November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

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 action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 17, 2012. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

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

Dated: September 27, 2012.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal

Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart F—California

■ 2. Section 52.222 is amended by adding paragraph (a)(2)(iii) to read as follows:

§ 52.222 Negative declarations.

(a) * * *

(2) * * *

(iii) Fiberglass and Boat Manufacturing Materials and Automobile and Light-Duty Truck Assembly Coatings were submitted on July 12, 2012 and adopted on March 22, 2012.

* * * * *

[FR Doc. 2012–25383 Filed 10–16–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0759; FRL–9364–9]

Buprofezin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide buprofezin in or on multiple commodities which are identified and discussed later in this document. In addition, this regulation removes established tolerances for certain commodities/groups superseded by this action, and corrects the spelling of some commodities. The Interregional Research Project #4 (IR–4) and Nichino America Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 17, 2012. Objections and requests for hearings must be received on or before December 17, 2012, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2011–0759, is available at *http://www.regulations.gov* or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Amaris Johnson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–9542; email address: *johnson.amaris@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 those engaged in the following activities:

- 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 to provide 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 get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those

objections. 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–2011–0759 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before December 17, 2012. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0759, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of November 9, 2011 (76 FR 69690) (FRL–9325–1), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petition (PP) 1E7908 by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540, and PP 1F7905 by Nichino America, Inc., 4550 New Linden Hill Road, Suite 501, Wilmington, DE. The petitions requested that 40 CFR 180.511 be amended by establishing tolerances for residues of the insecticide buprofezin (2-[(1,1-dimethylethyl)imino]tetrahydro-3(1-methylethyl)-5-phenyl-4*H*-1,3,5-thiadiazin-4-one) in or on bean, succulent at 0.02 parts per million (ppm); Brassica, leafy greens, subgroup 5B at 55 ppm; turnip, greens at 55 ppm; vegetable, fruiting, group 8–10 at 3.0 ppm; fruit, citrus, group 10–10 at 2.5 ppm; fruit, pome, group 11–10 at 4.0 ppm; persimmon at 1.9 ppm; and tea at 20 ppm (PP 1E7908) and PP 1F7905 requested tolerances for residues in or on nut, tree, group 14 at 0.05 ppm and pistachios at 0.05 ppm. PP 1E7908 also requested removal of tolerances for non-bell pepper; fruiting vegetable group 8, except non-bell pepper; fruit, citrus, group 10; and fruit, pome, group 11 which will be covered by the newly requested tolerances. That notice referenced a summary of the petition prepared by Nichino America, Inc., the registrant, which is available in the docket, *http://www.regulations.gov.* Two general comments were received on the notice of filings. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance levels for several commodities. Due to insufficient data, EPA is not establishing the citrus group 10–10 tolerance. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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 * * *.''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for buprofezin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with buprofezin 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.

Buprofezin has low acute toxicity via the oral, dermal and inhalation routes of exposure. It is not an eye or skin irritant; nor is it a dermal sensitizer. In subchronic toxicity studies, the primary effects of concern in the rat were increased microscopic lesions in male and female liver and thyroid, increased liver weights in males and females, and increased thyroid weight in males. 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. The increase in carcinomas was not statistically significant when analyzed separately. Based on the increased incidence of combined benign and malignant liver tumors in female mice only, no evidence of carcinogenicity in rats, and no evidence of genotoxicity in submitted guideline studies using *in vitro* and *in vivo* genotoxicity assays, EPA classified buprofezin as having no greater than suggestive evidence of carcinogenicity.

Developmental and reproductive toxicity studies do not indicate concern for increased susceptibility in offspring. Toxicity in the offspring was found at dose levels that were also toxic to the parent and the effects observed in the offspring were not more severe, qualitatively, than the effects observed in the parent. No neurotoxic effects were observed at any dose in a subchronic neurotoxicity study in rats at the highest dietary doses of 5,000 ppm. An immunotoxicity study did not demonstrate immunotoxic effects by buprofezin. A special study is required to generate specific data on the thyroid to protect the developing nervous

system from thyroid hormone disrupting chemicals.

Specific information on the studies received and the nature of the adverse 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 at *http://www.regulations.gov* in the document ''Buprofezin Human Health Risk Assessment for Proposed Use of Buprofezin on Tree Nut Crop Group 14 including Pistachio, Brassica Leafy Greens Subgroup 5B, Turnip Greens, Tea and Persimmon & Expanded Uses on Fruiting Vegetables, Succulent Beans, Citrus Fruit, and Pome Fruit,'' pp. 40—42 in docket ID number EPA–HQ–OPP–2011–0759.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for buprofezin used for human risk assessment is shown in the Table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BUPROFEZIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–49 years of age).	NOAEL = 200 mg/kg/day UF_A = 10 UF_H = 10 FQPA SF = 1x	Acute RfD = 2.0 mg/kg/day aPAD = 2.0 mg/kg/day	Developmental Toxicity Study-Rat. LOAEL = 800 mg/kg/day based on reduced ossification & decreased body weight in offspring.
Acute dietary (General population including infants and children).	No endpoint is available for this population because no effect attributable to a single day oral exposure was observed in animal studies.		
Chronic dietary (All populations).	NOAEL= 1.0 mg/kg/day UF_A = 3 UF_H = 10 FQPA SF = 10 UF_{DB}	Chronic RfD = 0.033 mg/kg/day cPAD = 0.0033 mg/kg/day	Two-year Chronic Toxicity/Carcinogenicity 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).	Suggestive Evidence of Carcinogenicity. The cRfD would be protective of potential carcinogenic effects from exposure to buprofezin.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to buprofezin, EPA considered exposure under the petitioned-for tolerances as well as all existing buprofezin tolerances in 40 CFR 180.511. EPA assessed 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.

Such effects were identified for buprofezin in the population subgroup females age 13–49. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance level residues for buprofezin and estimated residue levels of the BF4 Conjugate, a metabolite of concern, based on buprofezin metabolism data. The BF4 Conjugate is not detectable by data collection methods and thus is not included in the tolerance level. Given the potential for the buprofezin metabolites BF9 and BF12 to concentrate to a greater degree than buprofezin in processed commodities, Dietary Exposure Evaluation Model (DEEM) (Version 7.81) default processing factors were retained for all commodities, except for tomato paste and puree, which were reduced based on empirical data. Total residues of concern in meat and milk were based on feeding study data. EPA also assumed 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. A refined chronic dietary analysis was conducted using PCT estimates when available and 100 PCT for all other crops. Buprofezin residues in crop commodities were estimated based on average residue levels from field trial data, average residue levels from USDA Pesticide Data Program (PDP) data, or tolerance level residues. As with the acute exposure assessment,

EPA estimated residue levels of the metabolite BF4 Conjugate were based on metabolism data. Given the potential for the buprofezin metabolites BF9 and BF12 to concentrate to a greater degree than buprofezin in processed commodities, DEEM (Version 7.81) default processing factors were retained for all commodities, except for tomato paste and puree, which were reduced based on empirical data. Total residues of concern in meat and milk were based on feeding study data.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to buprofezin and the cRfD would be protective of cancer effects.

The cRfD was based on an endpoint of toxicity from a rat combined chronic/oncogenicity study. The NOAEL in this study was 1.0 mg/kg/day based on increased incidence of follicular cell hyperplasia and hypertrophy in the thyroid of males at 8.7 mg/kg/day. Buprofezin was not carcinogenic in rats. Administration of buprofezin in the diet was associated with increased incidence of liver tumors in female mice only at the mid- and high-doses but not at the low dose of 1.82 mg/kg/day which was considered to be the NOAEL for the females. Because the positive evidence of cancer was limited to one sex of one species (female mice), there was no evidence of mutagenicity, and no carcinogenic effects in rats, EPA concluded that the weight-of-the-evidence indicated that the carcinogenic findings in female mice are a threshold effect. The NOAEL of 1 mg/kg/day from the rat study on which the cRfD is based on is lower than the NOAEL for liver tumors of 1.82 mg/kg/day from the mouse. Therefore, the cRfD would be protective of potential carcinogenic effects from exposure to buprofezin.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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:

- Condition a: 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 the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: 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 FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows:

Almond 1%; Cantaloupes 5%; Cotton 1%; Grapefruit 1%; Honeydew 2.5%: Lemons 2.5%; Lettuce (head and leaf) 1%; Oranges 2.5%; Pears 15%; Pistachio 5%; Pumpkins 1%; Squash (summer) 1%; Tomatoes 2.5%; Watermelons 2.5%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

Buprofezin has only been registered for use on some commodities since late 2009. Therefore, PCT estimates based on actual usage data were not deemed sufficient indicators of potential usage on these recently registered crops. In 2009 the EPA used PCT estimates for these commodities based on the market leader approach and has determined these are still appropriate estimates to be used in risk assessment. The Agency estimated the PCT for the uses registered in 2009 as follows:

Spinach 30%; Celery 18%; Broccoli 55%; Cabbage 40%, Celery 18%, Chinese Broccoli 55%; Brussel Sprouts 61%; Cauliflower 48%; Kohlrabi 5%; Apple 5%; Apricot 51%; Cherry 72%; Nectarine 51%; Peach 13%; Plum 37%; Grape 15%; Strawberry 39%;

For additional information regarding the PCT estimates for these commodities refer to the final rule published in the **Federal Register** of July 10, 2009 (74 FR 33153) (FRL–8421–3).

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, 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 reliable 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 used screening level water exposure models in the dietary exposure analysis and risk assessment for buprofezin in drinking water. These simulation models take into account

data on the physical, chemical, and fate/transport 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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of buprofezin for acute exposures are estimated to be 58.2 parts per billion (ppb) for surface water and 0.09 ppb for ground water. The EDWCs for chronic exposures are estimated to be 18.6 ppb for surface water and 0.09 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 58.2 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 18.6 ppb was used to assess 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 any specific use patterns 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.''

EPA has not found buprofezin to share a common mechanism of toxicity with 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 assumed that buprofezin does not have 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 EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10x) 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10x, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased quantitative or qualitative susceptibility following *in utero* (rats and rabbits) and pre-and post-natal exposure (rats) to buprofezin.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x for acute exposures. However, the 10x FQPA safety factor has been retained for chronic exposure. These decisions are based on the following findings:

i. The toxicity database for buprofezin is complete except for submission of the thyroid toxicity study that will inform the Agency's understanding of buprofezin's chronic effects. A chronic POD of 1.0 mg/kg/day (NOAEL) was selected for the general population from a 2-year chronic feeding study in rats based on increased incidence of follicular cell hyperplasia and hypertrophy in the thyroid in males at the LOAEL of 8.7 mg/kg/day. A UF 300× (10× for intraspecies variation; 3× for interspecies extrapolation—reduced from 10× based on demonstrated evidence that rats are more susceptible to thyroid effects than humans; 10× for protection of infants and children) was applied to the dose to obtain a cPAD. The 10× FQPA Safety Factor was retained due to uncertainty caused by the lack of a thyroid assay in young rats. In rat chronic, subchronic, and reproductive toxicity studies effects such as thyroid enlargement and follicular cell hyperplasia were seen in adult animals. However, hormone levels, thyroid organ weights, and histopathology were not evaluated for pups in any reproductive studies. To assess the potential toxic characteristics to thyroid structure or hormone homeostasis during development, the Agency is requiring a developmental thyroid study.

ii. There is no indication that buprofezin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that buprofezin results in increased susceptibility to *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessment was performed based on 100 PCT and a conservative estimate of total residues of concern for buprofezin. The chronic dietary food exposure assessment was performed based, in part on, average field trial residues, average USDA PDP residues, and PCT were used where available. Nonetheless, the chronic exposure assessment is conservative and is likely to overestimate risks based on a number of factors including, use of 100 PCT assumptions for several crops for which data were unavailable, use of a conservative factor to account for the BF4 Conjugate, use of default processing factors, and use of drinking water exposure estimates for application of buprofezin to coffee, which is grown in limited areas of the U.S. (e.g., Puerto Rico, Hawaii). Likewise, EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to buprofezin in drinking water. These assessments will not underestimate the exposure and risks posed by buprofezin.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

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 aPAD for females 13–49 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to buprofezin from food and water will utilize 91% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for buprofezin.

3. *Short and intermediate-term risk.* Short and intermediate-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short and intermediate-term adverse effect was identified; however, buprofezin is not registered for any use patterns that would result in short-term residential exposure. Short and intermediate-term risk is assessed based on short and intermediate-term residential exposures plus chronic dietary exposure. Because there is no short and intermediate-term residential exposures and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short and intermediate-term risk), no further assessment of short and intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short and intermediate-term risk for buprofezin.

4. *Aggregate cancer risk for U.S. population.* The Agency considers the chronic aggregate risk assessment, making use of the cPAD, to be protective of any aggregate cancer risk. Based on the limited evidence of carcinogenicity (driven by benign liver tumors) of buprofezin to female mice only and not males or rats, and no mutagenicity, EPA concluded a threshold approach is appropriate for the risk assessment. Therefore, the chronic assessment is considered protective for the cancer risk estimate.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate gas chromatography with nitrogen phosphorus detection (GC/NPD) and a GC/mass spectrometry (MS) method for confirmation of buprofezin residues in plant commodities is available to enforce the tolerance. These methods are available in the Pesticide Analytical Manual (PAM) Volumes I & II for enforcement of buprofezin tolerances.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The tolerance level being established by this action for tree nut group 14 is harmonized with the Codex MRL for almond. There is an established Codex MRL of 2.0 ppm in/on pepper and 1.0 ppm in/on tomato. The petitioner proposed a tolerance of 3.0 ppm for the Fruiting vegetable group 8–10, which contains both peppers and tomatoes. EPA cannot harmonize the U.S. tolerance on tomatoes with the tomato MRL because the residue field trial data submitted to support the fruiting vegetable group 8–10 tolerance reported residues higher than the 1.0 ppm level established by Codex for tomato. However, the residue field trial data was consistent with a tolerance of 2.0 ppm for the fruiting vegetable group 8–10, so EPA was able to harmonize with the Codex MRL for peppers. For pome fruit, the Codex MRLs and the U.S. tolerances are harmonized for ''fruit, pome (except pear and pear, Asian) at 3.0 ppm and pear and pear, Asian at 6.0 ppm. There are currently no established Codex MRLs for buprofezin in/on the remainder of the tolerances being established.

C. Response to Comments

EPA received two comments to the notice of filings PP 1E7908 and 1F7905, which said that toxic chemicals should not be allowed on food that Americans eat. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

D. Revisions to Petitioned-for Tolerances

The tolerance for fruit, citrus, group 10–10 is not being established at this time due to a lack of residue chemistry data. Based on the data supporting the petition, EPA has revised the proposed tolerance on Brassica, leafy greens, subgroup 5B and turnip greens from 55 ppm to 60 ppm. The Agency revised these tolerance levels based on analysis of the residue field trial data using the Organization for Economic Co-operation and Development (OECD) tolerance calculation procedures.

Additionally, the Agency revised the proposed tolerance in or on vegetables, fruiting, group 8–10 from 3.0 to 2.0 to harmonize with the Codex MRL on pepper and will establish separate tolerances for fruit, pome, group 11–10 (except pear and pear, Asian) at 3.0 ppm and pear and pear, Asian oriental at 6.0 ppm to harmonize with Codex. A tolerance is not needed for pistachio since there is already a pistachio tolerance in § 180.511. Finally, the Agency is correcting language for established commodities that are spelled incorrectly—Llama should be Ilama and Loganberry should be Logan.

V. Conclusion

Therefore, tolerances are established for residues of buprofezin 2-[(1,1-dimethylethyl)imino]tetrahydro-3(1-methylethyl)-5-phenyl-4*H* -1,3,5-thiadiazin-4-one, in or on bean, succulent at 0.02 ppm; Brassica, leafy greens, subgroup 5B at 60 ppm; fruit, pome, group 11–10 (except pear and pear, Asian) at 3.0 ppm; nut, tree, group 14 at 0.05 ppm; pear at 6.0 ppm; pear, Asian at 6.0 ppm; persimmon at 1.9 ppm; tea at 20 ppm; Turnip, greens at 60 ppm; vegetable, fruiting, group 8–10 at 2.0 ppm. Additionally, this regulation removes tolerances of buprofezin in or on almond at 0.05 ppm, fruit, pome group 11 at 4.0 ppm, okra at 4.0 ppm, nonbell pepper at 4.0 ppm and vegetable, fruiting group 8, except nonbell pepper at 1.3 ppm as they will be superseded by the tolerances being established with this action.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). 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.,* 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).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: October 4, 2012.

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. In § 180.511 the table in paragraph (a) is amended as follows:

■ i. Remove the entries for Almond; Fruit, pome, group 11; Okra; Pepper, nonbell and Vegetable, fruiting, group 8, except nonbell pepper;

■ ii. Revising the entries for Llama and Loganberry to read Ilama and Logan respectively; and

■ iii. Add alphabetically new entries.

The revisions and additions read as follows:

§ 180.511 Buprofezin; tolerances of residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Bean, succulent	0.02
* * * * *	
Brassica, leafy greens, subgroup 5B	60
* * * * *	
Fruit, pome, group 11–10, except pear and pear, Asian	3.0
* * * * *	
Ilama	0.30
* * * * *	
Logan	0.30
* * * * *	
Nut, tree group 14	0.05
* * * * *	
Pear	6.0
Pear, Asian	6.0
Persimmon	1.9
* * * * *	
Tea[1]	20
Turnip, greens	60
* * * * *	
Vegetable, fruiting, group 8–10	2.0
* * * * *	

[1] There are no U.S. registrations at this time.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412

[CMS–1588–F2]

RIN 0938–AR12

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers; Correcting Amendment

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correcting amendment.