ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0237; FRL–8127–3]

Fenpyroximate; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of fenpyroximate in or on honey. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide in managed beehives. This regulation establishes a maximum permissible level for residues of fenpyroximate in this food commodity. The tolerance expires and is revoked on December 31, 2010.

DATES: This regulation is effective May 9, 2007. Objections and requests for hearings must be received on or before July 9, 2007, 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–2007–0237. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are 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: Stacey Groce, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–2505; e-mail address: *groce.stacey@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 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 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 Federal Food, Drug, and Cosmetic Act (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–2007–0237 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 July 9, 2007.

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–2007–0237 by one of the following methods:

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

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a time-limited tolerance for combined residues of the miticide fenpyroximate in or on honey at 0.10 parts per million (ppm). This tolerance expires and is revoked on December 31, 2010. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations (CFR).

Section 408(l)(6) of the FFDCA requires EPA to establish a tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency

exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the 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 the 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 the 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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Fenpyroximate on Honey and FFDCA Tolerances

The varroa mite, (*Varroa jacobsoni*), is an ectoparasite of honeybees. It was first detected in the continental United States in 1979 and is currently the most important pest of honey bee colonies. The feeding of varroa mites has a number of effects on the bee from damaging tissue to shortening the bee's life span as an adult. Further, the mites vector disease viruses and heavy levels of parasitism increase bee mortality and weaken colonies. Fluvalinate is currently registered for the control of varroa mites; however, populations of varroa mites have developed resistance to fluvalinate. The applicants for this use pattern assert that the continued survival of managed bee colonies is critical to the production of many agricultural crops and it is becoming increasingly difficult to control varroa mites due to pesticide resistance. EPA has authorized under FIFRA section 18 the use of fenpyroximate on honey for control of varroa mites in Nebraska, North Dakota, New York, Idaho, Oregon, and Washington States. In addition, EPA has authorized under the FIFRA section 18 crisis provision the use of fenpyroximate in beehives for control of varroa mites in Texas. After having reviewed the submission, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of fenpyroximate in or on honey. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this time-limited tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although this time-limited tolerance expires and is revoked on December 31, 2010, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on honey after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether fenpyroximate meets EPA's registration requirements for use on honey or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of fenpyroximate by a State for special local needs under FIFRA section 24(c). Nor does this time-limited tolerance serve as the basis for any States other than Idaho, Nebraska, Minnesota, New York, North Dakota, Texas, and Washington States to use this pesticide on bee hives under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for fenpyroximate contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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*.

Consistent with section 408(b)(2)(D) of the 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 fenpyroximate and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for combined residues of fenpyroximate in or on honey at 0.10 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

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 endpoint. 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the

FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 X 10^{6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for fenpyroximate used for human risk assessment is discussed in Table 1 on page 5 of the Fenpyroximate Human Health Risk Assessment dated December 4, 2006: *Section 18 Request for Use in Bee Hives*, and can be located by searching for docket ID number EPA–HQ–OPP–2007–0237. Double-click on the document to view the referenced information.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.566) for the combined residues of the miticide fenpyroximate in or on a variety of raw agricultural commodities. Tolerances have also been established for fenpyroximate and its metabolites (E)-4-[(1,3-dimethyl-5-phenoxypyrazol-4-yl)-methylene aminooxymethyl] benzoic acid and (E)-1,1-dimethylethyl-2-hydroxyethyl 4-[[[[(1,3-dimethyl-5-phenoxy-1 H-pyrazol-4-yl) methylene] amino]oxy]methyl]benzoate, calculated as the parent compound at 0.015 ppm in milk, and the fat, meat, and meat byproducts (excluding liver and kidney) of cattle, goat, horse, and sheep at 0.03 ppm. Risk assessments were conducted by EPA to assess dietary exposures from fenpyroximate in food as follows:

i. *Acute exposure.* Acute dietary 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. The Dietary Exposure Evaluation Model (DEEM-FCID™) version 2.02 analysis evaluated the individual food consumption 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 acute exposure assessments: An unrefined Tier I acute dietary-exposure assessment was conducted for females 13–49 years old. The unrefined Tier I acute dietary 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, lime) and mint oils (peppermint and spearmint). The DEEM-FCID™ default processing factors were used for all other processing commodities.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the DEEM-FCID™ version 2.02 analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide 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 sub-populations. The unrefined Tier I chronic dietary 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, lime) and mint oils (peppermint and spearmint). The DEEM-FCID™ default processing factors were used for all other processing commodities.

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

2. *Dietary exposure from drinking water*. The Agency determined that in addition to the parent compound, known as fenpyroximate, M-1, the z isomer of fenpyroximate, and the M-3 metabolite should be included in the drinking water assessment for fenpyroximate based on their structural similarity. Some surface water and ground water contamination may occur based on the proposed application rates and the environmental fate properties of fenpyroximate. However, the risk of water contamination from the parent compound is relatively low, based on its high sorption potential. Unlike the parent compound, sorption of the M-3 metabolite is much less, and it may move into water resources more readily. Fenpyroximate and M-1 are not expected to persist under terrestrial environmental conditions, with metabolism as the primary route of dissipation. Hydrolysis and photodegradation on soil are not expected to be significant routes of dissipation, but photodegradation in water could be significant assuming clear, well-mixed, shallow water bodies.

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-1 were calculated using the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM-EXAMS) shell. The acute and chronic non-cancer concentrations for Georgia (GA) pecan (highest exposure) are 12.9 and 1.8 microgram/Liter (ug/L), respectively. EPA used the Screening Concentration Ground Water (SCI-GROW2) model to estimate a ground water 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 incorporated directly into the dietary assessment using the estimated drinking water concentrations (EDWC) for surface water generated by the PRZM-EXAMS model. For the acute assessment, the peak concentration of 12.9 ppb was used to assess the contribution to drinking water; for the chronic assessment, the annual mean value of 1.8 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). 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 website at *http://www.epa.gov/pesticides/cumulative/*.

C. Safety Factor for Infants and Children

1. *In general*. Section 408 of the 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 database on toxicity and exposure unless EPA determines 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. These doses were supported partly by range finding data. The 2–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 increased 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 database is complete for FQPA purposes and there are no residual uncertainties for prenatal/postnatal toxicity.

3. *Conclusion*. There is a complete toxicity database for fenpyroximate and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor 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 database 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 database.

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

iv. The dietary food exposure assessment is an unrefined, Tier I, acute and chronic analyses, which assumed that fenpyroximate residues were present in all commodities at tolerance levels and that 100% of all commodities (registered and proposed uses) were 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 that will not likely be exceeded.

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

D. Aggregate Risks and Determination of Safety

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs), which are used as a point of comparison against estimated drinking water concentrations (EDWCs). The DWLOC values are not regulatory standards for drinking water, but are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. More information on the use of DWLOCs in dietary aggregate risk assessments can be found at *http://www.epa.gov/oppfead1/trac/science/screeningsop.pdf*.

More recently, the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface water and ground water EDWCs are directly incorporated into the dietary exposure analysis, along with food. This approach provides a more realistic estimate of exposure because actual body weights and water exposures are then added to estimated and water consumption form the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in developing drinking water modeling inputs. The risk assessment for fenpyroximate used in this tolerance document uses this approach of incorporating water exposure directly into the dietary exposure analysis.

There are no registered or proposed uses of fenpyroximate, which result in residential exposures, so the aggregate exposure assessment required by FFDCA section 408(b)(2)(D)(vi) consists solely of dietary (food + drinking water) exposures.

Aggregate exposure risk assessments were conducted by incorporating the drinking water concentrations directly into the dietary exposure assessment for the acute and chronic aggregate exposures (food + drinking water). These aggregate exposures do not exceed the Agency's level of concern since they were less than 100% of the respective population adjusted doses (PADs).

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 discussed in this unit for chronic exposure, EPA has concluded that exposure to fenpyroximate from food and water will utilize 9.8% of the chronic population adjusted 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 which 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*. A cancer aggregate-risk assessment was not performed because fenpyroximate has been classified as not likely to be carcinogenic to humans.

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.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology and high-performance liquid chromatography/mass spectrometry/mass spectrometry (HPLC/MS/MS) is available to enforce the tolerance expression. The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address:*residuemethods@epa.gov*.

B. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) for the residues of fenpyroximate in honey. Therefore, there are no international harmonization concerns at this time.

VI. Conclusion

Therefore, the time-limited tolerance is established for combined residues of fenpyroximate, (E)-1,1-dimethylethyl 4-[[[(E)-[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl)methylene] amino]oxy]methyl]benzoate, in or on honey at 0.10 ppm. This tolerance expires and is revoked on December 31, 2010.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VIII. 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: April 26, 2007.

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 180.566 is amended by adding text and a table to paragraph (b) to read as follows:

§ 180.566 Fenpyroximate; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemption*. Time-limited tolerance is established for the combined residues of fenpyroximate, (E)-1,1-dimethylethyl 4-

[[[(E)-[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene] amino]oxy] methyl]benzoate in or on honey at 0.10 ppm. This tolerance expires and is revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Honey	0.10 ppm	12/31/2010

* * * * *

[FR Doc. E7–8954 Filed 5–8–07; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0880; FRL–8125–5]

Foramsulfuron; 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 foramsulfuron on corn, sweet (K+CWHR); corn, sweet, forage; corn, sweet, stover; corn, pop grain; and corn, pop, stover when applied/used as a herbicide. The Interregional Project Number 4 (IR-4) submitted a petition to EPA 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 foramsulfuron.

DATES: This regulation is effective May 9, 2007. Objections and requests for hearings must be received on or before July 9, 2007, 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–2006–0880. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are 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: 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 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 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in [insert appropriate cite to either another unit in the preamble or a section in a rule]. 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–2006–0880 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 July 9, 2007.

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–2006–0880, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.