is no evidence of carcinogenic potential.

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.510) for the combined residues of pyriproxyfen, in or on a variety of raw agricultural commodities. Permanent tolerances are established under 40 CFR 180.510(a) for residues of pyriproxyfen in/on the following commodities: pome fruits (crop group 11) (0.2 ppm), citrus fruits (crop group 10) (0.3 ppm), fruiting vegetables (except cucurbits) (crop group 8) (0.2 ppm), tree nuts (crop group 14) (0.02 ppm), cotton seed (0.05 ppm), cotton gin byproducts (2.0 ppm), almond hulls (2.0 ppm), citrus oil (20 ppm), and citrus pulp, dried (2.0 ppm). Tolerances are also proposed by McLaughlin Gormley King Company for residues of pyriproxyfen in/on all food commodities at 0.10 ppm from use of the pesticide in food handling establishments. Risk assessments were conducted by EPA to assess dietary exposures from pyriproxyfen in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. An acute dose and endpoint were not selected for any population subgroup because no effects that could be attributed to a single exposure were observed in oral toxicity studies. Therefore, an acute exposure assessment was not conducted.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992–nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic dietary exposure analysis for pyriproxyfen assumed tolerance level residues and 100% crop treated for all commodities with established or proposed tolerances.

iii. *Cancer.* A cancer dietary exposure assessment was not performed since there was no evidence of carcinogenicity in studies conducted with rats and mice.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for pyriproxyfen in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of pyriproxyfen.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentrations in Ground Water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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

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

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of pyriproxyfen for acute exposures are estimated to be 0.46 parts per billion (ppb) for surface water and 0.006 ppb for ground water. The EECs for chronic

exposures are estimated to be 0.11 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 residential non-dietary sites. Pyriproxyfen is the active ingredient in many registered residential (indoor, nonfood) products for flea and tick control. Formulations include foggers, aerosol sprays, emulsifiable concentrates and impregnated materials (pet collars). Pyriproxyfen residues from residential exposure to pet collars was estimated using the following assumptions: an application rate of 0.58 mg ai/day (product label), average body weight for a 1 to 6–year old child of 10 kg, the active ingredient dissipates uniformly through 365 days (the label instructs to change the collar once a year), and 1% of the active ingredient is available for dermal and inhalation exposure per day (assumption from Draft HED Standard Operating Procedures (SOPs) for Residential Exposure Assessments, December 18, 1997). The assessment also assumes an absorption rate of 100%. This is a conservative assumption since the dermal absorption was estimated to be 10%.

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

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

D. Safety Factor for Infants and Children

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

ii. *Prenatal and postnatal sensitivity*. There is no indication of increased susceptibility of rats or rabbit fetuses to *in utero* and/or postnatal exposure in the developmental and reproductive toxicity studies.

iii. *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 removed (reduced to 1X). The FQPA factor is removed because: (1) The toxicology data base is complete; (2) there is no indication of increased susceptibility of rats or rabbit fetuses to *in utero* and/or postnatal exposure in the developmental and reproductive toxicity studies; (3) a developmental neurotoxicity study is not required; (4) dietary (food) exposure estimates are unrefined (assuming tolerance level residues and 100% crop treated) and likely result in an overestimate of the actual dietary exposure; (5) the models are used for ground and surface source drinking water exposure assessments result in estimates that are upper-bound concentrations; and (6) the Draft Standard Operating Procedures for Residential Exposure Assessments have been used as the basis for all calculations which normally rely on one or more upper-percentile assumptions and are considered to be protective.

E. Aggregate Risks and Determination of Safety

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

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

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

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

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to pyriproxyfen from food will utilize 0.9% of the cPAD for the U.S. population, 1.6 % of the cPAD for all infants (< year) and 2.6% of the cPAD for children (1-6 years). With the exception of the pet collar uses, residential uses of pyriproxyfen result in short-term, intermittent exposures. Chronic residential postapplication risk

assessments were conducted to estimate the potential risk from the pet collar uses. The estimated chronic term MOE is 61,000 for children and 430,000 for adults. The risk estimates indicate that potential risks from pet collar use do not exceed EPA level of concern (MOEs> 100). In addition, there is potential for chronic dietary exposure to pyriproxyfen in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

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

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.35	0.9%	0.11	0.006	12,000
All Infants (<1 year)	0.35	1.6%	0.11	0.006	3,400
Children (1-6 years)	0.35	2.6%	0.11	0.006	3,400
Females (13-50 years)	0.35	0.7%	0.11	0.006	10,000

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Though residential exposure could occur with the use of pyriproxyfen, no toxicological effects have been identified for short-term toxicity. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population*. Pyriproxyfen is classified as Group E for human carcinogenicity; not carcinogenic in animal studies in two species.

5. *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

The gas-chromotography/nitrogen-phosphorous specific flame ionization detector (NPD) and high-pressure liquid chromotography/fluorescence (FLD) method RM-33N-2 is adequate for collecting data on residues of pyriproxyfen in/on nutmeat. Adequate method validation data have been submitted for this method and EPA has successfully validated the analytical method for analysis of nutmeat. The limit of quantitation (LOQ) is 0.02 ppm for residues of pyriproxyfen in/on nutmeat.

The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no CODEX, Canadian, or Mexican tolerances for pyriproxyfen residues in/on pistachios. Therefore, international harmonization is not an issue at this time.

V. Conclusion

Therefore, the tolerance is established for residues of pyriproxyfen in or on pistachio at 0.02 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301131 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 August 6, 2001.

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, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, 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, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

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

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301131, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 special considerations as required by 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 or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: May 17, 2001.

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.

2. Section 180.510 is amended by revising the introductory text in paragraph (a)(1) and alphabetically adding the commodity ''pistachio'' to the table to read as follows:

§ 180.510 Pyriproxyfen; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide pyriproxyfen 2-[1-methyl-2-(4-phenoxyphenoxy)ethoxypyridine in or on the following food commodities:

Commodity	Parts per million
* * * * *	
Pistachio	0.02
* * * * *	

* * * * *

[FR Doc. 01–14085 Filed 6–4–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301133; FRL–6783–5]

RIN 2070–AB78

Clethodim; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of clethodim in or on the root vegetable (except sugar beet) subgroup. The Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996. This final rule establishes permanent tolerances for clethodim and as part of that process the Agency has reassessed existing tolerances. By law, EPA is required to reassess 66% of the tolerances in existence on August 2, 1996, by August 2002, or about 6,400 tolerances. All permanent tolerances for clethodim that existed on August 2, 1996, were previously reassessed by April 1998. Consequently, regarding the actions in this final rule, no tolerance reassessments are counted toward the August 2002 review deadline of FFDCA section 408(q).

DATES: This regulation is effective June 5, 2001. Objections and requests for hearings, identified by docket control number OPP–301133, must be received by EPA on or before August 6, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301133 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–3194; and e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the**Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301133. 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.