

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 180.642 is added to read as follows:

§ 180.642 Gentamicin; tolerances for residues.

(a) *General.* [Reserved].

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of gentamicin in or on the

specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Apple	0.10	December 31, 2010

(c) *Tolerance with regional restrictions.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. E8-17337 Filed 7-29-08; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[EPA-HQ-OPP-2006-0857; FRL-8370-7]

Cyfluthrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of cyfluthrin in or on alfalfa, forage and revises the existing tolerance for residues of cyfluthrin in or on alfalfa, hay. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 30, 2008. Objections and requests for hearings must be received on or before September 29, 2008, 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-2006-0857. 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 website 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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT:

Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5218; e-mail address: stanton.susan@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information****A. Does this Action Apply to Me?**

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

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

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

the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

In addition to accessing 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 EPA’s tolerance regulations at 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 FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2006-0857 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before September 29, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2006-0857, 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. Petition for Tolerance

In the **Federal Register** of January 23, 2008 (73 FR 3964) (FRL-8345-7), 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 7F7226) by Bayer CropScience, 2.T.W. Alexander Drive, PO Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.436 be amended by establishing tolerances for residues of the insecticide cyfluthrin, cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate, in or on alfalfa, forage at 5.0 parts per million (ppm) and alfalfa, hay at 15.0 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available to the public at <http://www.regulations.gov> in the docket established for that action (EPA-HQ-OPP-2007-0506). Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the tolerance level for alfalfa, hay from 15.0 ppm to 13 ppm. The reason for this change is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of cyfluthrin on alfalfa, forage at 5.0 ppm and alfalfa, hay at 13 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

On February 27, 2008, the Agency published a final rule in the **Federal Register** (73 FR 10390) (FRL-8350-3) establishing tolerances for residues of cyfluthrin in or on grass, forage, fodder and hay group 17, forage at 12 ppm; grass, forage, fodder and hay, group 17, hay at 50 ppm; beet, sugar, roots at 0.10 ppm; and beet, sugar, dried pulp at 1.0 ppm. When the Agency conducted the risk assessments in support of the February 27, 2008 tolerance action, it considered the proposed use of cyfluthrin on alfalfa, incorporating potential residues of cyfluthrin in alfalfa commodities and secondary residues of cyfluthrin in livestock commodities from consumption of treated feedstuffs, including alfalfa forage and hay. Since EPA considered the alfalfa use in its most recent risk assessments, establishing the tolerances on alfalfa forage and hay will not change the estimated aggregate risks resulting from use of cyfluthrin, as discussed in the February 27, 2008 **Federal Register**. Refer to this **Federal Register** document, available at <http://www.regulations.gov>, for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies upon those risk assessments and the findings made in the **Federal Register** document in support of this action.

Based on the risk assessments discussed in the final rule published in the **Federal Register** of February 27, 2008, 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 cyfluthrin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology using gas chromatography/electron-capture (GC/EC) detection 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, Canadian or Mexican MRLs (maximum residue limits) established for cyfluthrin on alfalfa commodities.

C. Response to Comments

One comment was received from a private citizen in response to the notice of filing. The commenter stated "We need to further explore this issue concerning the pesticide usage." The comment contained no scientific data or other substantive evidence to rebut the Agency's finding that there is a reasonable certainty that no harm will result from aggregate exposure to cyfluthrin from the establishment of these tolerances. In making this finding, EPA considered all available scientific data for cyfluthrin and the estimated aggregate exposure to the pesticide, including anticipated dietary (food and drinking water) and residential exposures. EPA, therefore, disagrees with the commenter that there is a need for further exploration.

D. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA has revised the tolerance level for alfalfa, hay from 15.0 ppm to 13 ppm. EPA revised the tolerance level based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data*.

V. Conclusion

Therefore, tolerances are established for residues of cyfluthrin, cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate, in or on alfalfa, forage at 5.0 ppm and alfalfa, hay at 13 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section

12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: July 16, 2008.
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 180.436 is amended by revising the tolerance for alfalfa, hay and alphabetically adding the commodity alfalfa, forage to the table in paragraph (a)(1) to read as follows:

§ 180.436 Cyfluthrin; tolerances for residues.

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

Commodity	Parts per million
* * *	* *
Alfalfa, forage	5.0
Alfalfa, hay	13
* * *	* *

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[FR Doc. E8-17062 Filed 7-29-08; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2007-0214; FRL-8373-2]

Pyraclostrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of pyraclostrobin and its desmethoxy metabolite in or on the following commodities: Borage, seed; castor oil plant, seed; chinese tallowtree, seed; crambe, seed; cuphea, seed; echium, seed; euphorbia, seed; evening primrose, seed; flax, seed; gold of pleasure, seed; hare's ear mustard, seed; jojoba, seed; lesquerella, seed; lunaria, seed; meadowfoam, seed; milkweed, seed; mustard, seed; niger seed, seed; oil radish, seed; poppy, seed; rapeseed, seed; rose hip, seed; safflower, seed; sesame, seed; stokes aster, seed; sweet rocket, seed; tallowwood, seed; tea oil plant, seed; and vernonia, seed. It also increases the existing tolerance for residues of pyraclostrobin and its desmethoxy metabolite in or on sunflower. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 30, 2008. Objections and requests for hearings must be received on or before September 29, 2008, 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-2007-0214. 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](http://www.regulations.gov) website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [regulations.gov](http://www.regulations.gov). Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are