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 6, 2000) do not apply to this rule. In addition, This 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: March 26, 2008.

Daniel C. Kenny,

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 180.553 is amended by alphabetically adding the following commodities to/in the table in paragraph (a) to read as follows:

§180.553 Fenhexamid; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Asparagus	0.02
* * *	* *

* * * * *

[FR Doc. E8–7038 Filed 4–8–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0426; FRL–8356–9]

Buprofezin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of buprofezin in or on berry, low growing , subgroup 13-07G; okra; olive; olive, oil; pepper, nonbell; radicchio; vegetable, fruiting, group 8, except nonbell pepper; and vegetable, leafy, except *Brassica*, group 4, except head lettuce and radicchio; and increases the existing tolerance for residues of buprofezin in or on head lettuce. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also removes existing tolerances for residues of buprofezin in or on leaf lettuce and tomato and modifies 40 CFR 180.511 by removing the third column (Expiration/Revocation Date) from the table in paragraph (a), since it is no longer applicable.

DATES: This regulation is effective April 9, 2008. Objections and requests for hearings must be received on or before June 9, 2008, 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–2007–0426. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather 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 an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2007–0426 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 June 9, 2008.

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–2007–0426, 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'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 July 25, 2007 (72 FR 40877) (FRL–8137–1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E7207) 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-4*H*-1,3,5-thiadiazin-4-one, in or on vegetable, leafy, except *Brassica*, group 4 at 25 parts per million (ppm); olive at 3.0 ppm; olive, oil at 9.0 ppm; and strawberry, bearberry, bilberry, lowbush blueberry, cloudberry, cranberry, lingonberry, muntries and partridge berry at 2.5 ppm. That notice referenced a summary of the petition prepared by Ninchino America, Inc., the registrant, which is available to the public in the docket, *http://www.regulations.gov*.

In the **Federal Register** of October 24, 2007 (72 FR 60369) (FRL–8150–8), 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 7E7253) 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-4*H*-1,3,5-thiadiazin-4-one, in or on vegetable, fruiting, group 8; and okra at 1.8 ppm. That notice referenced a summary of the petition prepared by Ninchino America, Inc., the registrant, which is available to the public in the docket, *http://www.regulations.gov*.

Comments were received in response to the notices of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petitions, EPA has revised the tolerance levels for several commodities (okra; olive; olive, oil; vegetable, leafy, except *Brassica,* group 4; and vegetable, fruiting, group 8) and determined that separate tolerances are appropriate for head lettuce and radicchio of the leafy vegetable, except *Brassica*, group 4; and nonbell pepper of the fruiting vegetable group 8. EPA has also determined that a tolerance on berry, low growing, subgroup 13-07G is appropriate in lieu of the proposed tolerances on individual berry commodities. 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....'' These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

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 the petitioned-for tolerance for residues of buprofezin, 2-[(1,1-dimethylethyl)imino]tetrahydro-3(1-methylethyl)-5-phenyl-4*H*-1,3,5-thiadiazin-4-one, on berry, low growing, subgroup 13-07G at 2.5 ppm; lettuce, head at 6.0 ppm; okra at 4.0 ppm; olive at 3.5 ppm; olive, oil at 4.8 ppm; pepper, nonbell at 4.0 ppm; radicchio at 6.0 ppm; vegetable, fruiting, group 8, except nonbell pepper at 1.3 ppm; and vegetable, leafy, except *Brassica*, group 4, except head lettuce and radicchio at 35 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

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 but found the evidence to be sufficiently weak that quantification of cancer risk was not deemed to be appropriate.

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 - Human-Health Risk Assessment for Application to Low-Growing Berries, Olives, Leafy Vegetables (except Brassica), and Fruiting Vegetables*. 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–2007–0426-0004 in that docket.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from 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) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC 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 risks by comparing aggregate 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 LOC by all applicable UFs. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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 - Human-Health Risk Assessment for Application to Low-Growing Berries, Olives, Leafy Vegetables (except Brassica), and Fruiting Vegetables* at page 11. 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–2007–0426-0004 in that docket.

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 USDA 1994-1996 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). Since residues were only detected in the livestock feeding study when feed contained 6.8-9.3x the maximum theoretical dietary burden (MTDB), residues in these commodities 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) that are not included in the tolerance expression 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 USDA 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA relied upon anticipated residues and PCT information for some commodities. The

chronic analysis employed the same anticipated residue estimates for meat and milk as those employed in the acute analysis. For apple, pear, orange, and orange juice, average residues from the 2003, 2004 and/or 2005 USDA Pesticide Data Program (PDP) monitoring data were used for estimation of total buprofezin and metabolite residues. For all other plant commodities, tolerance-level or average field trial residues were used. 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) that are not included in the tolerance expression 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 incorporated screening-level PCT estimates for several registered crops and projected percent crop treatment (PPCT) estimates for apple, peach, apricot, nectarine, cherry, plum, celery, lettuce, spinach, strawberry and tomato. Default processing factors were assumed for all commodities except tomato paste and purèe. The tomato paste and purèe 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 and has determined that quantification of human cancer risk is not appropriate. Therefore, a cancer exposure assessment 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 pursuant to FFDCA section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. 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 this tolerance.

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:

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 such pesticide residue.

b. The exposure estimate does not underestimate exposure for any significant subpopulation group.

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%; citrus 1%; grape 1%; honeydew 1%; pear 10%; pistachio 1%; pumpkin 1%; squash 1%; and watermelon 1%.

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available federal, state, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of five percent except for those situations in which the average PCT is less than one. In those cases 1% is used as the average. 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 Center for Food and Agriculture Policy (NCFAP) for the most recent six years.

EPA used PPCT estimates for the following commodities: Apple 5%; peach 13%; apricot 40%; nectarine 60%; sweet cherry 44%; tart cherry 76%; plum 35%; celery 18%; head lettuce 67%; lettuce (other) 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 is more efficacious or 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 *Projected Percent Crop Treated for the Insecticide Buprofezin on Six Crops: Grapes, Apricots, Nectarines, Sweet Cherries, Tart Cherries, and Plums* and *Projected Percent Crop Treated (PPCT) for the Insecticide Buprofezin on Five Crops: Celery, Lettuce, Spinach, Strawberries, and Tomatoes*; and in Attachment #2 to the document *Buprofezin - Acute and Chronic Dietary Exposure and Risk Assessments*. The referenced documents are available at *www.regulations.gov* in docket ID number EPA–HQ–OPP–2007–0426.

The Agency believes that the three conditions listed in this unit 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 information on the regional consumption of food to which buprofezin may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for buprofezin in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate 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 environmental concentrations (EECs) 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 12.5 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 12.5 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 use on any sites that would result in residential exposure.

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to buprofezin and any other substances and buprofezin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that buprofezin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold (''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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

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 contains all of the standard toxicity studies. However, there is uncertainty regarding potential thyroid effects seen in some of these 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 requested a buprofezin comparative thyroid assay study in rats (28–day; young versus adults) to determine if the thyroid effects occur at a lower dose in young versus adult animals. Since this study has not been submitted, EPA concludes that the 10X FQPA safety factor to account for database uncertainty should be retained and applied to 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 the young due to the buffering of thyroid hormone concentrations by homeostatic mechanisms for compounds with short half lives, like buprofezin.

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 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. EPA has also determined that the traditional 10X uncertainty factor to account for interspecies variation may be reduced to 3X for these 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

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC 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 acute endpoint of concern was identified for the remaining population groups.

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

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

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

5. *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.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, 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. Response to Comments

Comments were received from a private citizen in response to the notices of filing of pesticide petitions PP7E7253 and PP7E7207. In response to the notice of filing of PP7E7207, the commenter indicated that she was unable to open ''the report on the proposal'' and complained generally about the government website, *http://www.regulations.gov*. If by ''the report on the proposal'' the commenter is referring to the registrant's summary of the petition, EPA notes that it is available in the docket in two common file formats, MicroSoft Word and Portable Document Format (PDF,) and cannot explain the commenter's inability to open it. In response to the notice of filing of PP7E7253, the commenter objected to any residues on vegetables and ''exemptions'' for ''this product'' on the basis of its potential carcinogenicity. EPA considered the carcinogenic potential of buprofezin in its risk assessment and determined that it did not pose a cancer risk. Comments received contained no scientific data or other substantive evidence to rebut this conclusion or the Agency's finding that there is a reasonable certainty that no harm will result from aggregate exposure to buprofezin from the establishment of these tolerances. The Agency has received these same or similar comments from this commenter on numerous previous occasions. Refer to **Federal Register** 70 FR 37686 (June 30, 2005), 70 FR 1354 (January 7, 2005), and 69 FR 63096 (October 29, 2004) for the Agency's previous responses to these objections.

D. Changes to Proposed Tolerances

Based upon review of the data supporting the petitions, EPA has revised the tolerance levels for several commodities and determined that separate tolerances are appropriate for certain members of the leafy (except *Brassica*) and fruiting vegetable groups. EPA revised the tolerances for okra from 1.8 ppm to 4.0 ppm; olive from 3.0 ppm to 3.5 ppm; olive, oil from 9.0 ppm to 4.8 ppm; vegetable, leafy, except *Brassica*, group 4, except head lettuce and radicchio from 25 ppm to 35 ppm;

and vegetable, fruiting, group 8, except nonbell pepper from 1.8 ppm to 1.3 ppm. EPA revised these tolerance levels 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* and the results of the olive processing study. EPA also determined that separate tolerances should be established for head lettuce and radicchio at 6.0 ppm and for nonbell pepper at 4.0 ppm, since there is more than a 5-fold difference between residues on these crops and other members of their respective crop groups: vegetable, leafy (except *Brassica*) group 4; and vegetable, fruiting group 8. A tolerance already exists for residues of buprofezin on head lettuce at 5.0 ppm; it will be increased to 6.0 ppm.

IR-4 petitioned for individual tolerances on strawberry, bearberry, bilberry, lowbush blueberry, cloudberry, cranberry, lingonberry, muntries and partridgeberry (PP 6E7163). In the **Federal Register** of December 7, 2007 (72 FR 69150) (FRL–8340–6), EPA issued a final rule that revised the crop grouping regulations. As part of this action, EPA expanded and revised berries group 13. Changes to crop group 13 included adding new commodities, revising existing subgroups and creating new subgroups (including a low growing berry subgroup consisting of the commodities requested in PP 7E7207 and cultivars, varieties, and/or hybrids of these). EPA indicated in the December 7, 2007 final rule as well as the earlier May 23, 2007 proposed rule (72 FR 28920) (FRL–8126–1) that, for existing petitions for which a Notice of Filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA is establishing a tolerance on low growing berry subgroup 13-07G. EPA concludes it is reasonable to establish the tolerance on the newly created subgroup, since the individual commodities for which tolerances were requested are identical to those which comprise low growing berry subgroup 13-07G.

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 berry, low growing , subgroup 13-07G at 2.5 ppm; lettuce, head at 6.0 ppm; okra at 4.0 ppm; olive at 3.5 ppm; olive, oil at 4.8 ppm; pepper, nonbell at 4.0 ppm; radicchio at 6.0 ppm; vegetable, fruiting, group 8, except nonbell pepper at 1.3 ppm; and vegetable, leafy, except *Brassica*, group 4, except head lettuce and radicchio at 35 ppm. Further, the existing tolerances in/on ''lettuce, leaf'' at 13.0 ppm and ''tomato'' at 0.50 ppm are deleted, since residues of buprofezin on these commodities will be covered by the higher tolerances being established on ''vegetable, leafy, except *Brassica*, group 4, except head lettuce and radicchio '' and ''vegetable, fruiting, group 8, except non-bell pepper''.

The table of buprofezin tolerances at 40 CFR 180.511(a) currently includes a third column for expiration/revocation dates. Since none of the existing tolerances is time-limited and EPA is not time-limiting the new tolerances listed in this unit, there is no need for this column. Therefore, the third column of the table is being deleted.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) 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 6, 2000) do not apply to this rule. In addition, This 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: March 26, 2008.

Daniel C. Kenny,

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 by revising paragraph (a) to read as follows:

§ 180.511 Buprofezin; tolerances for residues.

(a) *General.* 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 the following food commodities:

Commodity	Parts per million
Acerola	0.30
Almond	0.05
Almond, hulls	2.0
Apricot	9.0
Atemoya	0.30
Avocado	0.30
Banana	0.20
Bean, snap, succulent	0.02
Berry, low growing, subgroup 13-07G	2.5
Birida	0.30
Canistel	0.90
Cattle, fat	0.05
Cattle, kidney	0.05
Cattle, liver	0.05
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Cherimoya	0.30
Citrus, dried pulp	7.5
Citrus, oil	80
Cotton, gin byproducts	20.0
Cotton, undelinted seed	0.35
Custard apple	0.30
Feijoa	0.30
Fruit, citrus, group 10	2.5
Fruit, pome, group 11	4.0
Fruit, stone, group 12, except apricot and peach	1.9
Goat, fat	0.05
Goat, kidney	0.05
Goat, liver	0.05
Goat, meat	0.05
Goat, meat byproducts	0.05
Grape	2.5
Guave	0.30
Hog, fat	0.05
Hog, kidney	0.05
Hog, liver	0.05
Hog, meat	0.05
Hog, meat byproducts	0.05
Horse, fat	0.05
Horse, kidney	0.05
Horse, liver	0.05
Horse, meat	0.05
Horse, meat byproducts	0.05
Llama	0.30
Jaboticaba	0.30
Lettuce, head	6.0
Loganberry	0.30
Lychee	0.30
Mango	0.90
Milk	0.01
Okra	4.0
Olive	3.5
Olive, oil	4.8
Papaya	0.90
Passionfruit	0.30
Peach	9.0
Pepper, nonbell	4.0
Pistachio	0.05
Pulasan	0.30
Radicchio	6.0
Rambutan	0.30
Sapodilla	0.90
Sapote, black	0.90
Sapote, mamey	0.90
Sheep, fat	0.05
Sheep, kidney	0.05
Sheep, liver	0.05
Sheep, meat	0.05
Sheep, meat byproducts	0.05
Soursop	0.30
Spanish lime	0.30
Star apple	0.90
Starfruit	0.30
Sugar apple	0.30
Vegetable, cucurbit, group 9	0.50
Vegetable, fruiting, group 8, except nonbell pepper	1.3
Vegetable, leafy, except Brassica, group 4, except head lettuce and radicchio	35
Wax jambu	0.30

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BILLING CODE 6560–50–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: Base (1% annual chance) Flood Elevations (BFEs) and modified BFEs are made final for the communities listed below. The BFEs and modified BFEs are the basis for the flood plain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The date of issuance of the Flood Insurance Rate Map (FIRM) showing BFEs and modified BFEs for each community. This date may be obtained by contacting the office where the maps are available for inspection as indicated on the table below.

ADDRESSES: The final BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: William R. Blanton, Jr., Engineering Management Branch, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3151.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Assistant Administrator of the Mitigation Directorate has resolved any appeals resulting from this notification.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for flood plain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community.

The BFEs and modified BFEs are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This final rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

Regulatory Flexibility Act. As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601–612, a regulatory flexibility analysis is not required.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This final rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This final rule meets the applicable standards of Executive Order 12988.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.