Commodity	Parts per million
Pistachio	0.1
Rice, bran	15
Rice, grain	7.0
Rice, hulls	20
Rice, straw	18
Rye, bran	0.6
Rye, forage	1.7
Rye, grain	0.3
Rye, straw	10
Sheep, fat	0.05
Sheep, kidney	2.0
Sheep, liver	2.0
Sheep, meat	0.05
Sheep, meat byproducts, except liver and kidney	0.05
Sorghum, grain, forage	12
Sorghum, grain, grain	3.5
Sorghum, grain, stover	15
Soybean, forage	11
Soybean, hay	30
Soybean, seed	2.0
Spearmint, tops	3.5
Strawberry	1.3
Wheat, bran	0.6
Wheat, forage	1.7
Wheat, grain	0.3
Wheat, hay	1.4
Wheat, straw	10

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* A tolerance with regional registration, as defined in §180.1(m), is established for residues of 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound, in or on the following commodities:

Commodity	Parts per million
Cranberry	1.0
Rice, wild	0.5

(d) *Indirect or inadvertent residues.* Tolerances are established for the combined residues of the fungicide 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-1H-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in or on the following commodities when present therein as a result of application of propiconazole to growing crops in paragraphs (a) and (c) of this section:

Commodity	Parts per million
Alfalfa, forage	0.1
Alfalfa, hay	0.1

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0170; FRL–8092–2]

Buprofezin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues or residues of buprofezin in or on almond hulls; cotton, gin byproducts: Cottonseed; and tomato. Nichino America, Inc., Linden Park Suite 501, 4550 New Linden Hill Road, Wilmington, DE 19908 requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 22, 2006. Objections and requests for hearings must be received on or before November 21, 2006, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0170. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kevin Sweeney, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5063; e-mail address: *sweeney.kevin@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers.

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

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*

C. Can I File an Objection or Hearing Request?

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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2006–0170. 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 21, 2006.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2006–0170, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of June 21, 2000 (65 FR 38549) (FRL–6557–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F6087) by Nichino America, Inc., Linden Park, Suite 501, 4550 New Linden Road, Wilmington, DE, 19808. The petition requested that 40 CFR 180. 511 be amended by establishing a tolerance for combined residues or residues of the insecticide buprofezin, 2[(1,1-dimethylethyl)imino]tetrahydro-3(1-methylethyl)-5-phenyl-4H-1,3,5-thiadizin-4-one, in or on almond hulls at 0.7 parts per million (ppm); cotton, gin byproducts at 23 ppm; cotton, undelinted seed at 1.0 ppm; and tomato at 0.8 ppm at tolerance level ppm. That notice included a summary of the petition prepared by Aventis CropScience USA LP (formerly AgrEvo USA Company), 2 T.W. Alexander Drive, Research Triangle Park, NC 27709, the registrant. There were no comments received in response to the notice of filing. Subsequently, in the **Federal Register** of September 5, 2001 (66 FR 46381) (FRL–6696–6), EPA issued a Final Rule to section 408 of FFDCA, 21 U.S.C. 345a(d)(3), that established time limited tolerances for residues of the insecticide [buprofezin, 2-[(1,1-dimethylethyl)imino]tetrahydro-3(1-methylethyl)-5-phenyl-4H-1,3,5-thiadiazin-4–1], in or on almond hulls at 0.7 ppm; cotton, gin byproducts at 15.0 ppm; cotton, undelinted seed at 0.4 ppm; and tomato at 0.40 ppm. These tolerances expired on December 31, 2005. The conditions for these time limited tolerances were as follows: A comparative thyroid assay (young/adult rat), 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 Radiovalidation, 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. EPA reevaluated the available thyroid toxicity data in regard to the severity of effects and hormonal measurements and concluded that a study evaluating thyrioid levels in adult rats would be more appropriate. This study is confirmatory and is not a condition of granting these tolerances. All of the conditions above have been addressed and the Agency is issuing permanent tolerances based on the registrant's proposed final rule request dated August 25, 2005 (November 30, 2005 (70 FR 71838) (FRL–7735–7)).

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues or residues of buprofezin on almond, hulls at 2.0 ppm; cotton, gin byproducts at 20 ppm; cotton, undelinted seed at 0.35 ppm; and tomato at 0.40 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. Specific information on the studies received and the nature of the toxic effects caused by buprofezin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found in the OPP Regulatory Public Docket number EPA–HQ–OPP–2006–0170.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAEL

identified 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/pesticides/health/human.htm.*

A summary of the toxicological endpoints for buprofezin used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR BUPROFEZIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern (LOC) for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13-49 years of age)	NOAEL = 200 mg/kg/day UF = 100 Acute RfD = 2.0 mg/kg/day	Special FQPA SF = 1 aPAD = acute RfD/Special FQPA SF = 2.0 mg/kg/day	LOAEL = 800 mg/kg/day based on incomplete ossification and reduced pup weight
Acute dietary (general population including infants and children)	NOAEL = NA[1] mg/kg/day UF = NA Acute RfD = NA mg/kg/day	Special FQPA SF = NA[1] aPAD = acute RfD Special FQPA SF = NA mg/kg/day	No appropriate endpoint was identified for the general population LOAEL = NA mg/kg/day based on NA
Chronic dietary (all populations)	NOAEL = 1.0 mg/kg/day UF = 300 Chronic RfD = 0.0033 mg/kg/day	Special FQPA SF = 1 cPAD = chronic RfD Special FQPA SF = 0.0033 mg/kg/day	Two–year chronic feeding study - rat LOAEL = 8.7 mg/kg/day based on organ weight changes and microscopic findings in the liver and thyroid of both males and females and in the kidney of males
Short-term incidental oral (1-30 days) (Residential = NA[2])	Oral NOAEL = 13.0 mg/kg/day	Residential = NA[2]	90–day oral toxicity study -rat LOAEL 68.6 mg/kg/day based on
Short-term dermal (1 to 30 days) (Residential = NA[2]	Dermal NOAEL = 300 mg/kg/day (dermal absorption rate = NA[2≠])	Occupational LOC for MOE = <100 (Residential = NA[2])	24–Day dermal toxicity study - rat LOAEL = 1,000 mg/kg/day based on inflammatory infiltrate of the liver in females and increase in acanthosis and hyperkeratosis of the skin in females
Intermediate-term dermal (1 week to several months) (Residential = NA[2])	Dermal NOAEL = 300 mg/kg/day (dermal absorption rate = NA[2≠])	Occupational LOC for MOE = <100 (Residential = NA[2])	24–Day dermal toxicity study - rat LOAEL = 1,000 mg/kg/day based on inflammatory infiltrate of the liver in females and increase in acanthosis and hyperkeratosis of the skin in females
Long-term dermal (several months to lifetime) (Residential = NA[2])	Oral NOAEL = 1.0 mg/kg/day (dermal absorption rate = 10%)	Occupational LOC for MOE = <300 (Residential = NA[2])	Two-year chronic feeding study - rat LOAEL = 8.7 mg/kg/day based on based on increased incidence of follicular cell hyperplasia and hypertrophy in the thyroid in males
Short-term inhalation (1 to 30 days) (residential = NA[2])	Oral study NOAEL = 13.0 mg/kg/day (inhalation absorption rate = 100%)	Occupational LOC for MOE = <300 (Residential = NA[2])	90–Day oral toxicity study - rat LOAEL = 68.6 mg/kg/day based on organ weight changes and microscopic findings in the liver and thyroid of both males and females and in the kidney of males
Intermediate-term inhalation (1 week to several months) (Residential = NA[2])	Oral study NOAEL = 13.0 mg/kg/day (inhalation absorption rate = 100%)	Occupational LOC for MOE = <300 (Residential = NA[2])	90–Day oral toxicity study - rat LOAEL = 68.6 mg/kg/day based on organ weight changes and microscopic findings in the liver and thyroid of both males and females and in the kidney of males

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR BUPROFEZIN FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern (LOC) for Risk Assessment	Study and Toxicological Effects
Long-term inhalation (several months to lifetime) (Residential = NA[2])	Oral study NOAEL = 1.0 mg/kg/day (inhalation absorption rate = 100%)	Occupational LOC for MOE = <300 (Residential = NA[2])	Two–year chronic feeding study -rat LOAEL = 8.7 mg/kg/day based on increased incidence of follicular cell hyperplasia and hypertrophy in the thyroid of males
Cancer (oral, dermal, inhalation)	No quantification	No quantification	No quantification is appropriate because the evidence was limited to one sex in one species of animal. The data show no greater than suggestive evidence of carcinogenicity.

[1]NA = Not applicable.
[2]NA = Not applicable. There are no residential uses for buprofezin.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.511) for the combined residues or residues of buprofezin, in or on a variety of raw agricultural commodities. Tolerances of buprofezin are established in milk at 0.01 ppm and in ruminant fat (0.05 ppm), meat byproducts (0.05 ppm), and liver at 0.05 ppm. Risk assessments were conducted by EPA to assess dietary exposures from buprofezin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and 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™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: The acute analysis assumed DEEM (ver. 7.76) default processing factors and 100% crop treated (CT) for all commodities. Tolerance level residues were assumed for all commodities excluding meat and milk. Since meat and milk (LOQ tolerances) residues were only detected in the feeding study at 6.8–9.3x the Maximum Theoretical Dietary Burden (MTDB), residues in these commodities were normalized to 1x the MTDB. The acute analysis also incorporated the acute Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM-EXAMS) surface drinking water estimate resulting from application of buprofezin to citrus in Florida (highest acute drinking water estimate). No acute endpoint was identified for the remaining population subgroups.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM™ software with the FCID, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic analysis assumed DEEM (ver. 7.76) default processing factors for all commodities and incorporated percent crop treated (PCT) estimates or projected PCT estimates. Tolerance level or average field trial residues were assumed for all crop commodities and since meat and milk (LOQ tolerances) residues were only detected in the feeding study at 6.8–9.3x the MTDB, residue in these commodities were normalized to 1x the MTDB. The chronic analysis also incorporated the chronic PRZM-EXAMS surface drinking water estimate resulting from application of buprofezin to citrus in Florida (highest chronic drinking water estimate).

iii. *Cancer.* Due to the fact that the data showed no greater than suggestive evidence of carcinogenicity, the chronic exposure and risk assessment was deemed protective of any cancer effect.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: 10% CT for cantaloupes; 5% CT for cauliflower; 2.5% CT for cotton, grapefruit, grapes, honeydew, lemons, oranges, tomatoes, and watermelon; market share PCT was projected not to exceed 5% for apples, and 13% for peaches for the first four to five years buprofezin is on the market. All other crops currently registered and/or proposed commodities were assumed to be 100% CT. The Agency believes that the three conditions listed in Unit C.1.iv. 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. For previously registered crops, EPA used an average of the values from these surveys over the last 5 years for estimating PCT for chronic dietary exposure assessments. For most newly registered crops, the Agency assumed 100% CT. In estimating PCT for the apples, EPA assumed that the PCT for

buprofezin would at least equal or exceed the PCT for the leading comparable insect growth regulator pesticide alternative on that crop. For peaches, PCT for buprofezin was projected to potentially exceed the leading alternative's PCT because buprofezin has a slight cost advantage over the alternative on that crop. With regards to apples, buprofezin was projected to slightly exceed sales of the leading alternative's PCT because buprofezin is an excellent technical fit as an insect pest management insecticide for apples. 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.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for buprofezin 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 buprofezin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the PRZM/EXAMS and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of buprofezin for acute exposures are estimated to be 19.2 parts per billion (ppb) for surface water and 0.1 ppb for ground water. The EECs for chronic exposures are estimated to be 4.5 ppb for surface water and 0.1 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the DEEM™/FCID. For chronic dietary risk assessment, the annual average concentration of 4.5 ppb was used to access the contribution to drinking 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).

Buprofezin is not registered for use on any sites that would result in residential exposure.

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to buprofezin and any other substances and 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines based on reliable data 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. Prenatal and postnatal sensitivity is not of concern for buprofezin based on the results of the developmental toxicity studies in rats and rabbits and the two-generation reproduction study in rats. The results indicate that there is no increased susceptibility of rats or rabbits following *in utero* exposure or of rats following prenatal/postnatal exposure to buprofezin. The toxicology data do not indicate a basis for concern for neurotoxicity, therefore, acute, subchronic, and developmental neurotoxicity studies are not required.

3. *Conclusion*. Oral exposure to buprofezin produced marginal thyroid toxicity in adult rats manifested as increased incidence of follicular cell hyperplasia, increased in thyroid weights and microscopic findings in the thyroid. Although rats are very susceptible to thyroid hormone disruption and thyroid follicular cell carcinogenesis, no thyroid tumors were observed in chronic and carcinogenicity studies in mice and rats. It is unknown to what extent buprofezin alters thyroid hormones (T3, T4 and Thyroid-Stimulating hormone levels) because these were not measured. Given the marginal thyroid toxicity found, it is anticipated that any effects of buprofezin on thyroid hormones may also be marginal. Thus, a measurement of thyroid hormones in adult rats is viewed as a confirmatory test to evaluate its effect on thyroid homeostasis. A FQPA factor of 10X in the form of database UF is applied to chronic Referance Dose (cRfD), chronic dermal exposure (endpoint based on oral study) and all inhalation exposure durations as a conservative approach to address any residual uncertainty associated with potential susceptibility of the young to thyroid disruption. This FQPA factor in the form of database uncertainty is not applicable to acute oral RfD because a single dose of a chemical would not be expected to perturb thyroid homeostasis in the adult or young due to the buffering of thyroid hormone concentrations by homeostatic mechanisms for compound with short half lives, like buprofezin (half-life of a couple of days). This FQPA factor in the

form of database uncertainty is not applicable to short-and intermediate-term dermal exposure because the endpoint of concern is based on dermal study where liver toxicity was the critical effect (thyroid effects were not observed). Since the thyroid effects were seen in rats and it has been established that rats are more susceptible to thyroid effects than humans, the Agency concluded that the interspecies extrapolation factor for these assessments may be reduced to 3X. The intraspecies variability factor remains as 10x. There is no evidence of increased susceptibility due to postnatal exposure to buprofezin in rats and rabbits or prenatal and postnatal exposure in two-generation reproduction study. Therefore, there is no need to retain the FQPA safety factor (SF) based on prenatal or postnatal toxicity issues. Based on the conservative residue assumptions used in the dietary risk assessment (there are currently no residential exposures), and the completeness of the residue chemistry and environmental fate databases, there is no need to retain the FQPA SF based on exposure issues.

The total UF for chronic dietary, inhalation assessments (all durations) and long-term dermal assessment is 300X (10X FQPA database uncertainty, 3X interspecies variation, and 10X intraspecies variation) and the total UF for acute dietary and dermal assessments (short-term and intermediate-term) is 100X (10X interspecies variation and 10x intraspecies variation).

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to buprofezin will occupy 5% of the acute population adjusted dose (aPAD) for females 13-49 years old. EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

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 40% of the chronic population adjusted dose (cPAD) for the U.S. population, 56% of the cPAD for all infants less than 1–year old, and 87% of the cPAD for children 1-2 years old. There are no residential uses for buprofezin that result in chronic residential exposure to buprofezin. Therefore, the EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Aggregate cancer risk for U.S. population.* In chronic studies in the rat, an increased incidence of follicular cell hyperplasia and hypertrophy in the thyroid of males was reported. Increased relative liver weights were reported in female dogs. Buprofezin was not carcinogenic to male and female rats. In the mouse, increased absolute liver weights in males and females, along with an increased incidence of hepatocellular adenomas and hepatocellular adenomas plus carcinomas in females were reported. Buprofezin was negative *in vitro* and *in vivo* genotoxicity assays. The findings from the published literature indicate that buprofezin causes cell transformation and induces micronuclei *in vitro*. In the absence of a positive response in an *in vivo* micronucleus assay, the Agency concluded that buprofezin may have aneugenic potential, which is not expressed *in vivo*. In summary, buprofezin was negative in the rat, negative for mutagenicity and negative for male mice; however, in female mice, a slight or marginal increase in combined adenomas and carcinomas was observed. Given these findings in the cancer and mutagenicity studies, EPA regards the carcinogenic potential of buprofezin as very low and concludes that it poses no greater than a negligible cancer risk to humans.

4. *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-Plants

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

B. International Residue Limits

There are no Canadian, Mexican, or Codex maximum residue limits established for buprofezin in/on any of the commodities associated with the current petition.

V. Conclusion

Therefore, the tolerance is established for combined residues or residues of buprofezin, in or on almond, hulls at 2.0 ppm; cotton, gin byproducts at 20 ppm; cotton, undelinted seed at 0.35 ppm; and tomato at 0.40 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various

levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: September 12, 2006.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.511 is amended by alphabetically revising commodities and adding cotton seed to the table in paragraph (a) to read as follows:

§ 180.511 Buprofezin; tolerance for residues

(a) * * *

Commodity	Parts per million	Expiration/revocation dates
* * * * *		
Almond hulls	2.0	None
* * * * *		
Cotton, gin byproducts	20.0	None
Cotton seed	0.35	None
* * * * *		
Tomato	0.40	None
* * * * *		

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0299; FRL–8093–8]

Trifloxystrobin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of Trifoxystrobin (Benzeneacetic acid, (E,E)-α-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl) phenyl]ethylidene]amino]oxy]methyl]-, methyl ester and the free form of its acid metabolite CGA-321113 ((E,E)-methoxyimino-(2-[1-(3-trifluoromethylphenyl) ethylideneaminooxymethyl] phenyl)acetic acid)) in or on soybean, forage at 10.0 parts per million (ppm), soybean, hay at 25.0 ppm, and soybean, seed at 0.08 ppm. Bayer CropScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 22, 2006. Objections and requests for hearings must be received on or before November 21, 2006, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0299. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly