at anchor shall get underway and shall move to its new designated position within 2 hours after notification.

(6) The Captain of the Port may prescribe specific conditions for vessels anchoring within the anchorages described in this section, including, but not limited to, the number and location of anchors, scope of chain, readiness of engineering plant and equipment, usage of tugs, and requirements for maintaining communication guards on selected radio frequencies.

(7) No vessel at anchor or at a mooring within an anchorage may transfer oil to or from another vessel unless the vessel has given the Captain of the Port the four hours advance notice required by § 156.118 of this chapter.

(8) No vessel shall anchor in a ''dead ship'' status (propulsion or control unavailable for normal operations) without prior approval of the Captain of the Port.

(d) *Regulations for vessels handling or carrying dangerous cargoes or Class 1 (explosive) materials.* (1) This paragraph (d) applies to every vessel, except a U.S. naval vessel, handling or carrying dangerous cargoes or Class 1 (explosive) materials.

(2) The Captain of the Port may require every person having business aboard a vessel handling or carrying dangerous cargoes or Class 1 (explosive) materials while in an anchorage, other than a member of the crew, to hold a form of identification prescribed in the vessel's security plan.

(3) Each person having business aboard a vessel handling or carrying dangerous cargoes or Class 1 (explosive) materials while in an anchorage, other than a member of the crew, shall present the identification prescribed by paragraph (d)(2) of this section to any Coast Guard Boarding Officer who requests it.

(4) Each non-self-propelled vessel handling or carrying dangerous cargoes or Class 1 (explosive) materials must have a tug in attendance at all times while at anchor.

(5) Each vessel handling or carrying dangerous cargoes or Class 1 (explosive) materials while at anchor must display by day a bravo flag in a prominent location and by night a fixed red light.

Dated: March 25, 2005.

Ben Thomason, III,

Captain, U.S. Coast Guard, Acting Commander, Fifth Coast Guard District.

[FR Doc. 05–6956 Filed 4–7–05; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0412; FRL–7691–8]

Buprofezin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of buprofezin in or on avocado, papaya, star apple, black sapote, mango, sapodilla, canistel, mamey sapote, sugar apple, cherimoya, atemoya, custard apple, ilama, soursop, birida, guava, feijoa, jaboticaba, wax jambu, starfruit, passionfruit, and acerola at 0.30 parts per million (ppm); pome fruit at 0.30 ppm; peach at 9.0 ppm, meat (cattle, goat, hog, horse, and sheep) at 0.05 ppm; kidney (cattle, goat, hog, horse, and sheep) at 0.05 ppm.; lettuce, head at 5.0 ppm, Lettuce, leaf at 13.0 ppm, and Vegetable, cucurbit at 0.5 ppm; fruit, citrus, group 10 at 2.5 ppm; citrus, dried, pulp at 7.5 ppm; and citrus, oil at 80 ppm. Nichino America, Inc., Linden Park, Suite 501, 4550 New Linden Hill Road, Wilmington, DE 19808 requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective April 8, 2005. Objections and requests for hearings must be received on or before June 7, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0412. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Richard J. Gebken, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6701; e-mail address: *gebken.richard@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; residential users.

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 and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of March 17, 2004 (69 FR 12676) (FRL–7347–1), 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 3E6636, 3E6741, and 3E6747) by Interregional Research Project Number (IR–4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902 and Nichino America, Inc., Linden Park, Suite 501, 4550 New Linden Hill Road, Wilmington, DE 19808. The petition requested that 40 CFR 180.511 be amended by establishing a tolerance for residues of the insecticide buprofezin (2-[(1,1-dimethylethyl)imino]tetrahydro-3-(1-methylethyl)-5-phenyl-4H-1,3,5-thiadiazin-4-one), in or on the raw agricultural commodities: Fruit, pome, group 11, except apple and apple, pomace at 4.0 parts per million (ppm) (PP 3E6636), apple at 1.2 ppm (PP 3E6636), apple, pomace at 2.5 ppm (PP 3E6636), peach, apricot, and nectarine at 3.0 ppm (PP 3E6741), and avocado, papaya, star apple, black sapote, mango, sapodilla, canistel, mamey sapote, sugar apple, cherimoya, atemoya, custard apple, ilama, soursop, biriba, guava, feijoa, jaboticaba, wax jambu, starfruit, passionfruit, and acerola at 0.30 ppm (PP 3E6747).

In the **Federal Register** of June 21, 2000 (65 FR 38543) (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 Hill Road, Wilmington, DE 19808, (formerly Aventis CropScience, formerly AgrEvo USA Company). The petition requested that 40 CFR 180.511 be amended by establishing a tolerance for residues of the insecticide buprofezin] (2-[(1,1-dimethylethyl)imino]tetrahydro-3-(1-methylethyl)-5-phenyl-4H-1,3,5-thiadiazin-4-one), in or on the following meat commodities; (Cattle, goats, hogs, horse, and sheep at 0.05 ppm) and kidney commodities for (cattle, goats, hogs, horse, and sheep at 0.05 ppm) respectively.

In the **Federal Register** of December 22, 2004 (69 FR 76719) (FRL–7689–4), 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 4F6873) by Nichino America, Inc., Linden Park, Suite 501, 4550 New Linden Hill Road, Wilmington, DE 19808. The petition requested that 40 CFR 180.511 be amended by establishing increased tolerances for residues of buprofezin (2-[(1,1-dimethylethyl)imino]tetrahydro-3-(1-methylethyl)-5-phenyl-4H-1,3,5-thiadiazin-4-one) in or on the following agricultural commodities: Fruit, citrus, Group 10 at 2.5 ppm); citrus, dried pulp at 7.5 ppm; and citrus, oil at 80 ppm.

In the **Federal Register** of December 23, 2004 (69 FR 76942) (FRL–7694–1), 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 4F6887) by Nichino America, Inc., Linden Park, Suite 501, 4550 New Linden Hill Road, Wilmington, DE 19808. The petition requested that 40 CFR 180.511 be amended by establishing tolerances for residues of buprofezin (2-[(1,1-dimethylethyl)imino]tetrahydro-3-(1-methylethyl)-5-phenyl-4H-1,3,5-thiadiazin-4-one) in or on the following raw agricultural commodities: Head lettuce at 5 ppm, leaf lettuce at 13 ppm, and Vegetables, cucurbits, group 9 at 0.5 ppm.

Each respective notice included a summary of the petition prepared by the registrant Nichino America, Incorporated, 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808, or the previous, registrant Aventis CropScience.

A private citizen responded to petitions PP 3E6636, 3E6741, 3E6747, 4F6873, and 4F6887. The substantive public comments and corresponding Agency responses are addressed in a separate document available in the docket for this action under Docket identification (ID) number OPP–2004–0362.

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 FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of 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 residues of buprofezin in or on avocado, papaya, star apple, black sapote, mango, sapodilla, canistel, mamey sapote, sugar apple, cherimoya, atemoya, custard apple, ilama, soursop, birida, guava, feijoa, jaboticaba, wax jambu, starfruit, passionfruit, and acerola at 0.30 parts per million (ppm); pome fruit at 4.0 ppm; peach at 9.0 ppm, meat (cattle, goat, hog, horse, and sheep) at 0.05 ppm; kidney (cattle, goat, hog, horse, and sheep) at 0.05 ppm; Lettuce, head at 5.0 ppm, Lettuce, leaf at 13 ppm; Vegetable, cucurbit group 9 at 0.50 ppm; Fruit, citrus, Group 10 at 2.5 parts per million (ppm); Citrus, dried pulp at 7.5 ppm, and citrus, oil at 80 ppm.

EPA's assessment of exposures and risks associated with establishing the tolerance follows:

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by buprofezin as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of June 25, 2003 (68 FR 37765) (FRL–7310–7).

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.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

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 an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). 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 discussed in Unit III.B. of the final rule published in the **Federal Register** of June 25, 2003 (68 FR 37765) (FRL–7310–7).

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 for residues of buprofezin are currently established for ruminant fat, meat byproducts, and liver at 0.05 ppm (40 CFR 180.511). Tolerances are being established for meat (cattle, goat, hog, horse, and sheep) at 0.05 ppm; and kidney (cattle, goat, hog, horse, and sheep) at 0.05 ppm; based on additional animal metabolism studies provided from Nichino America, Inc. Risk assessments were conducted by EPA to assess dietary exposures from buprofezin in food as follows:

i. *Acute and chronic 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.

In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™) (ver. 1.30) and Lifeline™ (ver. 2.00) models, 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 acute exposure assessments: The acute analysis assumed tolerance level residues, 100% crop treated for all uses, and DEEM™ (ver. 7.76) default processing factors for all registered/proposed commodities (Tier 1). The chronic analysis assumed DEEM™ (ver.7.76) default processing factors for all registered/proposed commodities and incorporated percent crop treated estimates and average field trial residues.

ii. *Cancer.* In accordance with the EPA Guidelines for Carcinogen Risk Assessment, the Carcinogen Assessment Review Commission classified buprofezin as having ''suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential'' based on liver tumors in female mice. The Committee further recommended no quantification of cancer risk.

iii. *Anticipated residue and percent crop treated (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:

- 5% crop treated (PCT) for cantaloupes;
- 2.5% crop treated for cotton, grapefruit, grapes, lemons, limes, oranges, squash, tangelos, tangerines, tomatoes, and watermelon;
- Market share % crop treated was projected not to exceed 5% for apples, and 13% for peaches;
- All other crops currently registered and/or proposed commodities were assumed to be 100% crop treated.

The Agency believes that the three conditions listed in Unit C. 1. iii. 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% PCT. In estimating PCT for the apples and peaches as newly-registered crops, EPA assumed that the PCT for buprofezin would at least equal or exceed the PCT for the leading comparable insect growth regulatory pesticide alternative on that crop. For peaches, PCT for buprofezin was projected to potentially exceed the leading alternative's PCT by a factor of five 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 (IPM) 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.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentrations in Groundwater (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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used 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 in Unit E.

Based on the GENEEC, PRZM/EXAMS and SCI-GROW models, the 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.

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 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 OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site 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 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 uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. The Agency concluded that the available studies provided no indication of increased susceptibility of rats or

rabbits following *in utero* exposure or of rats following prenatal/postnatal exposure to buprofezin.

3. *Conclusion*. There is a complete toxicity data base for buprofezin and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be reduced to 1X.

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

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

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to buprofezin will occupy 5.0% of the aPAD for females 13 to 19 years old. 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 water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 1 of this unit:

TABLE 1.—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 (13–49 years old)	2.0	5	19.2	0.1	57,000

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, the chronic aggregate risk assessment takes into account average exposure estimates from dietary consumption of buprofezin (food and drinking water). However, there are no residential uses for buprofezin that result in chronic residential exposure to buprofezin. Therefore, the chronic aggregate risk assessment will consider exposure from food and drinking water only. There is potential for chronic dietary exposure to buprofezin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO BUPROFEZIN

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.01	38	4.5	0.1	220
All infants (<1 yr old)	0.01	64	4.5	0.1	36
Children (1–2 years old)	0.01	81	4.5	0.1	19
Youth (13–19 years old)	0.01	32	4.5	0.1	200
Adults (50 years + old)	0.01	39	4.5	0.1	21
Females (13–49 years old)	0.01	34	4.5	0.1	200

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 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 *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 sum, 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.

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

Plants. Adequate enforcement methodology gas chromatography using nitrogen phosphorus detection is available to enforce the tolerance expression.

Livestock. The Agency has successfully validated method BF/11/97 for enforcement of the livestock tolerances and the method was forwarded to FDA's Technical Editing Group for publication in a future revision of the Pesticide Analytical Manual I (PAM I).

The methods 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 (MRLs) established for buprofezin in/on any of the commodities associated with the current petition. Therefore, harmonization is not relevant.

V. Conclusion

Therefore, the tolerance is established for residues of buprofezin, in or on avocado, papaya, star apple, black sapote, mango, sapodilla, canistel, mamey sapote, sugar apple, cherimoya, atemoya, custard apple, ilama, soursop, birida, guava, feijoa, jaboticaba, wax jambu, starfruit, passionfruit, and acerola] at 0.30 ppm; Fruit, Pome, Crop Group 11 at 4.0 ppm; Peach at 9.0 ppm; Meat (cattle, goat, hog, horse, and sheep) at 0.05 ppm; and Kidney (cattle, goat, hog, horse, and sheep) at 0.05 ppm; Lettuce, head at 5.0 ppm; Lettuce, leaf at 13 ppm; and Vegetable, cucurbit group 9 at 0.50 ppm; Fruit, citrus, Group 10 at 2.5 ppm; citrus, dried pulp at 7.5 ppm; and citrus, oil at 80 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days. A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0412 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 June 7, 2005.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564–6255.

2. *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 *ADDRESSES*. Mail your copies, identified by docket ID number OPP–2004–0412, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy

of your request at many Federal Depository Libraries.

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

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

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of 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. The Agency hereby certifies that this rule will not have significant negative economic impact on a substantial number of small entities. 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.

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: March 29, 2005.

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 revising the entries for ''Fruit, citrus''; ''Lettuce, head''; ''Lettuce, leaf''; and ''Vegetable, cucurbit'' and by alphabetically adding commodities in the table in paragraph (a) to read as follows:

§ 180.511 Buprofezin; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration/ Revocation Date
Acerola	0.30	None
* * *	* * *	*
Atemoya	0.30	None
Avocado	0.30	None
* * *	* * *	*
Birida	0.30	None
Black sapote	0.30	None
Canistel	0.30	None
* * *	* * *	*
Cattle, kidney	0.05	None

Commodity	Parts per million	Expiration/ Revocation Date
* *	* *	*
Cattle, meat	0.05	None
* *	* *	*
Cherimoya	0.30	None
* *	* *	*
Citrus, dried pulp	7.5	None
Citrus, oil	80	None
* *	* *	*
Custard, apple	0.30	None
Feijoa	0.30	None
Fruit, Citrus, Group 10	2.5	None
Fruit, Pome, Crop Group 11	4.0	None
* *	* *	*
Goat, kidney	0.05	None
Goat, meat	0.05	None
* *	* *	*
Guava	0.30	None
* *	* *	*
Hog, kidney	0.05	None
Hog, meat	0.05	None
* *	* *	*
Horse, kidney	0.05	None
Horse, meat	0.05	None
* *	* *	*
Ilama	0.30	None
Jaboticaba	0.30	None
* *	* *	*
Lettuce, head	5.0	None
Lettuce, leaf	13.0	None
Mamey sapote	0.30	None
Mango	0.30	None
* *	* *	*
Papaya	0.30	None
Passion fruit	0.30	None
Peach	9.0	None
* *	* *	*
Sapodilla	0.30	None
* *	* *	*
Sheep, kidney	0.05	None
Sheep, meat	0.05	None
* *	* *	*
Soursop	0.30	None
* *	* *	*
Star apple	0.30	None
Starfruit	0.30	None
Sugar apple	0.30	None
* *	* *	*
Vegetable, Cucurbit, Group 9	0.50	None
Wax jambu	0.30	None

* * * * *

[FR Doc. 05–7066 Filed 4–7–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0054; FRL–7701–6]

Triflumizole; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of triflumizole in or on parsley, leaves; dandelion, leaves; swiss chard; collards; kale; kohlrabi; mustard greens; cabbage, chinese, napa; broccoli; and coriander, leaves (cilantro). This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on parsley; dandelion; swiss chard; collards; kale; kohlrabi; mustard greens; cabbage, chinese, napa; broccoli; and coriander, leaves (cilantro). This regulation establishes maximum permissible levels for residues of triflumizole in these food commodities. These tolerances will expire and are revoked on June 30, 2008.

DATES: This regulation is effective April 8, 2005. Objections and requests for hearings must be received on or before June 7, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0054. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9364; e-mail address: *Sec-18-Mailbox@epamail.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 code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

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

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

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

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 time-limited tolerances for combined residues of the fungicide triflumizole and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound, in or on parsley, leaves at 9.0 parts per million (ppm); dandelion, leaves at 7.0 (ppm); swiss chard at 7.0 (ppm); collards at 9.0 ppm; kale at 9.0 ppm;