that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

B. 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 the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 5, 2001. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action, approving Maryland's regulation imposing RACT to control VOC emissions from marine vessel coating operations, may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements.

Dated: August 28, 2001.

Thomas C. Voltaggio,

Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

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

Subpart V—Maryland

2. Section 52.1070 is amended by adding paragraph (c)(166) to read as follows:

§ 52.1070 Identification of plan.

* * * * *

(c) * * *

(166) Revisions to the Maryland State Implementation Plan submitted on August 20, 2001 by the Maryland Department of the Environment consisting of Reasonably Available Control Technology (RACT) requirements to reduce volatile organic compound (VOC) emissions from marine vessel coating operations.

(i) Incorporation by reference.

(A) A letter dated August 20, 2001 from the Maryland Department of the Environment transmitting an addition to Maryland's State Implementation Plan, pertaining to volatile organic compound (VOC) regulations in Maryland's air quality regulations, COMAR 26.11.19.27.

(B) Addition of new COMAR 26.11.19.27—Control of Volatile Organic Compounds from Marine Vessel Coating Operations, effective on October 20, 1997.

(ii) Additional Materials—Remainder of the August 20, 2001 submittal pertaining to COMAR 26.11.19.27—Control of VOC Emissions from Marine Vessel Coating Operations.

[FR Doc. 01–22267 Filed 9–4–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301159; FRL–6796–6]

RIN 2070–AB

Buprofezin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of buprofezin (2-tert-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one) in or on almonds; banana; citrus; citrus, oil; citrus, dried pulp; grape; grape, raisin; milk; fat (cattle, goats, hogs, horses, sheep); meat byproducts (cattle, goats, hogs, horses, sheep); liver (cattle, goats, hogs, horses, sheep). Aventis (formerly AgrEvo) requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. In addition, this regulation also establishes time-limited tolerances for residues of buprofezin (2-tert-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one) in or on almond, hulls; cotton, undelinted seed; cotton, gin byproducts; and tomato. Aventis (formerly AgrEvo) requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire on July 31, 2005.

DATES: This regulation is effective September 5, 2001. Objections and requests for hearings, identified by docket control number OPP–301159, must be received by EPA on or before November 5, 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–301159 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Richard J. Gebken, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6701; and e-mail address: gebken.richard@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	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 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/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm. 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.hhtml, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301159. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of June 21, 2000 (65 FR 38543) (FRL–6557–3), 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) for tolerance by AgrEvo USA Company, Little Falls Centre One, 2711 Centerville Road, Wilmington, DE 19808. This notice included a summary of the petition prepared by Aventis (formerly AgrEvo), the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.511 be amended by establishing a tolerance for residues of the insecticide buprofezin in or on almonds, nutmeats at 0.05 part per million (ppm); almonds, hulls, at 0.7 ppm; bananas at 0.1 ppm, the citrus crop group, fruit, at 0.7 ppm, cotton seed at 1.0 ppm, grapes at 0.4 ppm, and tomatoes, fruit at 0.8 ppm; in or on the following processed commodities: citrus oil at 26 ppm; citrus pulp, dried, at 2.5 ppm; cotton gin byproducts at 23 ppm; and raisins at 1.0 ppm; and in or on the following meat and milk commodities: the fat, meat and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.05 ppm; and milk at 0.01 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 buprofezin, on almond; banana; citrus; citrus, oil; citrus, dried pulp; grape; grape, raisin; milk; fat (cattle, goats, hogs, horses, sheep); meat byproducts (cattle, goats, hogs, horses, sheep); liver (cattle, goats, hogs, horses, sheep); almond, hulls; cotton, undelinted seed; cotton, gin byproducts and tomato at 0.05, 0.20, 2.0, 60, 6.0, 0.40, 0.60, 0.01, 0.05, 0.05, 0.05, 0.70, 0.40, 15, 0.40 ppm, respectively. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by buprofezin 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	90-Day oral toxicity rodents	NOAEL = 13.0 mg/kg/day males NOAEL = 16.3 mg/kg/day females LOAEL = 68.6 mg/kg/day males LOAEL = 81.8 mg/kg/day females based on increased relative thyroid weight for males, increased liver weights for both male and females, and increased microscopic lesions in liver and thyroid for both male and females.
870.3200	24-Day dermal toxicity	*Systemic* NOAEL = 300 mg/kg/day LOAEL = 1,000 mg/kg/day based on increased focal necrosis with an inflammatory infiltrate in liver for females. *Dermal* NOAEL = 300 mg/kg/day LOAEL = 1,000 mg/kg/day based on increased acanthosis and hyperkeratosis in skin for females.
870.3700	Prenatal developmental in rodents	*Maternal* NOAEL = 200 mg/kg/day LOAEL = 800 mg/kg/day based on mortality, decreased pregnancy rates, and increased resorption rates. *Developmental* NOAEL = 200 mg/kg/day LOAEL = 800 mg/kg/day based on reduced ossification, reduced pup weight, fetal edema.
870.3700	Prenatal developmental in non-rodents	*Maternal* NOAEL = 50 mg/kg/day LOAEL = 250 mg/kg/day based on decreased food consumption, decreased body weights. *Developmental* NOAEL = 250 mg/kg/day LOAEL = not established (less than 250 mg/kg/day)
870.3800	Reproduction and fertility effects	*Parental/systemic* NOAEL = 7.89 mg/kg/day LOAEL = 81.47 mg/kg/day based on decreased body weight gain and on organ weight changes. *Reproductive* NOAEL = 7.89 mg/kg/day LOAEL = 81.47 mg/kg/day based on decreased pup weight
870.4100	Chronic toxicity dogs	NOAEL = 2 mg/kg/day LOAEL = 20 mg/kg/day based on increased bile duct hyperplasia in both males and females, increased serum alkaline phosphatase activity in both males and females, increased relative and absolute liver weights and decreased liver function in females
870.4200	Carcinogenicity mice	NOAEL = 1.82 mg/kg/day for males and 17.4 mg/kg/day for females. LOAEL 17.40 and 191.0 mg/kg/day for males and females respectively, based on increased absolute liver weights, increased hepatocellular adenomas in females, and increased hepatocellular adenomas + carcinomas in females
870.4300	Carcinogenicity rats	NOAEL = 1 mg/kg/day LOAEL = 8.7 mg/kg/day based on increased incidence of follicular cell hyperplasia and hypertrophy in thyroid in males. No evidence of carcinogenicity
870.5100	Gene mutation salmonella	Not mutagenic, with or without activation tested up to cytotocic levels.
870.5100	Gene mutation mouse lymphoma	Not mutagenic, with or without activation tested up to cytotoxic levels.
870.5100	Gene mutation *in vitro* human cytogenetic assay	Negative for micronucleus induction in bone marrow cells of males and females. Tested up to cytotoxic levels.
870.5100	Unscheduled DNA synthesis	Negative for DNA repair tested up to cytotoxic levels.
870.7485	Metabolism and pharmacokinetics	79.1% recovered from feces, 12.9% from urine within 72 hours and 45.4% recovered as parent cpd, several metabolites identified.

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 buprofezin used for human risk assessment is shown in the following Table 2:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13-50 years of age)	NOAEL = 200 mg/kg/day UF = 100 Acute RfD = 2.0 mg/kg/day	FQPA SF = 3x aPAD = acute RfD ÷ FQPA SF = 0.67 mg/kg/day	Developmental toxicity rat LOAEL = 800 mg/kg/day based on skeletal effects and decreased body weight in offspring.
Acute dietary (general population including infants and children)	N/A	N/A	No appropriate study with a single-dose endpoint. This risk assessment is not required.
Chronic dietary (all populations)	NOAEL= 1.0 mg/kg/day UF = 100 Chronic RfD = 0.01 mg/kg/day	FQPA SF = 3x cPAD = chronic RfD divide FQPA SF = 0.003 mg/kg/day	2–Year chronic toxicity/carcinogenicity in rat LOAEL = 8.7 mg/kg/day based on increased incidence of follicular cell hyperplasia and hypertrophy in the thyroid of males.
Intermediate-term dermal (1 week to several months) (residential)	Dermal NOAEL = 300 mg/kg/day	LOC for MOE = 100 (Occupational)	24-Day dermal toxicity rat LOAEL = 1,000 mg/kg/day based on an increase of focal necrosis with an inflammatory infiltrate in liver in females
Short-term inhalation (1 to 7 days) (residential)	Inhalation (or oral) study NOAEL= 200 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational)	Developmental toxicity rat LOAEL = 800 mg/kg/day based on skeletal effects and decreased body weight in offspring
Intermediate-term inhalation (1 week to several months) (residential)	Oral study NOAEL = 13 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational)	90-day oral subchronic study in rat LOAEL = 68.6 mg/kg/day based on organ weight changes and microscopic findings in liver and thyroid (male and females) and kidney (males only).
Cancer (oral, dermal, inhalation)	Suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential	N/A	2–Year carcinogenicity study in mice. Liver tumors observed in female mice. The Agency's Cancer Assessment Review Committee (CARC) recommended that no quantification of cancer risk is required.

*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 180.511) for the residues of buprofezin, in or on a variety of raw agricultural commodities. Tolerances were corrected from the petitioner's original request from the following commodities: bananas at 0.1 ppm, citrus crop group, fruit, at 0.7 ppm, citrus oil at 26 ppm; citrus pulp, dried, at 2.5 ppm, and meat of cattle, goats, hogs, horses, and sheep at 0.05 ppm. The petitioner in the case of bananas, citrus and associated byproducts utilized the average residue values, and the Agency utilized the highest sample concentration for the purpose of evaluating the risk assessment. In addition, the Agency determined upon evaluation of the submitted data, that a residue for meat of cattle, goats, hogs, horses and sheep of 0.05 ppm was unnecessary. Risk assessments were conducted by EPA to assess dietary exposures from buprofezin 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. The Dietary Exposure Evaluation Model (DEEM™ ver 7.075) 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 acute analysis assumed tolerance level residues and 100% crop treated for all registered and proposed uses.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic analysis incorporated average residues calculated from field trial and processing studies and assumed 100% crop treated for all commodities except tomatoes (40% crop treated assumed). The acute and chronic dietary food exposure estimates to buprofezin, for all population subgroups, were less than the Agency's level of concern (greater than 100% aPAD and cPAD)

iii. *Cancer.* In accordance with the EPA Guidelines for Carcinogen Risk Assessment (proposed July 1999), the Agency's Cancer Assessment Review Committee has classified buprofezin as having ''suggestive evidence of carcinogenicity,'' but not sufficient to assess human carcinogenic potential, and further recommended that no quantification of cancer risk is required. Therefore, a cancer risk assessment is not required.

iv. *Anticipated residue and percent crop treated information.* Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a Data Call-In for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

The Agency used percent crop treated (PCT) information as follows.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which buprofezin may be applied in a particular area. All estimates assumed 100% crop treated for all commodities except tomatoes (40% crop treated assumed because Agency data indicates that actual application of buprofezin on all tomatoes produced in the U.S. would be less than 40%).

2. *Dietary exposure from drinking water.* The Agency Metabolism Assessment Review Committee has concluded that buprofezin was the only residue of concern in drinking water (acute and chronic ground water EECs of 0.09 ppb (SCI-GROW) and peak and 56–day average surface water concentrations of 34 ppb and 17.7 ppb (17.7/3 = 5.9 ppb), respectively (GENEEC; Tier 1)).

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in 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 buprofezin they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the EECs of buprofezin for acute and chronic ground water estimated EECs of 0.09 ppb (SCI-GROW) and peak and 56-day average surface water concentrations of 34 ppb and 17.7 ppb (17.7/3 = 5.9 ppb), respectively (GENEEC; Tier 1).

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).

Buprofezin is not registered for use on any sites that would result in residential 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 buprofezin 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, buprofezin 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 buprofezin 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*. It was concluded that toxicity data provide no indication of increased susceptibility of rats or rabbits following *in utero* exposure or of rats following prenatal/postnatal exposure to buprofezin. In the prenatal developmental toxicity study in rats, developmental effects were seen only in the presence of severe maternal toxicity including deaths. No developmental toxicity was seen at the highest dose tested in the prenatal developmental toxicity study in rabbits. In the two-generation reproduction study in rats, effects in the offspring were observed only at treatment levels which resulted in evidence of parental toxicity

iii. *Conclusion*. The toxicology data base for buprofezin is complete for FQPA assessment. The developmental toxicity studies in rats and rabbits and the two-generation reproduction study in rats are available and considered acceptable acute and subchronic neurotoxicity studies are not required for buprofezin.

The Agency determined that an additional developmental neurotoxicity study in rats is required based on the evidence of thyroid toxicity following subchronic and chronic exposures to rats as well as chronic exposures to dogs. In these studies, thyroid toxicity was characterized as decreases in serum thyroxine levels and increased thyroid weights in dogs and histopathological lesions in the subchronic and chronic toxicity studies in rats. While the Agency recognized the fact that thyroid toxicity was seen in the presence of hepatotoxicity, there was concern that thyroid effects were seen in two species following subchronic and chronic exposures.

The Agency concluded that the DNT study is needed to further evaluate the hormonal responses associated with the developing fetal nervous system. The Agency concluded that a safety factor is necessary for buprofezin since there is a data gap for a developmental neurotoxicity study in rats. This study is required due to the evidence of thyroid toxicity observed following subchronic and chronic exposures to rats and chronic exposure to dogs.

The safety factor was reduced to 3x because: (1) There is no evidence of increased susceptibility to young rats or rabbits following *in utero* exposure or following prenatal and/or postnatal exposure to rats; (2) adequate actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary (food and water) exposure assessment; (3) and there are no registered residential uses at the present time.

The FQPA safety factor for buprofezin is applicable to females 13-50 years and to infants and children due uncertainty resulting from data gap for the developmental neurotoxicity study in rats. This study will characterize the potential for neurotoxic effects on fetal development and may provide data that could be used in the toxicology endpoint selection for dietary exposure risk assessments for these population subgroups.

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, the Agency concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which the Agency has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because the Agency 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, the Agency 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*. To estimate acute aggregate exposure risk, the Agency combined the high-end value from food and water and compared it to the aPAD. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to buprofezin will occupy 4% of the aPAD for females 13 years and older (no endpoint was identified for the general population including infants and children). In addition, there is potential for acute dietary exposure to buprofezin 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 aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO BUPROFEZIN

Population Subgroup	aPAD (mg/kg)	%aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females (13-50)	0.67	4%	34	0.09	1.9×10^4

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to buprofezin from food will utilize 73% of the cPAD for all population subgroups. There are no residential uses for buprofezin that result in chronic residential exposure to buprofezin. In addition, there is potential for chronic dietary exposure to buprofezin 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 4:

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

Population Subgroup	cPAD mg/kg/day	Food Exposure mg/kg/day	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population (all)	0.0033	0.001226	5.9	0.09	73
All Infants (less than 1 year)	0.0033	0.000968	5.9	0.09	23
Children (1-6 years)	0.0033	0.002385	5.9	0.09	9
Children (7-12 years)	0.0033	0.001622	5.9	0.09	17
Females (13-50)	0.0033	0.001084	5.9	0.09	66
Males (13-19 years)	0.0033	0.001050	5.9	0.09	79
Males (20+ years)	0.0033	0.000999	5.9	0.09	81
Seniors (55+)	0.0033	0.001060	5.9	0.09	78

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). Buprofezin is not registered for use on any sites that would result in residential exposure. 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. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Buprofezin is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. In accordance with the EPA Guidelines for Carcinogen Risk Assessment (proposed July 1999), the Agency's Cancer Assessment Review Committee has classified buprofezin as having suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential, and further recommended that no quantification of cancer risk is required.

Therefore, a cancer risk assessment is not required.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

1. *Residue analytical methods–plants*. The petitioner proposed method BF/10/97 for enforcement of the almond, banana, citrus, cotton, and grape tolerances. Adequate radiovalidation and independent laboratory validation (ILV) have been received and the method was forwarded to the Analytical Chemistry Laboratory (ACL) for petition method validation (PMV). The petitioner will be required to make any modifications or revision to the proposed enforcement method resulting from PMV. The petitioner is requested to submit a confirmatory method and an interference study. If the petitioner proposes a confirmatory method which employs a mass spectrum detector (MS), then an interference study is not necessary (chromatograms and spectra of fortified samples should be submitted; structurally significant ions should be chosen with a m/z < 91 and intensity < 3x noise at the LOQ for the primary method).

2. *Residue analytical methods–livestock*. The petitioner proposed method BF/11/97 for enforcement of livestock tolerances. Adequate ILV has been received and the method was forwarded to the ACL for PMV (D271333, T. Bloem, 21-Dec-2000). The petitioner will be required to make any modifications or revision to the proposed enforcement method resulting from the PMV. The petitioner is also required to submit a radiovalidation study.

3. *Multiresidue method*. The petitioner submitted data concerning the behavior of buprofezin through FDA multiresidue testing protocols C–F. This information has been forwarded to FDA for inclusion in PAM I.

B. International Residue Limits

Codex has a maximum residue limit (MRL) for buprofezin in/on tomato (1 ppm) and oranges (0.5 ppm). Mexico has a MRL for buprofezin in/on cottonseed (0.05 ppm). Canada does not have any MRLs for the proposed crops. Since the orange and cottonseed MRLs are less than the tolerances determined appropriate by the Agency, harmonization is not possible. Since the tomato MRL is 2x the tolerance determined appropriate by the Agency, harmonization is not possible.

C. Conditions

Conditions for continued registration are as follows: A developmental neurotoxicity study in rats (OPPTS 870.6300) guideline requirement (40 CFR part 158) for Food/Feed Use due to possible endocrine disruptor effects, a revised Section B, a revised Section F, Plant Enforcement Method (BF/10/97) - Confirmatory Method, Interference Study, and successful Agency Validation, Plant Enforcement Method (BF/02/96) - Confirmatory Method and Interference Study, Livestock Enforcement Method - successful Agency Validation and Radioavalidation, Storage Stability Data, validation of frozen storage intervals, petition method validation, an interference study, Additional almond, banana, citrus, cotton, and tomato field trial data, and a citrus processing study.

V. Conclusion

Therefore, the tolerance is established for residues of buprofezin (2-tert-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one), in or on almond; banana; citrus; citrus, oil; citrus, dried pulp; grape; grape, raisin; milk; fat (cattle, goats, hogs, horses, sheep); meat byproducts (cattle, goats, hogs, horses, sheep); liver (cattle, goats, hogs, horses, sheep); almond, hulls; cotton, undelinted seed; cotton, gin byproducts and tomato at 0.05, 0.20, 2.0, 60, 6.0, 0.40, 0.60, 0.01, 0.05, 0.05, 0.05, 0.70, 0.40, 15, 0.40 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–301159 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 November 5, 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–301159, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); 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).

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: August 21, 2001.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.511 is amended by alphabetically adding the following commodities to the table in paragraph (a) and by removing and reserving paragraph (b) to read as follows:

§ 180.511 Buprofezin; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration/ Revocation Date
Almonds, nutmeat	0.05	none
Almond, hulls	0.70	12/31/05
Banana	0.20	none
Cattle, fat	0.05	none
Cattle, mbyp	0.05	none
Cattle, liver	0.05	none
Citrus fruit	2.0	none
Citrus, oil	60	none
Citrus, dried pulp	6.0	none
Cotton, gin byproducts	15	12/31/05
Cotton, undelinted seed	0.40	12/31/05
Goats, fat	0.05	none
Goats, mbyp	0.05	none
Goats, liver	0.05	none
Grape	0.40	none
Grape, raisin	0.60	none
Hogs, fat	0.05	none
Hogs, mbyp	0.05	none
Hogs, liver	0.05	none
Horses, fat	0.05	none
Horses, mbyp	0.05	none
Horses, liver	0.05	none
* * * * * * *		
Milk	0.01	none
Sheep, fat	0.05	none
Sheep, mbyp	0.05	none
Sheep, liver	0.05	none
Tomato	0.40	12/31/05
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(b) *Section 18 emergency exemption.* [Reserved]

[FR Doc. 01–22281 Filed 9–4–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301165; FRL–6798–6]

RIN 2070–AB78

Pyriproxyfen; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for the combined residues of pyriproxyfen in or on succulent beans. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on succulent beans. This regulation establishes a maximum permissible level for residues of pyriproxyfen in this food commodity. The tolerance will expire and is revoked on June 30, 2003.

DATES: This regulation is effective September 5, 2001. Objections and requests for hearings, identified by docket control number OPP–301165, must be received by EPA on or before November 5, 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 VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301165 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9367; and e-mail address: ertman.andrew@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected 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–301165. 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, 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

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for combined residues of the insect growth regulator pyriproxyfen, [2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine], in or on succulent beans at 0.10 part per million (ppm). This tolerance will expire and is revoked on June 30, 2003. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.