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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0327; FRL–8090–1]

Bifenazate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of bifenazate in or on pea, garden; pea, edible podded; vegetable, tuberous and corm, subgroup 1C; fruit, stone, group 12, except plum; plum; cattle fat; goat fat; hog fat; horse fat; and sheep fat. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 30, 2006. Objections and requests for hearings must be received on or before October 30, 2006, 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–2006–0327. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 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 provides 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 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2006–0327 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 on or before October 30, 2006.

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 your copies, identified by docket ID number EPA–HQ–OPP–2006–0327, 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 Building), 2777 S. Crystal Drive, 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 telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of May 3, 2006 (71 FR 26087) (FRL–8058–6), 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 petitions (PP 3E6762 and 5E6992) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902. 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 diazinecarboxylic acid, 2-(4-methoxy-

[1,1′-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate), in or on fruit, stone, group 12 at 2.0 parts per million (ppm); pea, garden at 0.2 ppm; pea, edible podded at 4.0 ppm; and vegetable, tuberous and corm at 0.01 ppm.

PP 3E6762 proposed to amend 40 CFR 180.572 by deleting existing peach and nectarine tolerances, and establish a tolerance for fruit, stone (Group 12) at 2.0 ppm. Following review of the residue chemistry data, EPA determined that the commodity terms and tolerances levels should be revised to the following: Pea, garden, succulent at 0.20 ppm; vegetable, tuberous and corm, subgroup 1C at 0.10 ppm; and fruit, stone, group 12, except plum at 2.5 ppm. Additionally, EPA determined subsequent revisions for existing tolerances for plum at 0.20 ppm, and fat of cattle, goat, hog, horse, and sheep at 0.10 ppm (previously established at 0.3 ppm (plum) and 0.1 ppm (animal fat commodities).

EPA is also deleting established tolerances in §180.572(a) for peach and nectarine since they will be replaced by the establishment of the tolerance for residues of bifenazate on fruit, stone, group 12, except plum. Additionally, EPA is deleting the time-limited tolerance for tomato under §180.572(b) since that tolerance has expired.

The notices referenced above included a summary of the petitions prepared by Crompton Uniroyal Chemical, the registrant. There were no comments received in response to the notice of filing.

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. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA–PEST/1997/November/Day–26/p30948.htm*.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined of bifenazate on pea, garden, succulent at 0.20 ppm; pea, edible podded, succulent at 4.0 ppm; vegetable, tuberous and corm, subgroup 1C at 0.10 ppm; fruit, stone, group 12, except plum at 2.5 ppm; plum at 0.20 ppm; and fat of cattle, goat, hog, horse, and sheep at 0.10 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follow.

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 toxic 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 www.regulations.gov (Docket ID EPA–HQ–OPP–2006–0327–0002, pages 10–12).

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which the LOAEL of concern is identified is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/pesticides/health/human.htm*.

A summary of the toxicological endpoints for bifenazate used for human risk assessment can be found at www.regulations.gov (Docket ID EPA–HQ–OPP–2006–0327–0002, page 15).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have been established (40 CFR 180.572) for the combined residues of bifenazate, in or on a variety of raw agricultural and livestock commodities. A tolerance is also established for milk. Risk assessments were conducted by EPA to assess 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 not performed.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic analyses incorporated tolerance-level residues for all commodities excluding squash, peach, tomato, and soybean (anticipated residues based on average field-trial residues were assumed) and milk (anticipated residue was assumed). The chronic analyses incorporated average percent crop treated (PCT) information. DEEM (ver. 7.81) default processing factors were assumed for all commodities excluding apple juice, grape juice, wine/sherry, tomato paste, and tomato puree. The processing factors for these commodities

were reduced to 0.23, 0.17, 0.17, 5.0, and 5.0, respectively, based on data from processing studies.

iii. *Cancer*. Bifenazate has been classified as ''not likely'' to be a human carcinogen. Therefore, a cancer dietary exposure assessment was not performed.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of the 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 chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such Data Call-Ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such Data Call-Ins 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 the Agency can make the following findings: Condition 1, that 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; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if 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 as follows: 1% for almonds, apples, apricots, cucumbers, pecans, peppers, walnuts, and watermelons; 5% for grapes, nectarines, prunes, plums, and tomatoes; 10% for peaches and pears, and 25% for strawberries.

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 and <2.5% is used as the maximum. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available federal, state, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five percent. 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 have been met. With respect to Condition 1, 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 2 and 3, 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 exposure 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 physical 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*.

Parent bifenazate degrades rapidly in aerobic soil conditions with a half-life of approximately 30 minutes. The first degradate formed (D3598; half-life of 7 hours) was reported in a concentration of 95% of the applied radioactivity. D3598 degrades to D1989 (reported at a maximum of 26% of the applied radioactivity), which is moderately persistent with an EFED-calculated half-life of approximately 96 days. Photodegradation and other routes of dissipation of parent bifenazate do not appear to be significant.

EPA concluded that the residue of concern in drinking water is D1989. Parent and D3598 were not included as a residue of concern in drinking water due to the short half-lives of these compounds and the lack of an acute dietary endpoint (toxicity of D3598 is assumed to be equivalent to bifenazate). Since ground water or surface water monitoring data are not available, a Tier I screening concentration in ground water (SCI-GROW) and surface water first index sceening tool reservoir (FIRST) were provided for the EECs of D1989. Both models were conducted using the strawberry application scenario (2 x 0.50 lbs ai/acre; 21–day RTI; highest registered/proposed application rate).

Based on the SCI-GROW and FIRST models, the estimated environmental concentrations (EECs) of bifenazate are estimated to be 6.38 parts per billion (ppb) for chronic surface water and <0.001 ppb for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID™). For chronic dietary risk assessment, the annual average concentration of 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 use on the following residential non-dietary site: Ornamentals. The risk assessment was conducted using the following residential exposure assumptions: EPA anticipated only short-term dermal and inhalation exposure for residential handlers. The proposed formulation was appropriate for application via pump up sprayers, garden hose-end sprayers, or similar ''homeowner'' pesticide devices. A

larger area per day may be treated with a hose-end sprayer than with a ''pump-up'' compressed-air sprayer, which in turn results in possibly greater contact with the active ingredient per day. Therefore, exposure from a hose-end sprayer was assessed rather than that of a compressed-air sprayer. With respect to post-application residential exposures, no significant post-application exposure is anticipated from landscape ornamentals, either by residents or professional applicators; therefore, no residential post-application assessment was conducted.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold 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 data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. 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 safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. The developmental studies in rats and rabbits did not demonstrate any qualitative or quantitative *in utero* extra sensitivity of fetuses to bifenazate. Similarly, increased qualitative or quantitativesusceptibility to offspring was not observed from bifenazate during prenatal or postnatal development in the reproduction study.

3. *Conclusion*. The Agency evaluated the bifenazate toxicological database in reference to the potential for enhanced sensitivity to infants and children. Acceptable developmental toxicity studies in the rat and rabbit are available, as is an acceptable 2–generation reproduction study in the rat. EPA concluded that a bifenazate developmental neurotoxicity study is not required. EPA also concluded the 10X FQPA safety factor could be reduced to 1X for bifenazate for the following reasons:

i. There is no indication of quantitative or qualitative increased susceptibility of rats and rabbits to *in utero* or postnatal exposure.

ii. A bifenazate developmental neurotoxicity study is not required.

iii. The toxicological database, the residue chemistry database and the environmental fate database, are complete for FQPA assessment.

iv. The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.

v. The residential handler assessment is based upon the residential standard operating procedures (SOPs). The residential SOPs are based upon reasonable worst-case assumptions and are not expected to underestimate risk. These assessments of exposure are not likely to underestimate the resulting estimates of risk from exposure to bifenazate.

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. No acute risk is expected from exposure to bifenazate since no acute endpoints were identified for the general U.S. population (including infants and children) or the females 13-50 years old population subgroup.

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 38% of the chronic population adjusted dose (cPAD) for the U.S. population, 79% of the cPAD for all infants (<1 year old), and 94% of the cPAD for children 1-2 years old. There are no residential uses for bifenazate that result in chronic residential exposure to bifenazate. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

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 margin of exposures (MOEs) of 1,600 for the U.S. population, 1,900 for females 13-49 years old, and 2,000 for adults 50 years and older. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food, water, and residential uses. Therefore, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern.

4. *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. Therefore, bifenazate is expected to pose at most a negligible cancer risk.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to bifenazate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

A method (UCC-D2341) is available for enforcement of the currently established plant tolerances. The methods used in the field trial and processing studies were similar to the current enforcement method. Since the

procedures are similar and adequate method validation and concurrent recoveries were attained in the field trial and processing studies, EPA concludes that the current enforcement method is appropriate for enforcement of the tolerances associated with this petition.

Adequate enforcement methodology is available to enforce the tolerance expression. 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

Canada, Codex, and Mexico do not have maximum residue limits (MRLs) for residues of bifenazate in/on tuberous and corm vegetables or succulent pea; therefore, harmonization is not an issue for these crops. However, Codex MRLs are established in/on peach, nectarines, plum, and prunes (no Canadian or Mexican stone fruit MRLs) at 2.0 ppm. The Codex MRL residue definition is for bifenazate per se. The U.S. and Codex tolerances/MRLs are not compatible with regard to tolerance expression and therefore, the levels can not be harmonized.

V. Conclusion

Therefore, the tolerance is established for combined residues of bifenazate, (1-methylethyl 2-(4-methoxy[1,1′-biphenyl]-3-yl)hydrazinecarboxylate) and diazinecarboxylic acid, 2-(4-methoxy-[1,1′-biphenyl]-3-yl), 1-methylethyl ester, in or on pea, garden, succulent at 0.20 ppm; pea, edible podded, succulent at 4.0 ppm; vegetable, tuberous and corm, subgroup 1C at 0.10 ppm; fruit, stone, group 12, except plum at 2.5 ppm; plum at 0.20 ppm; and fat of cattle, goat, hog, horse, and sheep at 0.10 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, 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). 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.*, or 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–). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 23, 2006.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—AMENDED

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

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

■ 2. Section 180.572 is amended by:

i. In paragraph (a)(1), in the table, by removing the commodities ''peach'' and ''nectarine''; revising the tolerance levels for the commodities ''cattle, fat''; ''goat, fat''; ''hog, fat''; ''horse, fat''; and ''sheep, fat'' and by alphabetically adding commodities ''fruit, stone, group 12, except 12''; ''pea, garden, succulent''; ''pea, edible podded, succulent''; and ''vegetable, tuberous and corm''; and

ii. In paragraph (b), in the table, by removing the commodity tomato.

The amendments read as follows.

§ 180.572 Bifenazate; tolerances for residues.

(a)(1) * * *

Commodity	Parts per million
* * * *	*
Cattle, fat	0.10
* * * *	*
Fruit, stone, group 12, except plum	2.5
Goat, fat	0.10
* * * *	*
Hog, fat	0.10
* * * *	*
Horse, fat	0.10
* * * *	*
Pea, garden, succulent	0.20
Pea, edible podded, succulent	4.0
* * * *	*
Plum	0.20
Sheep, fat	0.10
* * * *	*
Vegetable, tuberous and corm, subgroup 1C	0.10

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0292; FRL–8090–2]

S-metolachlor; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of S-metolachlor in or on pumpkin, and squash, winter. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 30, 2006. Objections and requests for hearings must be received on or before October 30, 2006, 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–2006–0292. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e–mail address: *brothers.shaja@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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 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 provides 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 40 CFR part 180 through the Government Printing Office's pilot e–CFR site at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2006–0292 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 on or before October 30, 2006.

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 your copies, identified by docket ID number