ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0589; FRL–8421–3]

Buprofezin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the residues of buprofezin in or on Brassica, head and stem, subgroup 5A; coffee, green bean; and pomegranate. Interregional Research Project Number 4 (IR–4) requested the tolerances for residues in or on coffee and pomegranates under the Federal Food, Drug, and Cosmetic Act (FFDCA). Nichino America, Inc., requested the tolerances for residues in or on Brassica, head and stem, subgroup 5A under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 10, 2009. Objections and requests for hearings must be received on or before September 8, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0589. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Samantha Hulkower, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 603–0683; e-mail address: *hulkower.samantha@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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2008–0589 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 as required by 40 CFR part 178 on or before September 8, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0589, by one of the following methods:

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

II. Petition for Tolerance

In the **Federal Register** of June 4, 2008 (73 FR 31862–31864) (FRL–8365–3), 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 8F7343) by Nichino America, Inc., 4550 New Linden Hill Rd., Suite 501, Wilmington, Delaware 19808. The petition 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-4H-1,3,5-thiadiazin-4-one, in or on Brassica, head and stem, subgroup 5A at 7.0 parts per million (ppm). In the **Federal Register** of August 13, 2008 (73 FR 47184) (FRL–8376–8), 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 8E7386) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition 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-4H-1,3,5-thiadiazin-4-one, in or on coffee at 0.35 ppm and in or on pomegranate at 1.9 ppm. Those notices referenced a

summary of the petition prepared by Nichino America, Inc., the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notices of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance levels for buprofezin in or on Brassica, head and stem, subgroup 5A. The reason 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 section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for the petitioned-for 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 Brassica, head and stem, subgroup 5A at 12.0 ppm, in or on coffee, green bean at 0.35 ppm, and in or on pomegranate at 1.9 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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. Based on the increased incidence of 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 suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential.

There is no evidence that buprofezin results in increased susceptibility of *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. Toxicity in the offspring was found at dose levels that were also toxic to the parent(s), and the effects observed in the offspring were not more severe, qualitatively, than the effects observed in the parent(s).

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 Revised Human Health Risk Assessment for Proposed Use of Buprofezin on Coffee, Pomegranate, and Brassica Head and Stem Crops (Subgroup 5A)*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as document ID number EPA–HQ–OPP–2008–0589–0005 in that docket.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account 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. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 can be found at *http://www.regulations.gov* in document *Buprofezin Revised Human Health Risk Assessment for Proposed Use of Buprofezin on Coffee, Pomegranate, and Brassica Head and Stem Crops (Subgroup 5A)* page 18 in docket ID number EPA–HQ–OPP–2008–0589.

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 in the toxicological studies for buprofezin for the population subgroup females 13–50 years old; no such effects were identified for the general population or other population subgroups.

In estimating acute dietary exposure of females 13–50 years old, 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 that residues are present at tolerance levels in all commodities except meat and milk. Anticipated residues were calculated for meat and milk commodities as follows: Tolerances for meat and milk are established at the analytical method limit of quantitation (LOQ). For milk, the residues of concern are buprofezin and an additional metabolite, BF23. Combined residues were included in the dietary exposure assessment, as appropriate, based on amounts detected in the dietary feeding study. Since residues were only detected in milk samples collected from cows fed feed containing 9.3x the maximum theoretical dietary burden (MTDB) for dairy cattle, residues in milk were normalized to 1x the MTDB in the acute dietary exposure assessment. For ruminant tissues, the residues of concern are buprofezin and an additional metabolite, BF2. Combined residues were included in the dietary exposure assessment as appropriate, based on amounts detected in the dietary feeding study. Since residues were only detected in tissue samples collected from cows fed feed containing 6.8x the MTDB, residues in meat, kidney, liver, fat, and meat byproducts were normalized to 1x the MTDB in the acute dietary exposure assessment. For fruits and crops with an extended interval from initial application to harvest (>50 day), additional metabolites of toxicological concern (BF4 and its conjugates, and BF12) were included in the dietary exposure assessment, as appropriate, based on the ratio of metabolite to parent found in plant metabolism studies. No adjustment was made to account for the percent of crops treated with buprofezin in the acute dietary exposure assessment. 100 percent crop treated (PCT) was assumed for all commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Departmemt of Agriculture (USDA) 1994–1996 and 1998 CSFII. As to residue levels in food, EPA conducted a refined dietary analysis. The chronic analysis assumed average field trial, average USDA Pesticide Data Program (PDP), or tolerance-level crop residues, based on the available data. The chronic analysis employed the same anticipated residue estimates for meat and milk as those employed in the acute analysis. As in the acute analysis, for fruits and crops with an extended interval from initial application to harvest (>50 day), additional metabolites of toxicological concern (BF4 and its conjugates, and BF12) were included in the dietary exposure assessment, as appropriate, based on the ratio of metabolite to parent found in plant metabolism studies. The chronic analysis used available screening-level PCT estimates or projected PCT estimates for some commodities. If no PCT data were available, 100 PCT was assumed. Default processing factors were assumed for all commodities excluding tomato paste and puree. The tomato paste and puree processing factors were reduced to 1.2x based on the results of a tomato processing study.

iii. *Cancer*. EPA has classified buprofezin as having suggestive evidence based on the occurrence of liver tumors in female mice. Since the increased incidence of liver tumors occurred in female mice only and there was no evidence of carcinogenicity in rats or evidence of genotoxicity in submitted guideline studies using *in vitro* and *in vivo* genotoxicity assays, EPA regards the carcinogenic potential of buprofezin as very low. Therefore, an exposure assessment for evaluating cancer risk was not conducted.

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 used PCT information as follows:

PCT estimates for existing uses: Almond 1%; cantaloupe 5%; cotton 1%; grapefruit juice 1%; grapefruit 1%; orange juice 1%; other citrus 2.5%; honeydew 2.5%; pear 15%; pistachio 1%; pumpkin 10%; squash 10%; and watermelon 2.5%.

In most cases, EPA uses available data from USDA National Agricultural Statistics Service (NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 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%.

The Agency used projected percent crop treated (PPCT) information as follows:

EPA used PPCT estimates for the following commodities: Apple 5%; peach 13%; apricot 51%; nectarine 60%; cherry 72%; plum 37%; grapes 15%; broccoli 55%; cabbage 40%; kohlrabi 5%; Chinese broccoli 55%;

cauliflower 48%; cabbage 40%; Brussels sprouts 61%; mustard 13%; celery 18%; head lettuce 67%; lettuce leaf 63%; spinach 30%; strawberry 39%; tomato (fresh) 42%; and tomato (processing) 25%.

EPA estimates PPCT for a new pesticide use by assuming that the PCT during the pesticide's initial five years of use on a specific use site will not exceed the average PCT of the market leader (i.e., the one pesticide with the greatest PCT) on that site over the three most recent surveys. Comparisons are only made among the chemicals of the same pesticide type (i.e., the leading insecticide on the use site is selected for comparison with the new insecticide). The PCT values included in the averages may be for the same pesticide or for different pesticides, since the same or different pesticides may dominate for each year selected. Typically, EPA uses USDA/NASS as the primary source for PCT data. When a specific use site is not surveyed by USDA/NASS, EPA uses other sources including proprietary data and calculates the PPCT.

This estimated PPCT, based on the average PCT of the market leader, is appropriate for use in chronic dietary risk assessment. The method of estimating a PPCT for a new use of a registered pesticide or a new pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial five years of actual use. The predominant factors that bear on whether the estimated PPCT could be exceeded are whether a new pesticide use or new pesticide controls a broader spectrum of pests than the dominant pesticide; whether there are concerns that increasing pest pressure may intensify the use of alternate pesticides; and/or whether the new pesticide has a shorter pre-harvest or re-entry interval than alternative insecticides. Based on all information currently available, EPA concludes that it is unlikely that actual PCT for buprofezin will exceed the PPCT during the next five years. A discussion of the factors considered in making this determination can be found in the documents *Update of PPCT Values Provided Previously for Use of Buprofezin on Grapes, Apricots, Nectarines, Sweet and Tart Cherries, Plums, Apples and Peaches (December 5, 2008)*; *PPCT for the Insecticide Buprofezin on five crops: Celery, Lettuce, Spinach, Strawberries, and Tomatoes (January 9, 2008)*; *PPCT Values for Buprofezin Use on Six New Crops: Broccoli, Cabbage, Cauliflower, Brussels sprout, Kohlrabi, and Mustard (December 5, 2008)*; and in Attachment #2 to the document *Buprofezin - Acute and Chronic Dietary and Drinking Water Exposure and Risk Assessments (January 14, 2009)*. The referenced documents are available at *www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0589.

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 57.4 parts per billion (ppb) for surface water and 0.09 ppb for ground water. The EECs 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 57.4 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of 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 website 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 of *in utero* rat or rabbit fetuses from exposure to buprofezin in prenatal

developmental toxicity studies; and there is no evidence of increased quantitative or qualitative susceptibility of rat offspring in the 2-generation reproduction study. There is evidence of thyroid toxicity following subchronic and chronic exposures of rats and dogs to buprofezin; however, data to determine whether young animals are more susceptible to these effects are not available.

3. *Conclusion*. EPA has determined that the FQPA safety factor of 10X must be retained and applied to all subchronic and chronic exposures whose endpoint is based on thyroid effects. For acute exposures, EPA has determined that the FQPA safety factor may be reduced to 1X. These decisions are based on the following findings:

i. The toxicity database for buprofezin lacks immunotoxicity testing; acute and subchronic neurotoxicity testing; and developmental thyroid testing. EPA began requiring functional immunotoxicity and acute and subchronic neurotoxicity testing of all food and non-food use pesticides on December 26, 2007. These studies are not yet available for buprofezin. In the absence of these data, EPA has evaluated the available buprofezin toxicity data to determine whether an additional database uncertainty factor is needed. In the available toxicity studies, there are no indications of effects on organs associated with immune function, such as the thymus and spleen. In addition, there are no indications of neurotoxic effects. Based on that, EPA does not believe that immurotoxicity or acute and subchronic testing would result in a lower POD for buprofezin that currently used. As such, an additional database uncertainty factor is not needed to account for potential immunotoxicity or acute and subchronic neurotoxicity.

However, there is uncertainty regarding potential thyroid effects seen in some of the toxicity studies. Based on the evidence of thyroid toxicity following subchronic and chronic exposures of rats (histopathological lesions) and dogs (decreases in serum thyroxine levels and increased thyroid weights), EPA has required that develomental thyroid testing be conducted.

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 in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. However, the developmental studies were not adequate to fully assess the potential for thyroid susceptibility from subchronic and chronic exposures. Consequently, there is concern for potential increased sensitivity or susceptibility in offspring regarding thyroid effects.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were refined for some commodities using reliable PCT/PPCT information and anticipated residue values calculated from the available monitoring data and field trial results. Dietary drinking water exposure is based on conservative modeling estimates. Residential exposures are not expected. These assessments will not underestimate the exposure and risks posed by buprofezin.

Although there are no residual uncertainties identified in the exposure databases, no neurotoxic concerns for buprofezin, and no evidence of increased susceptibility of offspring in available studies, there is sufficient uncertainty regarding thyroid effects, particularly thyroid effects in the young, that EPA is retaining the 10X FQPA safety factor for all subchronic and chronic exposures whose endpoint is based on thyroid effects. The FQPA Safety Factor of 10X is not applicable to the acute endpoint, since a single dose of buprofezin would not be expected to perturb thyroid homeostasis in the adult or young due to the buffering of thyroid hormone concentrations by homeostatic mechanisms for compounds with short half lives, like buprofezin.

EPA has also determined that the traditional 10X uncertainty factor to account for interspecies variation may be reduced to 3X for subchronic and chronic exposures, since it has been established that rats are more susceptible to thyroid effects than humans. These factors, together with the traditional 10X uncertainty factor to account for intraspecies variation, result in a total uncertainty factor of 300X (10X, 3X and 10X) for subchronic and chronic exposures. The total uncertainty factor for acute exposures is 100X (10X intraspecies variation and 10X interspecies variation).

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

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 7% of the aPAD for the population group females 13–49 years old. No adverse effect resulting from a single-oral exposure was identified for the remaining population groups and no acute dietary endpoint was selected. Therefore, buprofezin is not expected to pose an acute risk.

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 80% of the cPAD for the population groups receiving the greatest exposure, all infants <1 year old and children 1–2 years old.

Therefore, buprofezin is not expected to pose a chronic risk.

There are no residential uses for buprofezin.

3. *Short-term and intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Buprofezin is not registered for any use patterns that would result in residential exposure. Therefore, the short-term and intermediate-term aggregate risk is the sum of the risk from exposure to buprofezin through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population*. As discussed in Unit III.C.1.iii. EPA regards the carcinogenic potential of buprofezin as very low and concludes that it poses no greater than a negligible cancer risk to humans.

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

The gas chromatography/nitrogen phosphorus detector methods used in

the field trial studies were adequately validated and similar to the method validated by EPA's Analytical Chemistry Branch (ACB) and forwarded to the Food and Drug Administration for publication in the Pesticide Analytical Manual I. Since adequate method validation and concurrent recoveries were attained in the field trial studies, EPA concludes that the method validated by ACB is appropriate for enforcement of the tolerances associated with these petitions.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no Canadian, Mexican, or Codex maximum residue limits (MRLs) established for buprofezin in/on any of the commodities associated with the current petitions, except tomato. There are Codex and Mexican MRLs for residues of buprofezin *per se* on tomato of 1 ppm and 0.5 ppm, respectively. Both MRLs are lower than the tolerance of 1.3 ppm being established for fruiting vegetables, a group which includes tomato; however, since the field trial data considered in determining the U.S. tolerance level indicate the potential for residues in/on tomato to exceed the international MRLs, harmonization is not possible at this time.

C. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petitions, EPA has revised the tolerance level for Brassica, head and stem, subgroup 5A from 7.0 ppm to 12.0 ppm. EPA revised this tolerance level based on analyses of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data. EPA also revised the tolerance expression to clarify 1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of buprofezin not specifically mentioned; and 2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression. This change makes no substantive change to the meaning of the tolerance but rather only clarifies the existing language.

V. Conclusion

Therefore, tolerances are established 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 Brassica, head and stem, subgroup 5A at 12.0 ppm; in or on coffee, green bean at 0.35 ppm; and in or on pomegranate at 1.9 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 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 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.

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 section 408(n)(4) of FFDCA. 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) (Pub. L. 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: July 1, 2009.

G. Jeffery Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

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

§ 180.511 Buprofezin; tolerances for residues.

(a) *General.* Tolerances are established for residues of buprofezin, including its metabolites and degradates in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the buprofezin, 2-[(1,1-dimethylethyl)imino]tetrahydro-3(1-

methylethyl)-5-phenyl-4*H*-1,3,5-thiadiazin-4-one, in the commodity.

Commodity	Parts per million
* * * * *	
Brassica, head and stem, subgroup 5A	12.0
* * * * *	
Coffee, green bean	0.35
* * * * *	
Pomegranate	1.9
* * * * *	

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[FR Doc. E9–16367 Filed 7–9–09; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0271; FRL–8424–9]

Indoxacarb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of indoxacarb and its metabolites and degradates, to be determined by measuring only indoxacarb and its R-enantiomer, in or on beet, garden, roots; beet, garden, tops; and bushberry subgroup 13–07B. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 10, 2009. Objections and requests for hearings must be received on or before September 8, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0271. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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 Access Electronic Copies of this Document?

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

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2008–0271 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 as required by 40 CFR part 178 on or before September 8, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0271, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.