ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300860; FRL–6081–2]

RIN 2070–AB78

Aspergillus flavus AF36; Pesticide Tolerance Exemption

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 biological *Aspergillus flavus* AF36, a non-aflatoxin producing strain of *A. flavus,* on cotton when applied/used as an antifungal agent. The Interregional Research Project Number 4 (IR–4) submitted an amended Pesticide Petition (PP) 5E4575 to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), and also to comply with the Food Quality Protection Act of 1996 (FQPA) requesting an extension of the temporary exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Aspergillus flavus* AF36. The temporary exemption from the requirement of a tolerance will expire on December 30, 2000.

DATES: This regulation is effective May 26, 1999. Objections and requests for hearings must be received by EPA on or before July 26, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300860], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300860], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding 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 5.1/6.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP–300860]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Shanaz Bacchus, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 9th fl., CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–8097, e-mail: bacchus.shanaz@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 19, 1999 (64 FR 8358) (FRL–6081–2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA of 1996 (Pub. L. 104–170) announcing the filing of a pesticide tolerance petition by the IR–4, New Jersey Agricultural Experiment Station, Technology Center of New Jersey, Rutgers University, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. The notice included a summary of the petition prepared by the petitioner, IR–4. The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of *Aspergillus flavus* AF36 in/on cotton in Arizona.

Comments submitted to the Agency regarding the proposed use of the antifungal agent were by the cotton growers in the region who were all in favor of the extension of the temporary exemption from the tolerance. Both the toxigenic and atoxigenic strains are naturally occurring in Arizona. The growers were of the opinion that this technology is likely to reduce the high levels of the naturally occurring, toxin-producing strain of *A. flavus* by displacement.

I. Background and Statutory Findings

New section 408(c)(2)(A)(i) of the 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) 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) 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) 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 us in residential settings.

This extension of the temporary exemption from the requirement of a tolerance is associated with an extension of an Experimental Use Permit (69224–EUP–1), published in the **Federal Register** of February 14, 1996, (61 FR 5771) (FRL–5347–5), which was granted to the Southern Regional Research Center, United States Department of Agriculture, Agricultural Research Service (USDA ARS), 1100 Robert E. Lee Blvd., New Orleans, LA 70179–0687 on May 28, 1996 and expires May 20, 1999. Approximately 1,120 acres of cotton in Yuma County, Arizona, were treated at a rate of 10 pounds (lbs.) of the pesticide per acre over the 3–year period. A temporary exemption from the requirement of a tolerance was established in connection with this EUP as published in the **Federal Register** of June 14, 1996, (61 FR 30235) (FRL–5377–6). No adverse effects were reported in the annual reports which the registrant submitted as required in the EUP.

USDA ARS has amended the EUP and extended treatment to a total of 20,000 acres of commercial cotton fields in 5 of the 15 counties in Arizona. The aerial applications are to be made in the following counties: Yuma (3,000 A), LaPaz (1,000 A), Maricopa (9,000 A), Mohave (1,000 A) and Pinal (6,000 A). The antifungal agent is applied prebloom to the soil of treated cotton fields, where the mycelia germinate to displace the naturally occurring toxigenic strain.

Of the strains of *A. flavus* which abound naturally in Arizona, this atoxigenic L strain comprises 15% of the natural microbial population in the soil, as opposed to the predominant S or toxigenic S strain.

II. 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.

The toxicological profile in support of the extension of the temporary exemption from a tolerance of the residues of the atoxigenic (non-toxin producing) *A. flavus* AF36 demonstrates that the LD_{50} of *A. flavus* AF36 is greater than 5,000 milligrams/kilograms (mg/kg). No adverse clinical effects were observed after 14 days in rats treated by gavage with the microbial antifungal agent and no abnormalities or adverse effects were observed in any of the rats upon autopsy.

Studies were not conducted to evaluate the potential of the active ingredient as an agent linked to genotoxicity, or reproductive, developmental, subchronic or chronic effects, because the researchers have worked with the proposed microbial antifungal agent for several years in laboratory and field settings with no adverse effects. Also, the organism is a naturally occurring, ubiquitous microbe.

III. 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 reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to *A. flavus* AF36 from the limited use pattern of the experimental use permit. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

A. Dietary Exposure

1. *Food.* Application of the microbial pesticide prebloom in the cultural practice precludes the potential for direct residues of *A. flavus per se* to remain on the treated cotton. The proposed strain of *A. flavus*, AF36, is atoxigenic, i.e. not producing aflatoxin. Only the seed of the treated commodity, cotton, is likely to be processed as food for cottonseed oil. Residues of *A. flavus* AF36 or its metabolites are likely to be removed from cotton seed oil during this processing. Moreover, the applications are proposed for 5 of the 15 counties of Arizona only, on 3–7% of the total cotton, thus minimizing any potential dietary exposure. The Food and Drug Administration (FDA) regulates the levels of aflatoxin in cotton seed meal and other commodities associated with the production of cotton. Cottonseed is monitored for aflatoxin content during the ginning process, and all cotton seed from these experiments will be closely monitored for aflatoxin content as part of the experimental program. On the basis of the preceding discussion, dietary exposure to the treated commodity is likely to be minimal to human adults, infants and children.
exposure to immunocompromised human adults, infants and children. Moreover, the application of the microbial pesticide to specific counties during the EUP represents application to approximately 3–7% cultivated areas in these counties, thus minimizing exposure.

1. *Dermal exposure.* Non-occupational dermal exposure and risk to adults, infants and children are not likely if the pesticide is used as labeled. The antifungal agent is a naturally occurring microbe to be applied to the soil of cotton fields prebloom. It is ubiquitous in the environment. If the microbe exhibits dermal sensitizing properties which is associated with this genus of fungi, the boundaries and the large particle size of the spores are likely to maintain distribution near treated areas thus protecting nearby at-risk populations. Based on the low toxicity potential as evidenced by the data submitted, the microbial pesticide active ingredient is likely to pose a minimal to non-existent hazard if used as labeled.

2. *Inhalation exposure.* Based on the large spore size of AF36, and on the method of application to the soil of cultivated cotton fields prebloom with set boundaries, non-occupational inhalation exposure and risk to human adults, children and infants are likely to be minimal.

IV. Cumulative Effects

There are no other registered products containing *Aspergillus flavus* isolate AF36 or any other isolates (strains) of the microbial active ingredient. Moreover, data submitted to the Agency demonstrate that this strain does not produce aflatoxin on the crop or in artificial media in the lab. Data submissions also show that this strain has been shown to exclude the aflatoxin-producing strain when it is applied prior to flowering. Thus, the proposed use is not likely to result in appreciable increases in the long-term population of *A. flavus* on the crop beyond naturally occurring levels. Furthermore, there is no expectation of cumulative effects with other pesticides.

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

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- 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. In this instance, EPA believes there are reliable data to support the conclusion that there are no threshold effects of concern to infants, children and adults when *A. flavus* AF36 is used as labeled. As a result, the provision requiring an additional margin of exposure does not apply. The label will require applicators and other handlers to wear gloves, a dust/mist filtering respirator with National Institute of Occupational Safety and Health (NIOSH) approval prefix N-95, R-95 or P-95, long sleeved shirt and long pants, and shoes plus socks so worker exposure should not be a problem. Label language reflecting potential dermal sensitization is also required.

VI. Other Considerations

A. Endocrine Disruptors

EPA does not have any information regarding endocrine effects of this microbial pesticide at this time. The Agency is not requiring information on

the endocrine effects of this pesticide at this time; and Congress allowed 3 years after August 3, 1996, for the Agency to implement a screening and testing program with respect to endocrine effects.

B. Analytical Method(s)

Starter cultures are screened on the basis of vegetative incompatibility with the toxigenic strain, as well as for aflatoxin by standard procedures, which allow a zero tolerance for aflatoxin production. *A. flavus* AF36 does not demonstrate vegetative compatibility with the toxigenic S strain and has never been found to produce aflatoxin. According to the data submissions human pathogens are also within regulatory levels.

Treated cotton and its byproducts are screened for aflatoxin prior to introduction into the channels of commerce. FDA does not allow cottonseed products containing aflatoxin at 20 parts per billion (ppb) or higher to be used in dairy rations. FDA regulations also do not allow cottonseed products containing aflatoxin above 300 ppb to be used for feeding beef cattle.

C. Codex Maximum Residue Level

An exemption from temporary tolerance for residues of *Aspergillus flavus* isolate AF36 on cotton is currently in effect in conjunction with an Experimental Use Permit published in the **Federal Register** of June 14, 1996 (61 FR 30235).

VII. Objections and Hearing Requests

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) and as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 26, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the hearing clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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 tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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). 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). 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.

VIII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300860] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

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). 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) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority*

Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the [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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

X. Submission to Congress and the Comptroller General

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 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 the rule in the **Federal Register**. This 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 14, 1999.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division

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 added to subpart D to read as follows:

§ 180.1206 Aspergillus flavus AF 36; Exemption from the requirement of a tolerance.

Aspergillus flavus AF 36 is temporarily exempt from the requirement of a tolerance in/on cotton when used on cotton in Arizona in accordance with the Experimental Use Permit 69224–EUP–1. The temporary exemption from the requirement of a tolerance will expire on December 30, 2000.

[FR Doc. 99–13192 Filed 5–25–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300861; FRL–6080–6]

RIN 2070–AB78

Clomazone; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule extends a time-limited tolerance for residues of the herbicide clomazone and its metabolites in or on watermelons at 0.1 part per million (ppm) for an additional 2–year period, to May 30, 2001. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on watermelons. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA.

DATES: This regulation becomes effective May 26, 1999. Objections and