§ 1.20 Post issuance fees.

* * * * *

(e) For maintaining an original or reissue patent, except a design or plant patent, based on an application filed on or after December 12, 1980, in force beyond four years; the fee is due by three years and six months after the original grant:

By a small entity (§ 1.27(a))	$455.00
By other than a small entity	$910.00

(f) For maintaining an original or reissue patent, except a design or plant patent, based on an application filed on or after December 12, 1980, in force beyond eight years; the fee is due by seven years and six months after the original grant:

By a small entity (§ 1.27(a))	$1,045.00
By other than a small entity	$2,090.00

(g) For maintaining an original or reissue patent, except a design or plant patent, based on an application filed on or after December 12, 1980, in force beyond twelve years; the fee is due by eleven years and six months after the original grant:

By a small entity (§ 1.27(a))	$1,610.00
By other than a small entity	$3,220.00

* * * * *

■ 6. Section 1.492 is amended by revising paragraphs (a)(1) through (a)(3), (a)(5), (b), and (d) to read as follows:

§ 1.492 National stage fees.

* * * * *

(a) The basic national fee:

(1) Where an international preliminary examination fee as set forth in § 1.482 has been paid on the international application to the United States Patent and Trademark Office:

By a small entity (§ 1.27(a))	$365.00
By other than a small entity	$730.00

(2) Where no international preliminary examination fee as set forth in § 1.482 has been paid to the United States Patent and Trademark Office, but an international search fee as set forth in § 1.445(a)(2) has been paid on the international application to the United States Patent and Trademark Office as an International Searching Authority:

By a small entity (§ 1.27(a))	$385.00
By other than a small entity	$770.00

(3) Where no international preliminary examination fee as set forth in § 1.482 has been paid and no international search fee as set forth in § 1.445(a)(2) has been paid on the international application to the United States Patent and Trademark Office:

By a small entity (§ 1.27(a))	$540.00
By other than a small entity	$1,080.00

(4) * * *

(5) Where a search report on the international application has been prepared by the European Patent Office or the Japan Patent Office:

By a small entity (§ 1.27(a))	$460.00
By other than a small entity	$920.00

(b) In addition to the basic national fee, for filing or later presentation of each independent claim in excess of 3:

By a small entity (§ 1.27(a))	$43.00
By other than a small entity	$86.00

* * * * *

(d) In addition to the basic national fee, if the application contains, or is amended to contain, a multiple dependent claim(s), per application:

By a small entity (§ 1.27(a))	$145.00
By other than a small entity	$290.00

* * * * *

Dated: July 7, 2003.

James Rogan,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 03–17652 Filed 7–11–03; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0138; FRL–7311–6]

Aspergillus flavus AF36; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the microbial antifungal agent *Aspergillus flavus* AF36, a non-aflatoxin-producing member of the naturally-occurring genus of fungi *Aspergillus*, in or on the food/feed commodity cotton, when the pesticide is used according to its label instructions as a prebloom application. The 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), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Aspergillus flavus* AF36 in or on cotton and its food/feed commodities.

DATES: This regulation is effective July 14, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0138, must be received on or before September 12, 2003.

ADDRESSES: Written objections and hearing requests may be submitted by mail or through hand delivery/courier. Follow the detailed instructions as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8097; e-mail address: 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. 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 Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0138. The official public docket is intended to serve as a repository for materials (i.e.,documents and other information) submitted to the Agency in connection with this action and/or relied upon by the Agency in

taking this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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. To the extent that a particular document is not located in the official public docket, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

The legacy docket for this case is OPP–2003–0020, which was set up in connection with the Notice of Filing of this pesticide petition, 8E5001. It contains the **Federal Register** Notice dated February 14, 2003, (68 FR 7554), which was published to announce this petition, other relevant **Federal Register** documents associated with the exemption from temporary tolerance which preceded this permanent exemption from tolerance, and comments received in response to the publication of this petition.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of February 14, 2003 (68 FR 7554) (FRL–7289–9), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide tolerance petition (PP 8E5001) by Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, Technology Center of New Jersey, 681 U. S. Highway #1 South, North Brunswick, NJ 08902–3390, on behalf of the Arizona Cotton Research and Protection Council, 3721 East Wier Avenue, Phoenix, AZ 85040–2933. This notice included a summary of the petition prepared by the petitioner, IR-4, on behalf of the Arizona Cotton Research and Protection Council. In response to the notice of filing of this petition, comments in favor of the use of the pesticide were received from cotton growers, processors and ginners, mainly from Arizona and Texas.

The petition requested that 40 CFR 180.1206 be amended by establishing an exemption from the requirement of a tolerance for residues of *Aspergillus flavus* AF36 in or on cotton and its food/feed commodities.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement of 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 the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' Additionally, section 408(b)(2)(D) of the 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 the 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.

Aspergillus flavus AF36 (also referred to as AF36) is a non-aflatoxin-producing or atoxigenic strain of *Aspergillus flavus*, whose species are ubiquitous around the world. Some members of the genus *Aspergillus* produce mycotoxins, such as aflatoxin, a potent carcinogen produced by toxigenic strains of *A. flavus*. Other members of the genus *Aspergillus* have been domesticated for commercial use, such as *Aspergillus niger* for production of enzymes (e.g., alpha-galactosidase found in beano, a dietary supplement) and *Aspergillus oryzae* for production of soy sauce. The subject strain of this final rule, *Aspergillus flavus* AF36, is characterized as an atoxigenic strain by its lack of production of aflatoxin. It is not vegetatively compatible with the toxigenic strains of *A. flavus*, a feature which limits cross-over potential to, and, thus, further proliferation of, the toxigenic strains. Starter cultures, selected on the basis of the vegetative incompatibility with aflatoxin-producing strains, are to be monitored by standard thin layer chromatography (TLC) procedures, and visualization via scanning fluorescence densitometry scanning [Master Record Identification Number (MRID) 44626101; BPPD Data Evaluation Report of Analysis of Samples, dated March 29, 1999 (hereinafter referred to as ''BPPD review - March 29, 1999''); BPPD Review of Supplementary Information dated May 14, 1999 (hereinafter referred to as ''BPPD review - May 14, 1999'')]. In this manner, the applicant proposes to maintain batches free of aflatoxin contamination during production. Batches contaminated with aflatoxin, or human pathogens, or unintentional ingredients above regulatory levels are to be destroyed. Thus, use of AF36 is not likely to add to the environmental burden of the aflatoxin-producing strains of *A. flavus*.

The pesticide is proposed for a single prebloom application once a year to cotton fields to displace the aflatoxin-producing strains of *Aspergillus flavus* from cotton. Sterilized wheat seeds, colonized with *Aspergillus flavus* AF36,

are to be applied at 10 lb of end-use product (EP) (equivalent to the low rate of less than 0.01 lb active ingredient (ai) per acre). Within 3 days of application of the pesticide, the fields are furrow irrigated to promote germination of AF36, which apparently colonizes the cotton crop and soil, before the aflatoxin-producing strains of *A. flavus* proliferate. This competitive exclusion of the aflatoxin-producing strains does not increase the total *Aspergillus* population in the environment above background levels as demonstrated in soil and air monitoring studies. [MRIDs 45307201, 45307202; BPPD Review of Soil and Air Monitoring Studies and Product Performance Testing (Efficacy), dated May 15, 2003 (hereinafter referred to as ''BPPD Review - May 15, 2003'')]. The displacement of the toxigenic strain of *Aspergillus flavus* by AF36 may reduce aflatoxin contamination of cotton seed.

The toxicology and pathogenicity data generated by the petitioner in support of this tolerance exemption, and reviewed by the Agency, are summarized below. The following discussion of the evaluations of the submitted studies and information indicates that exposure to the pesticide is not likely to be greater than that which occurs normally to other ubiquitous *A. flavus* strains. Submitted data also indicate no toxicity or infectivity of AF36 in test mammalian systems. More detailed analyses of these studies can be found in the specific Agency reviews of the studies that are cited below.

1. *Acute oral toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3050; MRID 43972403).* Agency evaluation of submitted acute oral study indicates no toxicity/infectivity effects of the pesticide. Five male, and five female Sprague Dawley rats were treated orally with the microbial pesticide (500 milligrams/milliliter (mg/mL) or 6.3 x 10^3 cfu/mL) by gavage. No clinical signs or abnormalities were noted during the study, and the pesticide was considered to be neither toxic nor infective following oral administration of a single dose. The acute oral test resulted in a Toxicity Category IV classification with a lethal dose $(LD)_{50}$ greater than 5,000 milligrams/kilogram (mg/kg) body weight [MRID 43972403; BPPD Data Evaluation Report, Acute Oral Toxicity Study in Rats, dated April 23, 1996 (hereinafter referred to as ''BPPD Review - April 23, 1996'')].

2. *Acute pulmonary toxicity/ pathogenicity (OPPTS Harmonized Guideline 885.3150; MRID 45798201).* The Agency required an intratracheal pulmonary infectivity/pathogenicity study. This test involves intratracheal instillation of the test material and post mortem examination of lungs and other organs for clearance.

Three studies were submitted in support of the mammalian acute infectivity/pathogenicity pulmonary guideline: A range finding study and two complete acute pulmonary studies. The dose-range study concluded that 10^8 cfu/rat would be a suitable test dose level for the acute pulmonary studies [MRID 45739101; BPPD Data Evaluation Report, dated April 02, 2003a (hereinafter referred to as ''BPPD Review - April 02, 2003a'')]. In the first acute pulmonary study, conducted with Tween 80 as a surfactant in the test material, 26 male and 26 female Sprague Dawley rats (approximately 8 to 10 weeks old) each were dosed with a single intratracheal dose of 1.2 mL/kg at 5.30 x 10^8 cfu/mL (or 1.28 to 1.63 x 10^8 cfu/animal). Results from this study indicated that the test organism was neither infective nor pathogenic, in spite of rat mortality, which is believed to have been due to a severe acute inflammatory response to the Tween 80 [MRID 45798101; BPPD Data Evaluation Report, dated April 02, 2003a (hereinafter referred to as ''BPPD Review - April 02, 2003b'')].

In the second acute pulmonary study, which was a repetition of the first acute pulmonary test, but was conducted without Tween 80, 25 male and 25 female Sprague Dawley rats (approximately 8 to 10 weeks old) each received a single intratracheal dose of approximately 1.2 mL/kg. Mortality of 4 rats by day 2 appeared to be attributable to an initial dosing effect. The rest of the test animals showed an initial response, followed by a rapid recovery indicating no toxicity. Although some surviving rats lost weight intermittently, all surviving rats gained weight prior to scheduled sacrifice. No clinical signs that were considered to be due to the test organism were observed in the test rats. Organs were examined *post mortem* as previously described. *Aspergillus flavus* AF36 was detected in the lungs with clearance by day 8 after dosing. No test organisms were detected in any samples from the shelf control or inactivated test organism treated rats. Based on the presented/submitted data, including the clearance data, the test organism, *Aspergillus flavus* AF36, was considered not toxic, infective, or pathogenic to the rat pulmonary system. The study is acceptable.

3. *Acute inhalation (OPPTS Harmonized Guideline 152–32).* The inert is sterilized wheat seeds, comprising approximately 99% of this pesticidal product. It acts as a matrix and nutrient source for the germinating AF36. Because this constitutes the majority of the pesticide and does not contain respirable particles of less than 10 microns, an inhalation study was not required pursuant to 40 CFR 158.740(c). In addition, based on the results obtained through the acute pulmonary toxicity/pathogenicity studies summarized immediately above, AF36 is considered not toxic, infective, or pathogenic to the rat pulmonary system. On the basis of this study and the nature of the inert ingredients present, the pesticide was considered Toxicity Category III for acute inhalation effects. [MRID 45798201; BPPD Data Evaluation Report, dated April 02, 2003c (hereinafter referred to as ''BPPD Review - April 02, 2003c'')].

4. *Hypersensitivity incidents (OPPTS Harmonized Guideline 152–37; MRID 45739104).* The registrant submitted information (MRID 45739104) to demonstrate the lack of hypersensitivity to workers who have been exposed during the manufacture, application, and use of the pesticide in the research and experimental phases. No adverse hypersensitivity reaction to AF36 was recorded or reported by a state council or six companies during use for 3 or 6 years [MRID 45739104; BPPD Data Evaluation Report, dated April 02, 2003d (hereinafter referred to as ''BPPD Review - April 02, 2003d'')]. However, to comply with the Agency's requirements under section 6(a)(2), any incident of hypersensitivity associated with the use of this pesticide must be reported to the Agency.

5. *Data waivers.* Data waivers were requested for the following studies:

i. Acute dermal toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3100)

ii. Primary dermal irritation (OPPTS Harmonized Guideline 870.2500)

iii. Primary eye irritation (OPPTS Harmonized Guideline 870.2400)

iv. Intravenous, intracerebral, intraperitoneal injection (OPPTS Harmonized Guideline 885.3200)

v. Hypersensitivity study (40 CFR 152–36)

vi. Immune response (40 CFR 152–38)

With regards to the dermal and eye irritation guideline tests, it was impractical to apply the end-use product, sterilized wheat seeds inoculated with *Aspergillus flavus* AF36, as test material. Furthermore, non-occupational dermal and eye exposures, or exposures via any of the routes in Unit III.5.i.—vi., are not likely to be above naturally-occurring background levels for the following reasons.

First, *Aspergillus flavus*, a saprophytic fungus, is a normal

constituent of the microflora in air and soil. The naturally occurring soil and plant colonizer is also found on living and dead plant material throughout the world. Aflatoxin-producing strains of *Aspergillus flavus* are particularly prominent in hot, dry climates supplemented with irrigation and are ubiquitous components of the natural Arizona desert ecosystem. Quantities of *A. flavus* typically increase during crop production and the fungus occurs widely on crop debris left in the soil. Shortly after application, AF36 germinates, apparently displaces the aflatoxin-producing strains from cotton and the soil, and spore levels return to normal background, without increase of total *A. flavus*. This was demonstrated in soil and air monitoring studies submitted over multiple years of experimental usage [BPPD Review - May 15, 2003]. Thus exposures to AF36 are not likely to increase above those normally associated with the naturally occurring *A. flavus* background levels.

Second, the application rate is low, being less than 0.01 lb active ingredient per acre, and agricultural sites are treated, thus minimizing non-occupational and residential exposure. The proposed label rate is less than 0.01 pound of active ingredient in 10 pounds end-use product, or approximately 1.34 x 10^7 colony forming units (cfu) per acre.

Finally, drift is not expected during application based on the large granular nature of the pesticide (i.e., sterilized inoculated wheat seeds). In addition, only one prebloom application is made, and cultivation is not recommended after application. Thus, once again, the potential for non-occupational dermal and residential exposure is unlikely.

The acute oral toxicological study demonstrated an LD_{50} of greater than 5,000 mg/kg with no toxicity/infectivity effects, and demonstrable clearance from organs examined *post mortem* [MRID 43972403; BPPD Review - April 23, 1996]. This rationale supported the request to waive the acute intraperitoneal study.

A hypersensitivity study was waived since hypersensitivity incidents were not reported from maximally exposed workers and researchers during the research and experimental phases associated with the use of the active ingredient, *A. flavus* AF36 [BPPD Review - April 02, 2003d]. Nevertheless, reports of hypersensitivity incidents associated with the use of the pesticide are still required to comply with FIFRA section 6(a)(2) requirements.

Submitted toxicity/pathogenicity studies in the rodent (required for microbial pesticides) also indicate that following oral and pulmonary routes of exposure [BPPD Review - April 23, 1996; BPPD Review - April 02, 2003c], the immune system is still intact and able to process and clear the active ingredient. Thus, the request to waive the immune response study was granted.

On the basis of the foregoing rationales, and there being no documented problems associated with the non-aflatoxin producing strain, *Aspergillus flavus* AF36, data waivers for the studies listed in Unit III.5.i.—vi., were granted to the applicant for the proposed use of *Aspergillus flavus* AF36 on cotton.

6. *Subchronic, chronic toxicity and oncogenicity, and residue.* Based on the data generated in accordance with the Tier I data requirements set forth in 40 CFR 158.740(c), the Tier II and Tier III data requirements were not triggered and, therefore, not required in connection with this action. In addition, because the Tier II and Tier III data requirements were not required, the residue data requirements set forth in 40 CFR 158.740(b) also were not required.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the 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).

There is a potential for aggregate exposure of adult humans, infants and children to the microbe because of the ubiquitous distribution of *Aspergillus* fungal strains in the environment. The Agency has considered the incremental exposure and risk associated with the proposed application of this strain of *Aspergillus flavus*, AF36, as summarized below, and concludes that use of AF36 is not likely to add an incremental risk above that posed by the normal exposure of adults, infants and children to *Aspergillus flavus* strains present in the environment. In fact, use of the pesticide, AF36, may decrease potential environmental aflatoxin exposure to exposed populations.

A. Dietary Exposure

1. *Food.* Based on submitted studies, the end-use product, *Aspergillus flavus* AF36, demonstrates low acute oral toxicity category IV potential [BPPD Review - April 23, 1996]. No toxicity endpoints were indicated to justify setting a numerical tolerance for the fungal active ingredient, *Aspergillus flavus* AF36. An LD_{50} greater than 5,000 mg/kg body weight, in the acute oral studies discussed above, indicates that consumption of food commodities treated with AF36 poses no incremental risk via dietary exposure. Indeed, the submitted data indicate no toxicity or infectivity of AF36 in the acute oral test mammalian systems.

Cotton itself is not a food commodity. Residues of *A. flavus* AF36, the microbial active ingredient, are not likely to survive the heating and pressure associated with the processing of cottonseed into cottonseed meal. Moreover, *A. flavus* AF36 will not separate into the edible fraction, cotton seed oil. Thus, potential transfer of residues of *A. flavus* AF36 to edible cotton food/feed commodities is not expected. Consequently, human dietary exposure to *A. flavus* AF36 via cottonseed oil, or by secondary transfer of *A. flavus* AF36 residues to meat and milk via cottonseed meal, is not expected. Therefore, the Agency has determined that dietary exposure to *A. flavus* AF36 is not likely to result in any undue health effects and risk.

While the Agency has concluded that AF36 is not likely to add to the dietary burden, any potential contribution by AF36 to aflatoxin contamination was also considered, for a conservative estimate of the health effects of this pesticide. This is because aflatoxin is considered a public health hazard (see Unit VII.D.) and AF36 is proposed as a biocontrol agent for aflatoxin-producing strains of *A. flavus*. Even if AF36 does not control aflatoxin levels in the treated cotton food/feed commodities, a safety net exists in the screening of cotton and its by-products for aflatoxin prior to their introduction into the channels of commerce. For instance, FDA does not allow cotton seed products containing aflatoxin above 20 parts per billion (ppb) to be used in dairy rations or above 300 ppb to be used for feeding beef cattle. As previously stated, the registrant claims that quality control and selection procedures will not allow aflatoxin production in the starter cultures for pesticide manufacture [BPPD review - March 29, 1999; BPPD review - May 14, 1999]. Any batches with aflatoxin are to be destroyed. For these reasons, the Agency has determined that use of AF36 will not add to the dietary burden of aflatoxin, but is rather more likely to ameliorate aflatoxin levels in treated cotton food/feed commodities. Therefore, dietary exposure to aflatoxin, as a result of AF36 use, is not likely to be greater, and may even be less, than that which currently exists.

2. *Drinking water exposure*. Exposure to AF36 via drinking water is not likely to be greater than current/existing exposures to *A. flavus* strains. Potential risks via exposure to drinking water or runoff are adequately mitigated by, among other things, percolation through soil. Thus, exposure via drinking water from the proposed use of this non-aflatoxin-producing strain of *Aspergillus flavus* is not likely to pose any incremental risk to adult humans, infants and children. In fact, displacement of the toxigenic strains of *A. flavus* by AF36 may decrease exposure and risk to the toxigenic strains of *A. flavus* in the environment.

B. Other Non-Occupational Exposure

1. *Dermal exposure*. The potential for non-occupational dermal exposure to AF36 is unlikely because the potential use sites, are commercial and agricultural, and because of the granular nature of the pesticide, which minimizes spray drift. As discussed earlier (see Unit III.), lack of hypersensitivity incidents, low application rates, and return of levels of *Aspergillus flavus* to background shortly after germination, poses minimal risk to populations via dermal, non-occupational exposure. Thus, dermal non-occupational exposure to the non-aflatoxin strain is not likely to be greater than the existing exposure to *A. flavus* at current levels.

2. *Inhalation exposure*. For the reasons stated immediately above, non-occupational inhalation exposure to AF36 is not expected to be greater than that which currently exists for *A. flavus* strains.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to *Aspergillus flavus* AF36 and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. *Aspergillus flavus* AF36 does not appear to be toxic or pathogenic to humans. There is no indication that the fungus *A. flavus* AF36 shares any common mechanisms of toxicity with other registered pesticides. In addition, there are no other registered pesticide products containing *Aspergillus flavus* AF36, and other *A. flavus* strains abound naturally in the environment. Moreover, the displacement of the toxigenic strain of *A. flavus* by AF36 may reduce aflatoxin contamination of cottonseed. Based on the low toxicity potential of AF36, the fact that it is non-aflatoxigenic, and the safety net already in place to monitor for aflatoxin, no cumulative or incremental effect is expected from the use of AF36 on cotton.

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

There is reasonable certainty that no harm will result from aggregate exposures to residues of *A. flavus* AF36, in its use as an antifungal agent, to the U. S. population, including infants and children. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, there appears to be no potential for harm, from this fungus in its use as an antifungal agent via dietary exposure since the organism is non-toxic and non-pathogenic to animals and humans. The Agency has arrived at this conclusion based on the very low levels of mammalian toxicity for acute oral and pulmonary effects with no toxicity or infectivity at the doses tested (see Unit III above). Moreover, non-occupational inhalation or dermal exposure is not expected above background levels (see Unit V).

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional ten-fold margin of exposure (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 unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, the Agency concludes that the fungus, *A. flavus* AF36, is non-toxic to mammals, including infants and children. 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.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen-and thyroid systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority, to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency is not requiring information on the endocrine effects of this active ingredient, *Aspergillus flavus* AF36, at this time. The Agency has considered, among other relevant factors, available information concerning whether the microorganism may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known metabolite that acts as an ''endocrine disrupter'' produced by this microorganism. The submitted toxicity/infectivity or pathogenicity studies in the rodent (required for microbial pesticides) indicate that, following oral and pulmonary routes of exposure, the immune system is still intact and able to process and clear the active ingredient (see Unit III.). In addition, based on the low potential exposure level associated with the proposed single, seasonal, prebloom application of the pesticide, the Agency expects no adverse effects to the endocrine or immune systems.

B. Analytical Method

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation. Accordingly, the Agency has concluded that for an exemption from tolerance, analytical methods are not needed for enforcement purposes for residues of *Aspergillus flavus* AF36 on treated cotton. Nonetheless, and for purposes of clarification, analytical methods are still required for product characterization, quality control, and quality assurance for manufacturing purposes [BPPD review - March 29, 1999; BPPD review - May 14, 1999]. Vegetative compatibility tests are used to screen starter cultures to identify the non-aflatoxin-producing *Aspergillus flavus* AF36 strain. Starter cultures of AF36 are also selected on the basis of

the lack of aflatoxin as monitored by standard thin layer chromatography (tlc) procedures and visualization via scanning fluorescence densitometry scanning. Other appropriate methods are required for quality control to assure product characterization, the control of human pathogens and other unintentional metabolites or ingredients within regulatory limits, and to ascertain storage stability and viability of the pesticidal active ingredient.

C. Codex Maximum Residue Level

There is no Codex maximum residue level for residues of *Aspergillus flavus* AF36.

D. Efficacy Data

PR Notice 2002-1 lists aflatoxin as a public health hazard, for which product performance or efficacy data are required according to 40 CFR 158.202(i). To demonstrate that this pesticide may reduce aflatoxin-producing strains and does not increase *A. flavus* populations above background levels, the applicant provided product performance or efficacy data from multiple years of soil and air monitoring studies.

Aflatoxin, one of the most potent human carcinogens, is the metabolite of concern produced by the target pest, aflatoxin-producing strains of *Aspergillus flavus*. As such, the Agency considers aflatoxin a public health hazard. In the soils of cotton-producing areas of Arizona and south Texas, especially in the dry regions, the toxigenic strains are prominent. Few alternatives, if any, exist to displace aflatoxin-producing *A. flavus* strains from cotton and other crops. Decontamination of crops via ammoniation is costly, not available universally, and decreases the value of the crop. Other methods to reduce aflatoxin formation include manipulation of harvest date, costly irrigation practices, and different methods of harvesting and storage practices.

Efficacy data submitted to the Agency include monitoring of soil and air levels of the toxigenic and non-aflatoxin-producing strains of *A. flavus* AF36 in the field and on the crops. Results from the environmental expression and population monitoring studies, during the experimental program, demonstrate that a single seasonal application of AF36 on cotton fields may incite significant changes in the incidence of toxigenic *A. flavus* strains resident in the agroecosystem, without altering the overall quantity of *A. flavus*. Soil and air population counts of *A. flavus* from treated fields were associated with concomitant decreases in incidences of toxigenic *A. flavus*, for many of the treated areas [BPPD review - May 15, 2003]. Reducing the aflatoxin-producing populations of fungi, and the concomitant reduction of aflatoxin, a potent carcinogen, is in the public interest.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the 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 the FFDCA, as was provided in the old sections 408 and 409 of the 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 OPP–2003–0138 in the subject line on the first page of your submission. All objections and hearing requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 12, 2003.

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 issues(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 (1900C), 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 Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0138, to: Public Information and Records Integrity Branch, Information Resources and Services 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 Unit

I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. 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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the 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 the FFDCA, such as the exemption from the tolerance requirement 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 the 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.

X. 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: July 2, 2003.

James Jones,

Director, 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), 346(a) and 371.

■ 2. Section 180.1206 is revised to read as follows:

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

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Aspergillus flavus* AF36 in or on cotton and its food/feed commodities.

[FR Doc. 03–17726 Filed 7–11–03; 8:45 am]

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