

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: May 22, 2009.

**Daniel J. Rosenblatt,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

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

**PART 180—[AMENDED]**

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

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

■ Section 180.476 is amended by revising the introductory text for paragraph (a)(1); by alphabetically adding the following commodities to the

table in paragraph (a)(1); by revising the introductory text for paragraph (a)(2); and by removing the entries for Broccoli; Collards; Coriander, leaves; Dandelion, leaves; Kale; Mustard, greens; Parsley, leaves; Swiss chard; and Turnip, greens from the table in paragraph (b) to read as follows:

**§ 180.476 Triflumizole; tolerances for residues**

(a) *General.* (1) Tolerances are established for residues of the fungicide triflumizole, including its metabolites and degradates, in or on the commodities listed in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the parent compound triflumizole, 1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino)-2-propoxyethyl)-1*H*-imidazole, and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as stoichiometric equivalent of the parent compound.

Commodity	Parts per million
Brassica, head and stem, subgroup 5A .....	8.0
Brassica, leafy greens, subgroup 5B .....	40
Canistel .....	2.5
Cilantro, leaves .....	35
Hop, dried cones .....	50
Leafy greens subgroup 4A, except spinach .....	35
Mango .....	2.5
Papaya .....	2.5
Pineapple .....	4.0
Sapodilla .....	2.5
Sapote, black .....	2.5
Sapote, mamey .....	2.5
Star apple .....	2.5
Swiss chard .....	18
Turnip, greens .....	40

(2) Tolerances are established for residues of the fungicide triflumizole, including its metabolites and degradates, in or on the commodities of animal origin listed in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the parent compound triflumizole, 1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino)-2-propoxyethyl)-1*H*-imidazole, the metabolite 4-chloro-2-hydroxy-6-trifluoromethylaniline sulfate, and other metabolites containing the 4-chloro-2-

trifluoromethylaniline moiety, calculated as the parent compound.

\* \* \* \* \*

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**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2007-0158; FRL-8416-7]

**Aspergillus flavus AF36 on Pistachio; Extension of Temporary Exemption From the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation amends the temporary exemption from the requirement of a tolerance for residues of the *Aspergillus flavus* AF36 (*A. flavus* AF36) on pistachio when applied/used

as an antifungal agent to displace aflatoxin-producing fungi. Interregional Research Project Number 4 (IR-4), on behalf of the Arizona Cotton Research and Protection Council, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the temporary tolerance exemption be amended. The amendment extends the expiration date to December 31, 2011.

**DATES:** This regulation is effective June 3, 2009. Objections and requests for hearings must be received on or before August 3, 2009, 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-2007-0158. All documents in the docket are listed in the docket index available at <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 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:** Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8097; e-mail address: [bacchus.shanaz@epa.gov](mailto:bacchus.shanaz@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 electronically available documents 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 e-CFR site at <http://www.gpoaccess.gov/ecfr>.

###### *C. Can I File an Objection or Hearing Request?*

Under section 408(g) of FFDCA, 21 U.S.C. 346a, 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-2007-0158 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 August 3, 2009.

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-2007-0158, 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 Facility’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**

In the **Federal Register** of March 16, 2009 (74 FR 11100) (FRL-8405-1), 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 tolerance petition (PP 8E7461) by IR-4, Rutgers University, 500 College Road East, Suite 201W., Princeton, NJ 08540, on behalf of the Arizona Cotton Research and Protection Council, 3721 East Weir Ave., Phoenix, AZ 85040-2933. The petition proposes to amend a temporary exemption from the requirement of a tolerance in 40 CFR 180.1206(b) for residues of the non-aflatoxin-producing microbial antifungal agent, *A. flavus* AF36, in or on pistachio.

This docket included a summary of the petition prepared by the petitioner IR-4 and Arizona Cotton Research and Protection Council. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(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. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a

tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require 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....” Additionally, section 408(b)(2)(D) of FFDCA requires that 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.”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

### III. Toxicological Profile

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 and considered its validity, completeness and reliability and the relationship of this information 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.

The toxicological profile of the microbial pesticide, *A. flavus* AF36 has been previously described in the final rule of the **Federal Register** issue of July 14, 2003 (68 FR 41535) (FRL-7311-6). The exemption from tolerance of *A. flavus* AF36, a non-aflatoxin-producing strain of *Aspergillus flavus*, on cotton was established in 40 CFR 180.1206. The database supporting that exemption from tolerance also supports the temporary exemption of this active ingredient on pistachio in 40 CFR 180.1206(b). See the **Federal Register** issue of May 23, 2007 (72 FR 28868) (FRL-8129-4).

The microbial pesticide was neither toxic nor infective via the oral and pulmonary routes. It was placed in Toxicity Category IV for acute oral effects. The Toxicity Category III designation for acute inhalation effects is based on the granular nature of the microbial pesticide and the submitted pulmonary studies. This microbial pesticide has been used for more than a decade in experimental laboratory and field trials and in agricultural practice

on cotton in Arizona, California, and Texas without any reports of adverse dermal irritation or hypersensitivity effects.

The petitioner now seeks to amend the temporary exemption from the requirement of a tolerance for *A. flavus* AF36 on pistachio in accordance with the Experimental Use Permit (EUP), EPA File Symbol 71693-EUP-1, published in the **Federal Register** issue of May 23, 2007 (72 FR 28971) (FRL-8128-8) and to extend it to December 31, 2011.

No further toxicological data are required for this amended temporary exemption from the requirement of a tolerance for *A. flavus* AF36 on pistachio.

### IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

For aggregate dietary and other non-occupational exposure and cumulative effects, the Agency continues to rely on its previous assessments published in the **Federal Register**, since the extension will not change these exposures and risks. See the previously published July 14, 2003 and May 23, 2007 **Federal Register** documents cited in Unit III.

### V. Determination of Safety for U.S. Population, Infants and Children

The Agency also relies on the previous assessments published in the July 14, 2003 and May 23, 2007 **Federal Register** documents cited in Unit III. to determine that there is reasonable certainty that no harm will result from aggregate exposures to residues of the antifungal agent *A. flavus* AF36. Because there are no threshold effects of concern to infants, children and adults when *A. flavus* AF36 is used as labeled, the provision requiring an additional margin of safety does not apply. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of *A. flavus* AF36.

### VI. Other Considerations

#### A. Analytical Methods and Endocrine Disruptors

The Agency continues to rely on its assessment for endocrine disruptors and analytical methods in the previously

published July 14, 2003 **Federal Register** document cited in Unit III.

#### B. Codex Maximum Residue Level

There is no Codex Maximum Residue Level (MRL) for residues of *A. flavus* AF36 on pistachio.

### VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance or exemption from 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *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 temporary tolerance exemption 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).

### 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: May 20, 2009.

**W. Michael McDavid,**

*Acting Director, Biopesticides and Pollution Prevention 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 180.1206(b) is revised to read as follows:

#### § 180.1206 *Aspergillus flavus* AF36, exemption from the requirement of a tolerance.

\* \* \* \* \*

(b) *Aspergillus flavus* AF36 is temporarily exempt from the requirement of a tolerance on pistachio when used in accordance with the Experimental Use Permit, EPA File

Symbol 71693-EUP-1. This temporary exemption from tolerance expires on December 31, 2011.

\* \* \* \* \*

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**BILLING CODE 6560-50-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Part 412

[CMS-1337-IFC]

RIN 0938-AP76

#### Medicare Program; Revisions to FY 2009 Medicare Severity-Long-Term Care Diagnosis-Related Group (MS-LTC-DRG) Weights

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Interim final rule with comment period.

**SUMMARY:** This interim final rule with comment period implements revised Medicare severity long-term care diagnosis-related group (MS-LTC-DRG) relative weights for payment under the long-term care hospital (LTCH) prospective payment system (PPS) for federal fiscal year (FY) 2009. We are revising the MS-LTC-DRG relative weights for FY 2009 due to the misapplication of our established methodology in the calculation of the budget neutrality factor. The revised FY 2009 MS-LTC-DRG relative weights are effective for the remainder of FY 2009 (that is, from June 3, 2009 through September 30, 2009).

**DATES:** *Effective date:* These regulations are effective on June 3, 2009.

*Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m., June 29, 2009.

**ADDRESSES:** In commenting, please refer to file code CMS-1337-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following

address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1337-IFC, P.O. Box 8011, Baltimore, MD 21244-8011.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1337-IFC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period has ended.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Tzvi Hefter, (410) 786-4487.

#### SUPPLEMENTARY INFORMATION:

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the