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: February 22, 2008.

Lois Rossi,

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 180.568 is amended by alphabetically adding the following commodities to the table in paragraph (a), and by removing the text and reserving paragraph (b) to read as follows:

§ 180.568 Flumioxazin; tolerances for residues.

(a) * * *

Commodity	Parts per million
Alfalfa, forage	3.0
Alfalfa, hay	8.0
* * *	* *
Asparagus	0.02
Bean, dry seed	0.05
Bushberry subgroup 13–07B	0.02
* * *	* *
Melon, subgroup 9A	0.02
Nut, tree, group 14	0.02
Okra	0.02
* * *	* *
Vegetable, fruiting, group 8	0.02
* * *	* *

(b) *Section 18 emergency exemptions.* [Reserved]

* * * * *

[FR Doc. E8–4102 Filed 3–4–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0302; FRL–8351–6]

Bifenazate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of bifenazate and its metabolite, diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate), in or on acerola; black sapote; caneberry subgroup 13-07A; canistel; feijoa; guava; jaboticaba; longan; lychee; mango; papaya; passionfruit; pea and bean, succulent shelled, subgroup 6B; pulasan; rambutan; sapodilla; sapote, mamey; soybean, succulent shelled; Spanish lime; star apple; starfruit; vegetable, legume, edible-podded, subgroup 6A; and wax jambu. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also deletes existing bifenazate tolerances on ''pea, edible podded, succulent'' and ''pea, garden, succulent'', which are superseded by the new tolerances on ''vegetable, legume, edible-podded, subgroup 6A'' and ''pea and bean, succulent shelled, subgroup 6B'', respectively.

DATES: This regulation is effective March 5, 2008. Objections and requests for hearings must be received on or before May 5, 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–2007–0302. 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–2007–0302 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 May 5, 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–2007–0302, 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 June 27, 2007 (72 FR 35237-35242) (FRL–8133–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E7167) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201 W, Princeton, NJ 08540–6635. The petition requested that 40 CFR 180.572 be amended by establishing tolerances for combined residues of the insecticide bifenazate, 1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl) hydrazinecarboxylate, and its metabolite, diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate), in or on papaya, star apple, black sapote, mango, sapodilla, canistel, and sapote, mamey at 6.0 parts per million (ppm); lychee, longan, Spanish lime, rambutan, and pulasan at 4.0 ppm; feijoa, guava, jaboticaba, wax jambu, starfruit, passionfruit, and acerola at 0.9 ppm; caneberry subgroup 13A at 6.0 ppm; wild raspberry at 6.0 ppm; edible podded legume vegetable, subgroup 6A at 4.0 ppm; succulent shelled pea and bean, subgroup 6B at 0.3 ppm; and succulent shelled soybean at 0.3 ppm. That notice referenced a summary of the petition prepared by Chemtura Corporation, the registrant, which is available to the public 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 modified many of the proposed tolerance levels and/or commodity terms. The reasons for these changes are explained in Unit V.

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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerance for combined residues of bifenazate and its metabolite, diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate), in or on acerola at 0.90 ppm; black sapote at 7.0

ppm; caneberry subgroup 13-07A at 5.0 ppm; canistel at 7.0 ppm; feijoa at 0.90 ppm; guava at 0.90 ppm; jaboticaba at 0.90 ppm; longan at 5.0 ppm; lychee at 5.0 ppm; sapote, mamey at 7.0 ppm; mango at 7.0 ppm; papaya at 7.0 ppm; passionfruit at 0.90 ppm; pea and bean, succulent shelled, subgroup 6B at 0.70 ppm; pulasan at 5.0 ppm; rambutan at 5.0 ppm; sapodilla at 7.0 ppm; soybean, succulent shelled at 0.70 ppm; Spanish lime at 5.0 ppm; star apple at 7.0 ppm; starfruit at 0.90 ppm; vegetable, legume, edible-podded, subgroup 6A at 6.0 ppm; and wax jambu at 0.90 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. 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 *''PP 6E7167; Bifenazate; (000586) Petition for Establishment of Tolerances for Uses on Caneberry ... and Acerola. HED Human-Health Risk Assessment.''* The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as document number EPA–HQ–OPP–2007–0302–0004 in that docket.

The acute toxicity data for bifenazate indicate that it 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. The dermal sensitization data for bifenazate are equivocal; bifenazate was shown to be a sensitizer using the Magnusson/Kligman method but was non-sensitizing using 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 of bifenazate in these species, with additional toxicity observed in the kidney (chronic dog) and adrenal gland (male rats). 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 EPA has classified bifenazate as ''not likely'' to be a human carcinogen by any relevant route of exposure. A full battery of mutagenicity studies was 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 of offspring was not observed with bifenazate during prenatal 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.

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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

A summary of the toxicological endpoints for bifenazate used for human risk assessment can be found at *http://www.regulations.gov* in document *''PP 6E7167; Bifenazate; (000586) Petition for Establishment of Tolerances for Uses on Caneberry ... and Acerola. HED Human-Health Risk Assessment''* at page 11 in docket ID number EPA–HQ–OPP–2007–0302.

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 USDA 1994–1996 and 1998 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 all of the new uses.

iii. *Cancer*. No evidence of carcinogenicity was seen in the cancer studies performed with bifenazate on rats and mice, and EPA has classified bifenazate as ''not likely'' to be a human carcinogen by any relevant route of exposure. Therefore, a cancer exposure assessment was not conducted.

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 percent crop treated (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 section 408(f)(1) of FFDCA 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 section 408(b)(2)(E) of FFDCA and authorized under section 408(f)(1) of FFDCA. 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 section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information in the chronic dietary exposure assessment as follows:

Almond 1%; apple 1%; apricot 1%; cucumber 1%; grape 5%; nectarine 5%; peach 10%; pear 10%; pecan 1%; pepper 1%; plum 5%; strawberry 25%; tomato 5%; walnut 1%; and watermelon 1%. 100 PCT was assumed for all new uses and the remaining currently registered uses.

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 6 years.

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 bifenazate 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 bifenazate 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 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 environmental concentrations (EECs) of bifenazate for chronic exposures are estimated to be 6.38 ppb for surface water and <0.001 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the chronic dietary risk assessment, the water concentration of value 6.38 ppb was used to access 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. Handler exposures were estimated assuming applications would be made using hose-end sprayers, since this application method may result in higher exposures than other application methods, such as pump sprayers or similar devices.

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 bifenazate and 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 not assumed that bifenazate 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 (''10X'') tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the 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*. 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 that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for bifenazate is complete.

ii. There is no indication that bifenazate 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 bifenazate 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.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessment utilizes tolerance level residues or, for a few commodities, anticipated residues that are based on reliable field trial data. For several currently registered commodities, the chronic assessment also utilizes PCT data that have a valid basis and are considered to be reliable. Conservative ground water and surface water modeling estimates were used. These assessments will not underestimate the exposure and risks posed by bifenazate.

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*. None of the toxicology studies available for bifenazate has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure; therefore, acute risk is not expected.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to bifenazate from food and water will utilize 47% of the cPAD for children 1 to 2 years old, the population group with the greatest estimated exposure. Based on the use pattern, chronic residential exposure to residues of bifenazate is not expected.

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).

Bifenazate is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for 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 of 3,900 for adults. 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 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).

Bifenazate is not registered for use on any sites that would result in intermediate-term 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*. Bifenazate has been classified as ''not likely'' to be a human carcinogen by any relevant route of exposure and is, therefore, not expected to pose a cancer risk.

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 methods may be requested from: Chief, Analytical Chemistry Branch,

Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican maximum residue limits (MRLs) for bifenazate in/on the commodities associated with this tolerance petition.

V. Conclusion

IR-4 petitioned for a tolerance on caneberry subgroup 13A and a separate tolerance on wild raspberry, since wild raspberry was not included in the caneberry subgroup at the time of the petition. In the **Federal Register** of December 7, 2007 (72 FR 69150-69158) (FRL–8343–1), EPA issued a final rule that revised the crop grouping regulations. As part of this action, EPA expanded and revised berries group 13 and its subgroups. The caneberries subgroup was expanded to include wild raspberries and designated as caneberry subgroup 13-07A, but the representative commodities remained unchanged. EPA indicated in the December 7, 2007 final rule as well as the earlier May 23, 2007 proposed rule (72 FR 28920-28930) (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. Because the representative commodities for subgroups 13A and 13-07A are the same and residue data on these commodities support inclusion of wild raspberry in the revised subgroup 13-07A, EPA is establishing a tolerance on caneberry subgroup 13-07A.

Based upon review of the data supporting PP 6E7167, EPA has also revised the proposed tolerance levels as follows: Increased the tolerance on papaya, star apple, black sapote, mango, sapodilla, canistel and sapote, mamey from 6.0 ppm to 7.0 ppm; increased the tolerance on lychee, longan, rambutan, Spanish lime and pulasan from 4.0 ppm to 5.0 ppm; decreased the tolerance on caneberry subgroup 13-07A from 6.0ppm to 5.0 ppm; increased the tolerance on vegetable, legume, edible-podded, subgroup 6A from 4.0 ppm to 6.0 ppm; and increased the tolerance on pea and bean, succulent shelled, subgroup 6B and soybean, succulent shelled from 4.0 ppm to 6.0 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 Standard Operating Procedure (SOP).

Therefore, the tolerances are established for combined residues of bifenazate, 1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl) hydrazinecarboxylate and its metabolite, diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester] (expressed as bifenazate), in or on acerola at 0.90 ppm; black sapote at 7.0 ppm; caneberry subgroup 13-07A at 5.0 ppm; canistel at 7.0 ppm; feijoa at 0.90 ppm; guava at 0.90 ppm; jaboticaba at 0.90 ppm; longan at 5.0 ppm; lychee at 5.0 ppm; sapote, mamey at 7.0 ppm; mango at 7.0 ppm; papaya at 7.0 ppm; passionfruit at 0.90 ppm; pea and bean, succulent shelled, subgroup 6B at 0.70 ppm; pulasan at 5.0 ppm; rambutan at 5.0 ppm; sapodilla at 7.0 ppm; soybean, succulent shelled at 0.70 ppm; Spanish lime at 5.0 ppm; star apple at 7.0 ppm; starfruit at 0.90 ppm; vegetable, legume, edible-podded, subgroup 6A at 6.0 ppm; and wax jambu at 0.90 ppm.

Tolerances currently exist for combined residues of bifenazate and its metabolite in or on pea, edible podded, succulent at 4.0 ppm and pea, garden, succulent at 0.20 ppm. These tolerances are no longer needed, since residues on these commodities will be covered by the new, higher tolerances being established on the edible-podded legume subgroup 6A at 6.0 ppm and on succulent shelled pea and bean subgroup 6B at 0.70 ppm. Therefore, EPA is revoking these existing, redundant tolerances.

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: February 22, 2008.

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 removing the entries ''Pea, edible podded, succulent'' and ''Pea, garden, succulent'' in the table in paragraph (a)(1) and alphabetically adding the following commodities to read as follows:

§ 180.572 Bifenazate; tolerance for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
Acerola	0.90
* * * * *	
Black sapote	7.0
Caneberry subgroup 13-07A	5.0
Canistel	7.0
* * * * *	
Feijoa	0.90
* * * * *	
Guave	0.90
* * * * *	
Jaboticaba	0.90
Longan	5.0
Lychee	5.0
Mango	7.0
* * * * *	
Papaya	7.0
Passionfruit	0.90
Pea and bean, succulent shelled, subgroup 6B	0.70
* * * * *	
Pulasan	5.0
Rambutan	5.0
Sapodilla	7.0
Sapote, mamey	7.0
* * * * *	
Soybean, succulent shelled	0.70
Spanish lime	5.0
* * * * *	
Star apple	7.0
Starfruit	0.90
Vegetable, legume, edible-podded, subgroup 6A	6.0
* * * * *	
Wax jambu	0.90

* * * * *

[FR Doc. E8–4142 Filed 3–4–08; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket No. 05–195; CC Docket No. 96–45; CC Docket No. 02–6; WC Docket No. 02–60; WC Docket No. 03–109; CC Docket No. 97–21; FCC 07–150]

Comprehensive Review of the Universal Service Fund

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: On August 29, 2007, the FCC released a *Report and Order*, Comprehensive Review of the Universal Service Fund Management, Administration, and Oversight; Federal-State Joint Board on Universal Service; Schools and Libraries Universal Service Support Mechanism; Rule Health Care Support Mechanism; Lifeline and Link-up; and Changes to the Board of Directors for the National Exchange Carrier Association, Inc., WC Docket No. 05–195; CC Docket No. 96–45; CC Docket No. 02–6; WC Docket No. 02–60; WC Docket No. 03–109; CC Docket No. 97–21; FCC 07–150. The information collection requirements in this *Report and Order* required approval from the Office of Management and Budget. This document announces the effective date of these information collection requirements.

DATES: The information collection requirements in amendments to §§ 54.202, 54.417, 54.619, and 54.706, published at 72 FR 54214, September 24, 2007, were approved by the Office of Management and Budget on January 23, 2008.

FOR FURTHER INFORMATION CONTACT: Mika Savir, Senior Attorney, Office of the Managing Director, (202) 418–0384, TTY 1 (888) 835–5322.

SUPPLEMENTARY INFORMATION: The *Report and Order* stated that the Commission would publish a notice announcing the effective date of the information collection requirements. On January 23, 2008, OMB approved the information collection requirements contained in this *Report and Order* pursuant to OMB Control Number: 3060–1112, Comprehensive Review of the Universal Service Fund Management, Administration, and Oversight. Accordingly, the information collection requirements contained in the *Report and Order* became effective on January 23, 2008. The expiration date for the information collection is January 31, 2011.

The Commission also published a separate Notice in the **Federal Register** on January 31, 2008 (73 FR 5843) in which the PRA various burden estimates for this information collection, 3060–1112, Comprehensive Review of the Universal Service Fund Management, which OMB has approved, were listed.

Pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520, an agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. Notwithstanding any other provisions of law, no person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Questions concerning this information collection, 3060–1112, should be directed to Leslie F. Smith, Federal Communications Commission, and (202) 418–0217 or via the Internet at *Leslie.Smith@fcc.gov*.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E8–4047 Filed 3–4–08; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 229

[Docket No. 080228330–8334–01]

RIN 0648–XF96

Taking of Marine Mammals Incidental to Commercial Fishing Operations; Atlantic Large Whale Take Reduction Plan

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule.