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: August 20, 2010.

Lois Rossi,

Director, Registration Division, Office of Pesticide Program.

■ 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 180.607 is amended by alphabetically adding the following commodities to the table in paragraph (a)(1) and revising paragraphs (a)(1) introductory text, (a)(2) introductory text, (b) introductory text, and (d) introductory text to read as follows:

§ 180.607 Spiromesifen; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide/miticide spiromesifen, including its metabolites and degradates, in or on the commodities listed below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of spiromesifen [2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate] and 4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one, calculated as the stoichiometric equivalent of spiromesifen, in or on the following primary crop commodities:

Commodity	Parts per million
* * * * *	
Leaf petiole subgroup 4B	6.0
* * * * *	
Pea, dry, seed	0.20
Peppermint, tops ..	45
Spearmint, tops	45
* * * * *	

(2) Tolerances are established for residues of the insecticide/miticide spiromesifen, including its metabolites and degradates, in or on the commodities listed below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of spiromesifen [2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate] and its metabolites containing the 4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one and 4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one moieties, calculated as the stoichiometric equivalent of spiromesifen, in the following livestock commodities:

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of the insecticide/miticide spiromesifen, including its metabolites and degradates, in or on the commodities listed below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of spiromesifen [2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate] and 4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one, calculated as the stoichiometric equivalent of spiromesifen, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the table.

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for the inadvertent or indirect residues of the insecticide/miticide spiromesifen, including its metabolites and degradates, in or on the commodities listed below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of spiromesifen [2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate], 4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one, and its metabolites containing the 4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one moiety, calculated as the stoichiometric equivalent of spiromesifen, in the following rotational crop commodities:

* * * * *

[FR Doc. 2010–21686 Filed 8–31–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0890; FRL–8840–9]

Bifenazate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of bifenazate in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project #4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation additionally deletes the time-limited tolerance for potato, as the tolerance expired on December 31, 2006, and deletes the time-limited tolerances for tart cherry, soybean hulls, soybean meal, soybean refined oil, and soybean seed, as the tolerances expired on December 31, 2009.

DATES: This regulation is effective September 1, 2010. Objections and requests for hearings must be received on or before November 1, 2010, 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–2009–0890. 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: Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington,

DC 20460–0001; telephone number: (703) 308–9367; e-mail address: *ertman.andrew@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0890 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before November 1, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0890, 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. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 4, 2010 (75 FR 5790) (FRL–8807–5), 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 9E7642) by Interregional Research Project #4 (IR-4), 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.572 be amended by establishing tolerances for residues of the the insecticide bifenazate, (1-methylethyl 2-(4-methoxy[1,1′-biphenyl]-3-yl)hydrazinecarboxylate) and diazinecarboxylic acid, 2-(4-methoxy-[1,1′-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate), in or on sugar apple, cherimoya, atemoya, custard apple, ilama, soursop, and biriba at 1.5 parts per million (ppm); avocado at 7.0 ppm; fruit, small, vine climbing subgroup 13–07F, except fuzzy kiwi fruit at 0.75 ppm; and berry, low growing, subgroup 13–07G at 1.5 ppm. That notice referenced a summary of the petition prepared by Chemtura Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has changed the tolerances for sugar apple, cherimoya, atemoya, custard apple, ilama, soursop, and biriba from the proposed level of 1.5 ppm to 1.6 ppm and for fruit, small, vine climbing subgroup 13–07F, except fuzzy kiwi tolerance from the proposed level of .75 ppm to 1.0 ppm. The reason for these changes is 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 bifenazate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with bifenazate 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.

Bifenazate is not acutely toxic by the oral, inhalation, or dermal routes of exposure. It is minimally irritating to the eye and slightly-irritating to the skin. Bifenazate is a dermal sensitizer by the Magnusson/Kligman method, but not the Buehler method. Subchronic

and chronic studies in rats and dogs indicate that the liver and hematopoietic system (spleen and/or bone marrow with associated hematological findings) are the primary target organs in these species, with additional toxicity in the kidney (chronic dog) and adrenal gland (male rats) also identified. Similarly, the hematopoietic system (spleen) was the primary target organ in the repeat-dose dermal toxicity study. Also associated with this toxicity in several studies were decreased body weight, body-weight gain, and food consumption. No evidence of carcinogenicity was seen in the rat and mouse studies and the Agency has classified bifenazate as "not likely" to be a human carcinogen by any relevant route of exposure. A full battery of mutagenicity studies were negative for mutagenic or clastogenic activity. The developmental studies in rats and rabbits did not demonstrate increased sensitivity of fetuses to bifenazate. Similarly, increased qualitative or quantitative susceptibility to offspring were not observed with bifenazate during pre- or postnatal development in the reproduction study. There was no evidence of neurotoxicity (clinical signs or neuropathology) in any of the toxicology studies conducted with bifenazate. Therefore, a bifenazate developmental neurotoxicity (DNT) study was not required by the Agency.

Specific information on the studies received and the nature of the adverse effects caused by bifenazate 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 titled "Bifenazate (000586); Petition to Add New Uses on: Avocado, Tropical Fruits (Sugar Apple, Cherimoya, Atemoya, Custard Apple, Ilama, Soursop, and Biriba), Small Vine Climbing Fruit (Subgroup 13–07F), and Low-Growing Berry (Subgroup 13–07G). HED Human-Health Risk Assessment," pp. 26–27 in docket ID number EPA–HQ–OPP–2009–0890.

B. Toxicological Points of Departure/Levels of Concern

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

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

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

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (all populations)	An acute dietary endpoint was not selected based on the absence of an appropriate endpoint attributed to a single dose.		
Chronic dietary (All populations)	NOAEL= 1.0 milligrams/kilogram/day (mg/kg/day) UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.01 mg/kg/day cPAD = 0.01 mg/kg/day	Chronic Toxicity in Dogs LOAEL = 8.9/10.4 mg/kg/day Male/Female (M/F) based on changes in hematological and clinical chemistry parameters, and histopathology in bone marrow, liver, and kidney in the 1–year dog feeding study.
Incidental oral short-term (1 to 30 days)	NOAEL= 10 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE ≤100	Prenatal Developmental in Rats Maternal LOAEL = 100 mg/kg/day based on clinical signs, decreased body weight and food consumption during the dosing period in the rat developmental study.
Incidental oral intermediate-term (1 to 6 months)	NOAEL= 0.9 mg/kg/day UF_A= 10x UF_H= 10x FQPA SF = 1x	LOC for MOE ≤100	90–Day Oral Toxicity non-Rodents-Dog LOAEL = 10.4/10.7 mg/kg/day (M/F) based on changes in hematologic parameters in the 90–day subchronic dog study.

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

Exposure/Scenario	Point of Departure and Uncertainty/ Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Short-, Intermediate- and Long-Term Dermal (1–30 days, 30 days– 6 months, and 6 months to lifetime)	Dermal study NOAEL = 80 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE ≤100	21–Day Dermal Toxicity-Rat LOAEL = 400 mg/kg/day based on decreased body weight and food consumption, hematologic effects, increased spleen weight and extramedullary hemapoiesis in the spleen in the 21–day dermal toxicity study in rats.
Inhalation short-term (1 to 30 days)	Oral study NOAEL= 10 mg/kg/day (inhalation absorption rate = 100%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE ≤100	Prenatal Developmental in Rats Maternal LOAEL = 100 mg/kg/day based on clinical signs, decreased body weight and food consumption during the dosing period in the rat developmental study.
Cancer (Oral, dermal, inhalation)	Bifenazate is classified as "not likely" to be a human carcinogen.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to bifenazate, EPA considered exposure under the petitioned-for tolerances as well as all existing bifenazate tolerances in 40 CFR 180.572. EPA assessed dietary exposures from bifenazate 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. No such effects were identified in the toxicological studies for bifenazate; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Continuing Survey of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed that all commodities, except squash, peach, tomato and milk, contained tolerance-level residues. For squash, peach and tomato, EPA assumed residues were present at average field trial levels. For milk, the tolerance level was adjusted upward to account for all of the residues of concern for risk assessment. Default processing factors were assumed for all commodities except apple juice, grape juice, wine/sherry, tomato paste, and tomato puree. The processing factors for these commodities were based on data from processing studies. The chronic analysis also incorporated average percent crop treated (PCT) information for some registered commodities but assumed 100 PCT for the new uses.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that bifenazate does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

Bifenazate contains hydrazine as part of its chemical structure. This side chain is structurally similar to unsymmetrical dimethyl hydrazine (UDMH), a category B2 animal carcinogen and possible human carcinogen. However, EPA has concluded that formation of free biphenyl hydrazine or other hydrazines is unlikely based on the results of submitted metabolism studies. The rat, livestock, and plant metabolism studies indicate that metabolism of bifenazate proceeds via oxidation of the hydrazine moiety of bifenazate to form D3598 (diazene). The D3598 is then metabolized to D1989 (methoxy biphenyl) and to bound residues by reaction with natural products. A radish metabolism study which specifically monitored for the formation of biphenyl hydrazine found none. Based on the results of the metabolism studies, especially the absence of biphenyl hydrazine in the radish metabolism study or in the excreta of rats in the rat metabolism study, EPA concluded that the formation of free hydrazines is unlikely. This conclusion is further supported by the lack of carcinogenic effects in the bifenazate carcinogenicity studies.

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

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows:

Almond 5%; apple 5%; apricot 1%; cherry 1%; cucumber 1%; grape 5%; nectarine 5%; peach 10%; pear 10%; pecan 1%; pepper 1%; pistachio 1%; plum 5%; strawberry 30%; tomato 1%; walnut 1%; and watermelon 1%. One hundred PCT was assumed for all new uses and the remaining currently registered uses.

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

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 bifenazate 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 bifenazate in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of bifenazate. 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 First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of bifenazate for chronic exposures for non-cancer assessments are estimated to be 11.2 parts per billion (ppb) for surface water and 0.044 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 11.2 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). Bifenazate is currently registered for the following residential non-dietary sites: Ornamental plants, including bedding plants, flowering plants, foliage plants, bulb crops, perennials, trees, and shrubs. There is a potential for short-term dermal and inhalation exposure of homeowners applying bifenazate on these sites. However, post-application exposures of adults and children from this use are expected to be negligible. Therefore, EPA assessed only short-term dermal and inhalation residential handler exposures for adults. Handler exposures were estimated assuming applications would be made using hose-end sprayers, since this application method is expected to result in higher exposures than other application methods, such as pump sprayers or similar devices. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

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 bifenazate to share a common mechanism of toxicity with any other substances, and bifenazate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that bifenazate 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 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*. The prenatal and postnatal toxicology database for bifenazate includes rat and rabbit developmental toxicity studies and a 2–generation reproduction toxicity study in rats. There was no quantitative or qualitative evidence of increased susceptibility of rats or rabbit fetuses to *in utero* exposure in the developmental studies, nor of rats following prenatal/postnatal exposure in the 2–generation reproduction study.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF

were reduced to 1X. That decision is based on the following findings:

• There are no residual uncertainties in the toxicity database. The bifenazate toxicological database is complete with the exception of an inhalation study, acute and subchronic neurotoxicity studies and an immunotoxicity study. The immunotoxicity and acute and subchronic neurotoxicity studies are now required as a part of new data requirements in the 40 CFR part 158 for conventional pesticide registration and a 28–day inhalation study has not been submitted. However, the Agency does not believe that conducting these studies will result in a lower POD than that currently used for overall risk assessment, and therefore, a database uncertainty factor (UFDB) is not needed to account for lack of these studies for the following reasons:

i. The toxicology database for bifenazate does not indicate that the immune system is the primary target organ. The observed effects on the immune system have been well characterized and were seen at dose(s) that produce evidence of overt systemic toxicity. These effects included increased spleen weight in females and histopathological changes in the spleen in males in a 90–day oral rat toxicity study, extramedullary hematopoiesis in the both sexes in a 21–day dermal toxicity study in rats, and changes in hematological parameters, clinical chemistry parameters in both sexes and histopathological effects in bone marrow (compensatory hyperplasia) in both sexes in a 1–year chronic toxicity study.

ii. The overall weight of evidence suggests that bifenazate does not directly target the immune system, and these findings may be due to secondary effect of overt systemic toxicity. Further, there is no evidence of neurotoxicity or neuropathology in the bifenazate database.

iii. A 28–day inhalation study is not available; however, the EPA has determined that the additional FQPA SF is not needed. Residential inhalation risk was estimated by calculating exposure using the Agency's Residential Standard Operational Procedure (SOPs). For chemicals with low vapor pressure (7.5×10^{-5} mmHg or below for outdoor uses at 20–30°C) these standard assumptions are expected to overestimate the exposure via the inhalation route. Bifenazate is such a compound and exposure through the inhalation route is expected to be minimal. Therefore, the risk estimate is conservative and is considered protective and the additional FQPA SF is not needed.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

• There is no quantitative or qualitative evidence of increased susceptibility of rats or rabbit fetuses to *in utero* exposure in developmental studies, nor following prenatal/postnatal exposure to rats in the 2–generation reproduction study.

• A DNT is not required because there is no evidence of neurotoxicity or neuropathology in the bifenazate database.

• The dietary food and drinking water exposure assessments will not underestimate the potential exposures for infants and children; and the residential use (ornamentals) is not expected to result in post-application exposure to infants and children.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, bifenazate 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 bifenazate from food and water will utilize 81% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of bifenazate is not expected.

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

Bifenazate is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to bifenazate.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs greater than or equal to 1,800 for the U.S. population. The aggregate MOEs for adults take into consideration food and drinking water exposures as well as dermal and inhalation exposures of adults applying bifenazate to ornamentals in residential areas. Since residential exposure of infants and children is not expected, short-term aggregate risk for infants and children is the sum of the risk from food and water, which does not exceed the Agency's LOC.

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

An intermediate-term adverse effect was identified; however, bifenazate is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for bifenazate.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, bifenazate is not expected to pose a 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 bifenazate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. High-performance liquid chromatography (HPLC) Method UCC-D2341 is available as a primary enforcement method for determination

of the combined residues of bifenazate and its metabolite, diazinecarboxylic acid, 2-(4-methoxy-[1,1′-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate), in/on crop matrices. The method has undergone a successful validation and has been forwarded to the Food and Drug Administration (FDA) for inclusion in the Pesticide Analytical Manual (PAM) Volume II. In addition, a method utilizing a liquid chromatographic system with tandem mass spectrometers (LC/MS/MS) was recently submitted as a confirmatory method (Method NCL ME 245) and has been forwarded to FDA. 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

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are currently no established Codex or Mexican MRLs for bifenazate on the commodities included in the subject petition; however, Canadian MRLs are established for residues of bifenazate and its metabolite diazinecarboxylic acid, 2-(4-methoxy-[1,1′-biphenyl]-3-yl, 1-methylethyl ester in or on strawberry at 1.5 ppm, grapes at 1.0 ppm and raisins at 1.2 ppm. Thus, the tolerance expression is harmonized; and the MRL/tolerance levels for residues in strawberry, raisins and grapes are harmonized.

C. Revisions to Petitioned-For Tolerances

The residue data for sugar apple were entered into the Agency's tolerance spreadsheet using the Guidance for Setting Pesticide Tolerances Based on Field Trial Data SOP to determine an appropriate tolerance level. The results of this determination indicate that a tolerance level of 1.6 ppm is adequate for residues of bifenazate and its metabolite (expressed as bifenazate) in/on sugar apple rather than 1.5 ppm as originally proposed. This determination is translated to cherimoya, atemoya, custard apple, ilama, soursop, and biriba for tolerance setting purposes.

V. Conclusion

Therefore, tolerances are established for residues of bifenazate, (1-methylethyl 2-(4-methoxy[1,1′-biphenyl]-3-yl)hydrazinecarboxylate) and diazinecarboxylic acid, 2-(4-methoxy-[1,1′-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate), in or on sugar apple, cherimoya, atemoya, custard apple, ilama, soursop, and biriba at 1.6 ppm; avocado at 7.0 ppm; fruit, small, vine climbing subgroup 13–07F, except fuzzy kiwi fruit at 1.0 ppm; and berry, low growing, subgroup 13–07G at 1.5 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) (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: August 20, 2010.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.572 is amended by:

■ i. Alphabetically adding commodities to the table in paragraph (a)(1), and

■ ii. Revising the table in paragraph (b), so the amendments to paragraphs (a)(1) and (b) read as follows:

§ 180.572 Bifenazate; tolerance for residues.

(a)(1) * * *

Commodity	Parts per million
* * * * *	
Atemoya	1.6
Avocado	7.0
* * * * *	
Berry, low-growing subgroup 13–07G	1.5
Biriba	1.6
* * * * *	
Cherimoya	1.6
* * * * *	
Custard apple	1.6
* * * * *	
Fruit, small, vine climbing subgroup 13–07F, except fuzzy kiwifruit	1.0
* * * * *	
Ilama	1.6
* * * * *	
Soursop	1.6
* * * * *	
Sugar apple	1.6
* * * * *	

(b) * * *

Commodity	Parts per million	Expiration/Revocation Date
Timothy, forage	50	12/31/10
Timothy, hay	150	12/31/10

[FR Doc. 2010–21719 Filed 8–31–10; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 107, 171, 172, 173, 176, 177, 179, and 180

[Docket No. PHMSA–2010–0195 (HM–244C)]

RIN 2137–AE61

Hazardous Materials: Minor Editorial Corrections and Clarifications

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Final rule.

SUMMARY: This final rule corrects editorial errors, makes minor regulatory changes and, in response to requests for clarification, improves the clarity of certain provisions in the Hazardous Materials Regulations. The intended effect of this rule is to enhance the accuracy and reduce misunderstandings of the regulations. The amendments contained in this rule are non-substantive changes and do not impose new requirements.

DATES: *Effective Date:* October 1, 2010.

FOR FURTHER INFORMATION CONTACT: Deborah Boothe, Office of Hazardous Materials Standards, 202–366–8553, PHMSA, East Building, PHH–10, 1200 New Jersey Avenue, SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

I. Background

The Pipeline and Hazardous Materials Safety Administration (PHMSA) annually reviews the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180) to identify typographical and other errors, outdated addresses or other contact information, and similar errors. In this final rule, we are correcting typographical errors, incorrect CFR references and citations, inconsistent use of terminology, misstatements of certain regulatory requirements and inadvertent omissions of information. Because these amendments do not impose new requirements, notice and public comment procedures are unnecessary. By making these amendments effective without the customary 30-day delay following publication, the changes will appear in the next revision of the 49 CFR.

II. Section by Section Review

The following is a summary by section of the minor editorial corrections and clarifications made in this final rule. The summary does not include minor editorial corrections such as punctuation errors or similar minor revisions.

Part 107

Section 107.117

This section sets forth conditions and procedures for emergency processing for an application for a special permit. The daytime telephone number for the Federal Motor Carrier Administration in paragraph (d)(3) is no longer correct. Accordingly, we are revising this contact number.

Section 107.329

This section sets forth the maximum and minimum civil penalties for violations of the Federal hazardous material transportation law, 49 U.S.C. 5101 *et seq.,* and violations of regulations issued pursuant to that law. Those maximum and minimum penalties were most recently adjusted on December 29, 2009 (74 FR 68701) to consider the effects of inflation since reauthorization of the Federal hazardous material transportation law in August 2005. We found that the inflation adjustment in the Federal Civil Penalties Inflation Adjustment Act (28 U.S.C. 2461 note) (the Act)—the change in the CPI–U over the prescribed period—was 12.5%, but that the Act limited the adjustment of the maximum and minimum civil penalties to 10%. These adjusted maximum and minimum civil penalties apply to any violation occurring on or after January 1, 2010.

More recently, it has been called to our attention that we did not apply the "rounding" requirement in Section 5 of the Act in making adjustments to the minimum civil penalty amounts. Applying the 12.5% increase in the CPI–U to the $450 minimum penalty for a violation related to training produces an increase of $56.25, which would be rounded to $100—except for the limitation in the Act that the initial adjustment may not exceed 10%. Thus, the adjusted minimum penalty of $495 for a violation related to training was correct. However, when the $250 minimum penalty amount for other violations is increased by 12.5%, the result would be an increase of $31.25, which must be rounded to the nearest $100—or $0. Thus, we should have left the minimum civil penalty for other violations at $250. Accordingly, we are correcting this error in both § 107.329 and § 171.1(g). PHMSA does not believe that the improper $275 civil penalty amount has been used in any enforcement case arising out of