ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0126; FRL–8804–1]

Bifenazate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance 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 bean, dry seed. Interregional Research Project #4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 23, 2009. Objections and requests for hearings must be received on or before February 22, 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–2008–0126. 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: Barbara Madden, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *madden.barbara@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 cite at *http://www.gpoaccess.gov/ecfr*

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0126 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 February 22, 2010.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0126 by one of the following methods:

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

II. Petition for Tolerance

In the **Federal Register** of March 12, 2008 (73 FR 13225) (FRL–8354–6), 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 8E7318) by Interregional Research Project #4 (IR-4), 500 College Road East, Suite 201 W, Princeton, NJ 08540. 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 bean dry, seed at 0.2 parts per million (ppm); grass, forage, fodder and hay, group 17, forage at 140 ppm; and grass, forage, fodder and hay, group 17, hay at 120 ppm. That notice referenced a summary of the petition prepared by Chemtura Corporation, the registrant, on behalf of IR-4, which is available to the public in the docket, *http://www.regulations.gov*. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

After the petition was submitted, IR-4 subsequently withdrew the tolerance request for grass, forage, fodder and hay, group 17, forage; and grass, forage, fodder and hay, group 17, hay. As such, these commodities are not considered in this document.

EPA reviewed the petition and determined that the tolerance should be set at 0.60 ppm on bean, dry seed. The

reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for 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 bean, dry seed at 0.60 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. 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; Petition for Establishment of Tolerances for the Use of Bifenazate on Dry Bean Seed. HED Human-Health Risk Assessment,'' pages 23–24 in docket ID number EPA–HQ–OPP–2008–0126.

B. Toxicological Endpoints

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

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for bifenazate used for human risk assessment can be found at *http://www.regulations.gov* in the document titled ''Bifenazate; Petition for Establishment of Tolerances for the Use of Bifenazate on Dry Bean Seed. HED Human-Health Risk Assessment,'' pages 10–11 in docket ID number EPA–HQ–OPP–2008–0126.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to bifenazate, EPA considered exposure under the petitioned-for tolerance 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 the new use.

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 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 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:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

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

The Agency used PCT information as follows:

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%; 100 PCT was assumed for all new uses and the remaining currently registered uses.

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

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 Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* 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 point of departure (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 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 pre/post-natal exposure to rats in the 2–generation reproduction study.

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

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute 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 50% 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 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 2,200 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 level of concern.

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).

Bifenazate is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to bifenazate through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

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

B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican maximum residue limits (MRLs) for bifenazate in/on dry bean seed.

C. Response to Comments

A comment was received from a private citizen indicating that testing conducted on animals have absolutely no validity and cruel to the test animals. The Agency disagrees with the commenter's claims regarding animal testing. Since humans and animals have complex organ systems and mechanisms for the distribution of chemicals in the body, as well as processes for eliminating toxic substances from their systems, EPA relies on laboratory animals, such as, rats and mice to mimic the complexity of human and higher-order animal physiological responses when exposed to a pesticide. EPA is committed, however, to reducing the use of animals whenever possible. EPA-required studies include animals only when the requirements of sound toxicological science make the use of an animal absolutely necessary. The Agency's goal is to be able to predict the potential of pesticides to cause harmful effects to humans and wildlife by using fewer laboratory animals as models and have been accepting data from alternative (to animals) test methods for several years. As progress is made on finding or developing non-animal test models that reliably predict the potential for harm to humans or the environment, EPA expects that it will need fewer animal studies to make safety determinations. Finally, because the commenter has not provided the Agency with a specific rationale (including supporting information) as to why the Agency's action is inconsistent with the legal standards in section 408 of FFDCA, EPA can not provide any more detailed response to the commenter's disagreement with the Agency's decision.

In addition, the commenter noted several adverse effects seen in animal toxicology studies with bifenazate and claims because of these effects no tolerance should be approved. EPA has found, however, that there is a reasonable certainty of no harm to humans after considering these toxicological studies and the exposure levels of humans to bifenazate.

D. Revisions to Petitioned-For Tolerances

The initial petition submitted by IR-4 proposed tolerance for grass, forage, fodder and hay, group 17, forage; and grass, forage, fodder and hay, group 17, hay. EPA reviewed the petition and concluded that in order to grant the use on grass, a ruminant metabolism and adequate feeding studies would be required. IR-4 subsequently withdrew these proposed tolerances.

EPA evaluated this petition and upon reviewing the submitted field trial data and entering it into the Agency's tolerance spreadsheet as specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP, it was determined that the tolerance should be set at 0.60 ppm for residues in/on bean, dry seed as opposed to the level proposed by IR-4.

Additionally, EPA has revised the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of bifenazate not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression. This change was made to both the tolerance expressions for plant commodities and livestock commodities because it makes no substantive change to the meaning of the tolerance but rather only clarifies the existing language.

V. Conclusion

Therefore, a tolerance is established 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 bean, dry seed at 0.60 ppm.

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 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: December 11, 2009.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.572 is amended by revising paragraphs (a)(1) introductory text, (a)(2) introductory text, and (b) introductory text; and alphabetically adding ''Bean, dry, seed'' to the table in paragraph (a)(1) to read as follows:

§ 180.572 Bifenazate; tolerance for residues.

(a) *General.* (1) Tolerances are established for residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1′-biphenyl]-3-yl)hydrazinecarboxylate) including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified are to be determined by measuring only the sum of bifenazate and its metabolite diazinecarboxylic acid, 2-(4-methoxy-[1,1′-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate) in or on the following food commodities:

Commodity	Parts per million
* * *	* *
Bean, dry seed	0.60
* * *	* *

* * * * *

(2) Tolerances are established for residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1′-biphenyl]-3-yl) hydrazinecarboxylate) including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified are to be determined by measuring only the sum of bifenazate and its metabolites diazinecarboxylic acid, 2-(4-methoxy-[1,1′-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate); 1,1′-biphenyl, 4-ol; and 1,1′-biphenyl, 4-oxysulfonic acid (expressed as 1,1′-biphenyl, 4-ol) in or on the following food commodities:

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1′-biphenyl]-3-yl)hydrazinecarboxylate) including its

metabolites and degradates in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. Compliance with the tolerance levels specified in the following table are to be determined by measuring only the sum of bifenazate and its metabolite diazinecarboxylic acid, 2-(4-methoxy-[1,1′-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate). The tolerances will expire and are revoked on the dates specified in the following table.

* * * * *

[FR Doc. E9–30138 Filed 12–22–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0536 and 2007–0097; FRL–8793–5]

Fenarimol; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenarimol in or on hop, dried cones. This regulation additionally increases the established tolerance in or on apple. Interregional Research Project Number 4 (IR-4) requested the tolerance on hop and EPA proposed the tolerance increase on apple under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 23, 2009. Objections and requests for hearings must be received on or before February 22, 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–2007–0536. 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: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7390; e-mail address: *nollen.laura@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Access Electronic Copies of this Document?

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

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a(g), 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–2007–0536 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 February 22, 2010.

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–2007–0536, by one of the following methods:

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

II. Petition for Tolerance

In the **Federal Register** of August 22, 2007 (72 FR 47010) (FRL–8142–5) (Docket ID number EPA-HQ-OPP-2007–0536, 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 6E7074) by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540–6635. The petition requested that 40 CFR 180.421 be amended by establishing tolerances for residues of the fungicide fenarimol,