ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0216; FRL–8087–6]

Fenpyroximate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of fenpyroximate and its z-isomer in or on hop, dried cones; almond hulls; nut, tree, group 14; pistachio; fruit, citrus, group 10; citrus, dried pulp; citrus, oil; peppermint, tops; and spearmint, tops. Interregional 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 23, 2006. Objections and requests for hearings must be received on or before October 23, 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–2006–0216. 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., cattleranchers 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*.

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–2006–0216 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 23, 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–2006–0216, 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 August 10, 2005 (70 FR 46444) (FRL–7729–3), 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 5E6943) by IR–4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. The petition requested that 40 CFR 180.566 be amended by establishing tolerances for combined residues of the insecticide/miticide fenpyroximate, (E)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene]amino]oxy]methyl]benzoate and its Z-isomer, (Z)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl)methylene]amino]oxy] methyl]benzoate, in or on almond hulls at 1.8 parts per million (ppm); nut, tree, group 14 at 0.1 ppm; pistachio at 0.1 ppm; fruit, citrus, group 10; citrus at 0.4 ppm, fruit, citrus, dried pulp at 2.5

ppm; citrus, oil at 15 ppm; hop at 4.5 ppm; peppermint, tops at 3.0 ppm; and spearmint, tops at 3.0 ppm. That notice included a summary of the petition prepared by Nichino America, the registrant. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C. below.

Following review of the residue chemistry data, EPA determined that the commodity terms and tolerance levels should be revised to the following: Almond, hulls at 3.0 ppm; hop, dried cones at 10 ppm ; nut, tree, group 14 at 0.10 ppm; pistachio at 0.10 ppm; fruit, citrus, group 10 at 0.60 ppm; fruit, citrus, dried pulp revised to read citrus, dried, pulp at 2.5 ppm; citrus, oil at 10 ppm; peppermint, tops at 7.0 ppm; and spearmint, tops at 7.0 ppm.

Time-limited tolerances for grape, wine and hop (currently revised to hop, dried cones) have expired under 40 CFR 180.566(a)(1). Permanent tolerances have been established for these commodities; therefore, grape, wine and hop, dried cones will be added to 40 CFR 180.566(a)(2). The petitioner for hop, dried cones has requested a domestic registration; therefore, footnote 1 to the table in § 180.566(a)(2) which reads ''There are no U.S. registration on hops'' has been removed. In addition, registrations for citrus fruits, hops, mint, tree nuts (including pistachio) have been deemed as conditional and are contingent upon submission of required additional data.

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 tolerances for combined residues of fenpyroximate and its z–isomer on almond, hulls at 3.0 ppm; hop, dried cones at 10 ppm; nut, tree, group 14 at 0.10 ppm; pistachio at 0.10 ppm; fruit, citrus, group 10 at 0.60 ppm; citrus, dried, pulp at 2.5 ppm; citrus, oil at 10 ppm; peppermint, tops at 7.0 ppm; and spearmint, tops at 7.0 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 fenpyroximate 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*, Docket No. EPA–HQ–OPP–2004–0174–0001, pages 2–4.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (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 adverse effects of concern are identified (the LOAEL) 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 fenpyroximate used for human risk assessment is discussed at *http://www.regulations.gov*, Docket No. EPA–HQ–OPP– 2005–0216–0001; pages 14–15.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established in 40 CFR 180.566(a)(2) for the combined residues of fenpyroximate and its z-isomer, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from fenpyroximate 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 one-day or single exposure.

An unrefined, Tier I acute dietary-exposure assessment was conducted for females 13 to 49 years old. The unrefined, Tier I acute analyses assumed that fenpyroximate residues were present in all commodities at tolerance levels and that 100% of all commodities (registered and proposed uses) are treated. Adequate processing data on apples, grapes, oranges and mint are available. Modified processing factors based on these data were used for apple juice, pear juice, grape juice, raisins, citrus juice (orange, grapefruit, lemon and lime) and mint oils (peppermint and spearmint). The Dietary Exposure Evaluation Model (DEEM™) default processing factors were used for all other processed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Data base (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: An unrefined, Tier I chronic dietary exposure assessment was conducted for the general U.S. population, and various population subgroups. The unrefined, Tier I chronic analyses assumed that fenpyroximate residues were present in all commodities at tolerance levels and that 100% of all commodities (registered and proposed uses) are treated. Adequate processing data on apples, grapes, oranges and mint are available. Modified processing factors based on these data were used for apple juice, pear juice, grape juice, raisins, citrus juice (orange, grapefruit, lemon and lime) and mint oils (peppermint and spearmint). DEEM™ default processing factors were used for all other processed commodities.

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

2. *Dietary exposure from drinking water*. The Agency determined in addition to the parent compound (M-1), the M-3 metabolite should be included in the drinking water assessment for fenpyroximate. Based on the proposed application rates and the environmental fate properties of fenpyroximate, some surface and ground water contamination may occur. However, the risk of water contamination from parent compound is relatively low, based on its high sorption potential. Unlike parent compound, the sorption of the M-3 metabolite is much less, and it may move into water resources more readily. Environmental fate data indicate that parent and its Z-isomer are stable to photolysis in soil and immobile in soil. Major degradates formed in the aqueous layer were M-3 (50%), M-8 (36%), M-16 (4-hydroxymethylbenzoic acid, 58%) and M-11 (25 to 30%), and M-3 (>10%), M-11 (25 to 30%) and M8 (16 to 19%) in the soil. However, data from a field dissipation study showed M3 (32%) being the only significant degradate found in the field. Based on the structural similarity between parent and M-3, the Agency concluded that parent and M-3 be included in the risk assessment.

Based on Tier II screening-level surface water modeling for drinking water, the Agency estimated concentrations in surface water to be used for acute, chronic non-cancer, and cancer exposure assessment. Tier II surface water concentrations for parent fenpyroximate and M-3 were calculated using the Pesticide Root Zone Model/ Exposure Analysis Modeling System (PRZM-EXAMS). The acute, and chronic non-cancer concentrations for GA pecan (highest exposure) are 12.9 and 1.8 microgram/liter, respectively. EPA used the Screening Concentration in Ground Water model (SCI-GROW2) to estimate a groundwater concentration of 0.059 parts per billion (ppb). These results for both surface water and ground water are consistent with the fate and transport properties of fenpyroximate.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID). For the acute assessment, the peak concentration of 12.9 ppb was used to access the contribution to drinking water; for the chronic assessment, the annual mean value of 1.8 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). Fenpyroximate is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of 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 fenpyroximate and any other substances and fenpyroximate 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 fenpyroximate 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 Web site 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 rat and rabbit developmental-toxicity studies were tested at doses that produced minimal maternal toxicity at best. These doses were supported partly by range finding data. The two generation reproductive-toxicity study indicated that maternal (decreased body weight) and offspring toxicity (decreased lactational weight gain) occurred at the same dose, suggesting no evidence of sensitivity or susceptibility. Reproductive parameters were not affected in this 2-generation reproduction study. There are no neurotoxicity studies other than a negative delayed acute-neurotoxicity study in the hen. There was no indication of neurotoxicity present in any of the existing subchronic or chronic toxicity studies. The toxicology data base is complete for FQPA purposes and that there are no residual uncertainties for prenatal/postnatal toxicity.

3. *Conclusion*. There is a complete toxicity data base for fenpyroximate and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be changed to 1X for the following reasons:

i. There are no concerns or residual uncertainties for prenatal or postnatal toxicity.

ii. The toxicological data base is complete for the assessment of toxicity and susceptibility following prenatal and/or postnatal exposures. No clinical

signs of neurotoxicity or neuropathology were observed in the data base.

iii. There are no residual concerns regarding completeness of the exposure data base.

iv. The dietary food exposure assessment is Tier I, screening level, which is based on tolerance level residues and assumes 100% of all crops will be treated with fenpyroximate. By using these screening-level assessments, actual exposures/risks will not be underestimated.

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

vi. There are currently no registered or proposed residential uses of fenpyroximate.

E. Aggregate Risks and Determination of Safety

1. *Acute risk.* An unrefined, acute dietary-exposure assessment was conducted for females 13 to 49 years old. Since an effect of concern attributable to a single dose in toxicity studies was not identified for the general U.S. population, an acute dietary-exposure assessment was not performed for this population. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fenpyroximate will occupy 6.8% of the acute population adjusted dose (aPAD) for females 13 years and older. EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fenpyroximate from food and water will utilize 9.8% of the chronic adjusted population dose (cPAD) for the U.S. population, 20% of the cPAD for all infants < 1 year old, and 34% of the cPAD for children 1 to 2 years old. There are no residential uses for fenpyroximate that result in chronic residential exposure to fenpyroximate. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Aggregate cancer risk for U.S. population.* Fenpyroximate has been classified as not likely to be carcinogenic to humans. Therefore, fenpryroximate is expected to pose at most a negligible cancer risk.

4. *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 fenpyroximate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An enforcement method has been developed which involves extraction of fenpyroximate from crops with acetone, filtration, partitioning and cleanup, and analysis by gas chromatography using a nitrogen/phosphorous detector. This method allows detection of residues at or above the proposed tolerances. The method has undergone independent laboratory validation.

B. International Residue Limits

Codex maximum residue limits (MRLs) are established for residues of fenpyroximate per se in/on apple, grapes, hops, oranges, and cattle commodities. The Codex MRLs differ from the proposed and established tolerances for all commodities except hops. Harmonization with the other Codex MRLs is not possible because the U.S. tolerance expressions include additional metabolites/isomers. There are currently no established Canadian or Mexican MRLs.

C. Response to Comments

Comments were received from a private citizen in Florham Park, New Jersey. The comments were in response to the notice of filing published in the **Federal Register** of August 10, 2005 (70 FR 46444) (FRL–7729–3). The commenter opposes the establishment of any food tolerances (greater than zero) and exemptions. However, under the existing legal framework provided by section 408 of the FFDCA, EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. The commenter also believes IR-4 and Rutgers University are profiteering, and expressed concerns about the Agency's partnership with IR-4. This comment was earlier addressed in the **Federal Register** of June 30, 2005 (70 FR 37683) (FRL–7718–3).

V. Conclusion

Therefore, the tolerances are established for combined residues of fenpyroximate, (E)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene] amino]oxy]methyl]benzoate and its Z-isomer, (Z)-1,1-dimethylethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl)methylene] amino]oxy]methyl]benzoate, in or on almond, hulls at 3.0 ppm; hop, dried cones at 10 ppm; nut, tree, group 14 at 0.10 ppm; pistachio at 0.10 ppm; fruit, citrus, group 10 at 0.60 ppm; citrus, dried, pulp at 2.5 ppm; citrus, oil at 10 ppm; peppermint, tops at 7.0 ppm; and spearmint, tops at 7.0 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 104-4). 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 11, 2006.

Donald R. Stubbs,

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 180.566 is amended by removing paragraph (a)(1), by redesignating paragraph (a)(2) as paragraph (a)(1), by revising the table in newly redesignated paragraph (a)(1), and by redesignating paragraphs (a)(3) and (a)(4) as paragraphs (a)(2) and (a)(3), respectively, to read as follows:

§ 180.566 Fenpyroximate; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Almond, hulls	3.0
Citrus, dried pulp	2.5
Citrus, oil	10
Cotton, gin byproducts	10
Cotton undelinted seed	0.10
Fruit, citrus, group 10	0.60
Fruit, pome, group 11	0.40
Grape	1.0
Hop, dried cones	10
Nut, tree, group 14	0.10
Peppermint, tops	7.0
Pistachio	0.10
Spearmint, tops	7.0

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BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0561; FRL–8084–3]

Phosphorous Acid; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of phosphorous acid and its ammonium, sodium, and potassium salts in or all food commodities to allow for post-harvest application to stored potatoes at 35,600 parts per million (ppm) or less of phosphorus acid. This exemption is being issued at EPA's own initiative under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of phosphorous acid and its ammonium, sodium, and potassium salts.

DATES: This regulation is effective August 23, 2006. Objections and requests for hearings must be received on or before September 7, 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–2006–0561. 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: Linda Hollis, Biopesticides and