

**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 180.593 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

**§ 180.593 Etoazole; tolerances for residues.**

(a) \* \* \*

| Commodity                              | Parts per million |
|----------------------------------------|-------------------|
| * * *                                  | * *               |
| Cherry .....                           | 1.0               |
| Hop, dried cones .....                 | 7.0               |
| Vegetable, cucurbit sub-group 9A ..... | 0.20              |

\* \* \* \* \*

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**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2007-0545; FRL-8342-1]

***Aspergillus Flavus* AF36 on Corn; Temporary Exemption From the Requirement of a Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the *Aspergillus flavus* AF36 on corn when applied/used before corn tasseling occurs. Arizona Cotton Research and Protection Council 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 the temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of *Aspergillus flavus* AF36. The temporary tolerance exemption expires on December 31, 2011.

**DATES:** This regulation is effective December 26, 2007. Objections and requests for hearings must be received on or before February 25, 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-2007-0545. 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:** 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in section 5 of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the regulations promulgated to carry out that provision of FIFRA (40 CFR part 172). 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 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. 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-2007-0545 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 February 25, 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 your copies, identified by docket ID number EPA-HQ-OPP-2007-0545, 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

In the **Federal Register** of August 8, 2007 (72 FR 44521) (FRL-8139-7), 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 tolerance petition (PP 7E7205) by Interregional Research Project Number 4 (IR-4), Rutgers University, 500 College Road East, Suite 201W, Princeton, NJ 08540 on behalf of the Arizona Cotton Research and Protection Council, 3721 E. Wier Ave., Phoenix, AZ 85040. The petition requested that 40 CFR 180.1206 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of *Aspergillus flavus* AF36. This notice included a summary of the petition prepared by the petitioner IR-4, on behalf of the 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 unconditionally registered microbial pesticide *Aspergillus flavus* AF36 for use on cotton has been previously described in the final rule of the **Federal Register** of July 14, 2003 (68 FR 41535). Those health effects data were the basis for establishing the exemption from tolerance of *Aspergillus flavus* AF36, a non-aflatoxin-producing strain of *Aspergillus flavus*, on cotton in 40 CFR 180.1206. This exemption from tolerance was amended to include a temporary exemption from tolerance for use of *Aspergillus flavus* AF36 on pistachio on May 23, 2007 (72 FR 28868) (FRL-8129-4). The database supporting the current exemption from tolerance also supports the proposed temporary exemption of this active ingredient on corn.

The pesticide is 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 pesticide and the submitted pulmonary studies. This 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, Arizona Cotton Research and Protection Council, now seeks to amend that exemption from tolerance of *Aspergillus flavus* AF36 on cotton, to include a temporary exemption from tolerance for residues of the fungal active ingredient on corn. An Experimental Use Permit (EUP), EPA Registration Number 71693-EUP-E, is proposed for three years to treat corn fields by ground or aerial application before corn tasseling occurs. The applicant also submitted additional data to support the EUP. This data included information from the public literature and from small field trials which indicate that there will not be any incremental harm from the use of the pesticide during the EUP. No further toxicological data are required for this temporary exemption from the requirement of a tolerance for *Aspergillus flavus* AF36 on corn.

## 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).

### A. Dietary Exposure

1. *Food.* The aforesaid final rule for the exemption from tolerance for residues of *Aspergillus flavus* AF 36 on cotton considered all studies submitted by the applicant and found them to be acceptable. Peeling or shucking of corn, washing, cooking, and processing of treated commodities will mitigate against potential dietary exposure.

2. *Drinking water exposure.* Those data are also acceptable to demonstrate that the proposed use of *Aspergillus flavus* AF36 on corn will not harm the U.S. adult, infant, and children population from dietary exposure, including food and drinking water. Percolation through the soil and municipal treatment of drinking water are expected to preclude exposure of the U.S. population, infants, and children to residues of the pesticide.

### B. Other Non-Occupational Exposure

1. *Dermal exposure.* Dermal non-occupational exposure is expected to be minimal to non-existent for the proposed use of *Aspergillus flavus* AF36 on corn. The pesticide is to be applied to agricultural sites not in the proximity

of residential areas, schools, nursing homes, or daycares.

2. *Inhalation exposure.* For the same reasons non-occupational inhalation exposure to AF36 is expected to be minimal to non-existent.

#### V. Cumulative Effects

Another non-aflatoxin-producing strain of *Aspergillus flavus*, NRRL 21882, is undergoing research trials on corn in Texas, but not in the same areas to be treated during this EUP for AF36. Cumulative effects of these strains are not expected to exceed the risk cup for the registered *Aspergillus flavus* strains, AF36 and NRRL 21882. Furthermore, these strains are expected to decrease the presence of aflatoxin-producing colonies of the fungus on treated commodities and, thus, decrease the risks posed by the potent liver carcinogen, aflatoxin.

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

Based on the previously evaluated data, it is not necessary to use a safety factor to determine safety to children (see **Federal Register** of July 14, 2003 (68 FR 41535), as cited in Unit III.).

#### VII. Other Considerations

##### A. Endocrine Disruptors

See **Federal Register** of July 14, 2003 (68 FR 41535), as cited in Unit III.

##### B. Analytical Method(s)

See **Federal Register** of July 14, 2003 (68 FR 41535), as cited in Unit III.

##### C. Codex Maximum Residue Level

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

#### VIII. 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).

#### IX. 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: December 14, 2007.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 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 is amended by adding paragraph (c) to read as follows:

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

\* \* \* \* \*

(c) *Apergillus flavus* AF36 is temporarily exempt from the requirement of a tolerance on corn when used in accordance with the Experimental Use Permit 71693-EUP-2. This temporary exemption from tolerance will expire December 31, 2011.

[FR Doc. E7-24979 Filed 12-21-07; 8:45 am]

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#### DEPARTMENT OF COMMERCE

##### National Oceanic and Atmospheric Administration

##### 50 CFR Part 648

[Docket No. 070808450-7714-02]

RIN 0648-AV83

##### Fisheries of the Northeastern United States; Northeast (NE) Multispecies Fishery; Regulatory Amendment to Adopt Fishing Gear Standards for the NE Multispecies Regular B Day-At-Sea (DAS) Program and the Eastern U.S./Canada Haddock Special Access Program (SAP)

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule.