

Dated: March 20, 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 180.555 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.555 Trifloxystrobin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Barley, grain	0.05
Barley, hay	0.3
Barley, straw	5.0
* * *	* *
Corn, sweet, cannery waste	0.6
Corn, sweet, forage	0.6
Corn, sweet, kernel plus cob with husks removed	0.04
Corn, sweet, stover	0.25
* * *	* *
Oat, forage	0.3
Oat, grain	0.05
Oat, hay	0.3
Oat, straw	5.0
* * *	* *

* * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2004-0132; FRL-7769-1]

Flonicamid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of flonicamid and its metabolites in or on head and stem brassica and mustard greens. ISK Biosciences Corporation requested this tolerance 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 March 29, 2006. Objections and requests

for hearings must be received on or before May 30, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number EPA-HQ-OPP-2004-0132. All documents in the docket are listed on the www.regulations.gov web site. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced Federal-wide electronic docket management and comment system located at <http://www.regulations.gov/>. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, i.e., 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 electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This 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: Ann Sibold, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6502; e-mail address: sibold.ann@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 and Other Related Information?

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II. Background and Statutory Findings

In the **Federal Register** of July 7, 2004 (69 FR 40916) (FRL-7362-5), 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 4F6832) by ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord, Ohio 44077. The petition requested that 40 CFR 180.613 be amended by establishing a tolerance for combined residues of the insecticide flonicamid [*N*-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide] and its metabolites TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] TFNG [*N*-(4-trifluoromethylnicotinoyl)glycine] in or on the raw agricultural commodities brassica, head and stem, subgroup 5A at 1.5 parts per million (ppm) and mustard greens at 11 ppm. That notice included a summary of the petition prepared by ISK Biosciences Corporation, the registrant. There were no comments received in response to the notice of filing. There was one comment received in response to the final rule published in the **Federal Register** of August 31, 2005 (70 FR 51604) (FRL-7731-6), which is referenced in today's rule. The Agency's response is set forth in Unit IV.C.

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 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 residues of flonicamid [N-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide] and its metabolites TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] TFNG [N-(4-trifluoromethylnicotinoyl)glycine] in or on the raw agricultural commodities brassica, head and stem, subgroup 5A at 1.5 ppm and mustard greens at 11 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the

sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic effects caused by flonicamid and its metabolites 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 Unit III.A. of the final rule published in the **Federal Register** of August 31, 2005 (70 FR 51604) (FRL-7731-6).

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.

A summary of the toxicological endpoints for flonicamid used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of August 31, 2005 (70 FR 51604) (FRL-7731-6).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.613) for the combined residues of flonicamid [N-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide] and its metabolites TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] and TFNG [N-(4-trifluoromethylnicotinoyl)glycine], in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from flonicamid and its metabolites in food as follows:

i. *Acute exposure.* No acute dietary exposure and risk assessment was

conducted as discussed in the final rule published in the **Federal Register** of August 31, 2005.

ii. *Chronic exposure.* The proposed tolerances for head and stem brassica and mustard greens were included in the chronic dietary exposure assessment for flonicamid residues on certain commodities as set forth in the final rule published in the **Federal Register** of August 31, 2005. Tolerances for head and stem brassica and mustard greens were not established in that final rule for the following reason: Acceptable residue chemistry data for a commodity is required before a tolerance may be established; the review of residue chemistry data for head and stem brassica and mustard greens had not been completed at that time. The residue chemistry data review for head and stem brassica and mustard greens is now complete. There is no increment to dietary exposure as it has already been taken into account.

2. *Dietary exposure from drinking water.* The dietary exposure from drinking water is discussed in the final rule published in the **Federal Register** of August 31, 2005.

3. *From non-dietary exposure.* As discussed in the final rule published in the **Federal Register** of August 31, 2005, flonicamid is not registered for any uses that are likely to result in non-dietary 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 flonicamid and any other substances and flonicamid 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 flonicamid 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.* As discussed in the final rule published in the **Federal Register** of August 31, 2005, there is no evidence of prenatal or postnatal sensitivity.

3. *Conclusion.* As discussed in the final rule published in the **Federal Register** of August 31, 2005, the FQPA Safety Factor is reduced to 1X because:

- i. There is a complete toxicity data base.
- ii. There is a lack of susceptibility evidence in the developmental studies and reproductive study (The effects seen in offspring were mild and occurred only in one species.
- iii. The dietary food exposure assessment utilizes proposed tolerance level, or higher residues and 100% crop treated information for all commodities.
- iv. The dietary drinking water assessment (Tier 1 estimates) utilizes values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations.

E. Aggregate Risks and Determination of Safety

1. *Acute risk.* No acute risk is expected for reasons that are discussed in the final rule published in the **Federal Register** of August 31, 2005.

2. *Chronic risk.* The proposed tolerances for head and stem brassica and mustard greens were included in

the chronic dietary risk assessment for flonicamid residues on certain commodities as set forth in the final rule published in the **Federal Register** of August 31, 2005. Chronic risk does not exceed levels of concern.

3. *Short-term and intermediate-term risk.* Short-term and intermediate-term risk assessment was not conducted because residential exposure is not expected from the use pattern and/or appropriate toxicity endpoints were not identified.

4. *Determination of safety.* 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 flonicamid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology liquid chromatography/mass spectrometry (LC/MS) 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

There are no Codex, Mexican or Canadian Maximum residue limits tolerances. Therefore, no compatibility questions exist with respect to Codex.

C. Response to Comments

One comment was received from a private citizen who opposes the approval of any pesticide that leaves a residue on food. The comment contained no specific information pertaining to flonicamid but was limited to general claims such as EPA was providing inadequate protection for Americans. The Agency has received the same comment from this commentator on numerous previous occasions and rejects it for the reasons previously stated (70 FR 1349, 1354, January 7, 2005), (70 FR 37686, June 30, 2005), and (69 FR 63096, 63098, (October 29, 2004).

V. Conclusion

Therefore, the tolerance is established for combined residues of flonicamid [N-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide] and its metabolites TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] TFNG [N-(4-trifluoromethylnicotinoyl)glycine] in or on the raw agricultural commodities brassica, head and stem, subgroup 5A at 1.5 ppm and mustard greens at 11 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2004-0132 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 May 30, 2006.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington,

DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564-6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number EPA-HQ-OPP-2004-0132, to: Public Information and Records Integrity Branch, Information Technology and Resources Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

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 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.

VIII. 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: March 20, 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 180.613 is amended by alphabetically adding commodities to the table in paragraph (a)(1) to read as follows:

§ 180.613 Fonicamid; tolerances for residues.

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

Commodity	Parts per million
Brassica, head and stem, sub-group 5A	1.5
Mustard greens	11

* * * * *

[FR Doc. 06-2977 Filed 3-28-06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2005-0105; FRL-7761-3]

Fenpropimorph; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of fenpropimorph in or on bananas. BASF Corporation Agricultural Products requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective March 29, 2006. Objections and requests for hearings must be received on or before May 30, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number EPA-HQ-OPP-2005-0105. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., 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

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FOR FURTHER INFORMATION CONTACT: Lana Coppelino, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-0086; e-mail address: coppelino.lana@epa.gov.

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- 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.

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II. Background and Statutory Findings

In the **Federal Register** of June 22, 2005 (70 FR 36155)(FRL-7710-1), 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 7E4874) by BASF Corporation Agricultural Products, 26 Davis Drive, P.O. Box 13528; Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.616 be amended by establishing a tolerance for residues of the fungicide fenpropimorph, (+)-cis-4-(3-((4-tert-butylphenyl))-2-methylpropyl)-2,6-dimethylmorpholine, in or on bananas at 1.5 parts per million (ppm). This petition was previously published in the **Federal Register** on December 7, 1998, identified by the docket control number PF-848. That notice included a summary of the petition prepared by BASF Corporation Agricultural Products, 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://>