

REFRIGERATION AND AIR CONDITIONING—Continued

End-Use	Substitute	Recommendation	Comments
Industrial process refrigeration (new).	HFC-134a/HBr (92/8) as a substitute for CFC-11, CFC-12, CFC-114, CFC-115 and R-502.	Acceptable	Users are expected to adhere to the 3 ppm Permissible Exposure Limit and Threshold Limit Value set by OSHA and ACGIH, respectively. Users are expected to follow all recommendations specified in Material Safety Data Sheets for HBr, HFC-134a and the blend. Additional warning signs, worker education and technician training is recommended to minimize exposures.
Refrigerated transport (new)	HFC-134a/HBr (92/8) as a substitute for CFC-12 and R-502.	Acceptable	Users are expected to adhere to the 3 ppm Permissible Exposure Limit and Threshold Limit Value set by OSHA and ACGIH, respectively. Users are expected to follow all recommendations specified in Material Safety Data Sheets for HBr, HFC-134a and the blend. Additional warning signs, worker education and technician training is recommended to minimize exposures.
Very low temperature refrigeration (retrofit and new).	PFC-330ST, PFC-550HC, PFC-660HC, PFC-1100HC, PFC-1100LT, PGC-100, PGC-150, PFC-331ST, PFC-551HC, PFC-661HC, PFC-1101HC and PGC-151 as substitutes for CFC-13, CFC-113, CFC-114 and blends thereof.	Acceptable.	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301124; FRL-6781-7]

RIN 2070-AB78

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends a temporary exemption from the requirement of a tolerance for residues of the biological *Aspergillus flavus* AF36, (*A. flavus*) a non-aflatoxin producing strain of *A. flavus*, on cotton when applied or used as aerial pre-bloom applications to cotton in specified counties of Arizona. The Interregional Research Project Number 4 (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, submitted an amended petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting the temporary exemption. This regulation eliminates the need to establish a maximum permissible level for residues of *Aspergillus flavus* AF36. The temporary tolerance exemption will expire on December 30, 2003.

DATES: This regulation is effective May 23, 2001. Objections and requests for hearings, identified by docket control number OPP-301124, must be received by EPA on or before July 23, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit III. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301124 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shanaz Bacchus, c/o Product Manager (PM) 90, Biopesticides and

Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703-308-8097; and e-mail address: bacchus.shanaz@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Cat-egories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to 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_180/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301124. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of May 26, 1999 (64 FR 28371) (FRL-6081-2), EPA issued a final rule pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a,

as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) establishing a temporary exemption from the requirement of a tolerance for residues of *A. flavus* AF36 on cotton grown in 5 counties in Arizona (40 CFR 180.1206). This final rule included a summary of the Agency's assessment of the health effects data submitted in support of the extension of the temporary tolerance exemption. The temporary exemption from tolerance was extended until December 2001 (64 FR 35049, June 30, 1999) (FRL-6087-3) to allow for passage of the treated commodities through the channels of trade.

Comments submitted to the Agency regarding the use of this competitive fungal agent were by the cotton growers in the region who were all in favor of the extension of the exemption from the temporary 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. No adverse effects were reported in the yearly annual reports of the Experimental Use Permit, and in some instances aflatoxin levels of cotton seed were reduced in treated cotton.

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 use in residential settings.

The fungal agent is applied prebloom to the soil of treated cotton fields. When conditions are appropriate, the AF 36 spores land on the cotton plant and germinate to displace the naturally occurring toxigenic strain. No adverse effects were reported in the annual reports which the registrant submitted as required in the EUP.

This extension of the exemption from the requirement of a temporary tolerance is associated with an extension of an Experimental Use Permit (EUP, EPA Reg. No. 69224-EUP-1). This extension of the EUP will allow aerial application of *A. flavus* AF36 in the following counties of Arizona: Yuma (3,300 acres), Maricopa (13,150 acres), Mohave (1,700 acres) and Pinal (1,850 acres). This final rule extends the temporary exemption from a tolerance for residues of *Aspergillus flavus* AF36 on cotton until December 30, 2003.

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

Summaries of the toxicological profile and other relevant manufacturing and health effects data, to comply with the guideline requirements of the Food Quality Protection Act of 1996, were reported in the **Federal Register** publication of the final rule of May 26, 1999, extending the temporary tolerance exemption. Based on the previously submitted data outlined in the final rule, 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 this experimental use permit. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

The Agency continues to require that the pesticide must not be applied within a boundary of 400 feet of residential areas, schools, daycare and health care facilities and hospitals to minimize exposure to human adults, infants and children.

Data have been submitted to demonstrate that this strain excludes 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, because this is the only registered experimental microbe in this genus.

As in the earlier EUP, the Agency requires that applicators and other handlers must wear gloves, a dust/mist filtering respirator with NIOSH approval prefix N-95, R-95 or P-95, long sleeved shirt and long pants, and shoes plus socks to mitigate potential worker 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. Treated cotton and its by products 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 *A. flavus* isolate AF36 on cotton (40 CFR 180.1206) is currently in effect in conjunction with an Experimental Use Permit (61 FR 30235, June 14, 1996, and extended to expire in December 2001) (FRL-5377-6).

III. 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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP-301124 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 July 23, 2001.

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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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 (202) 260-4865.

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.

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.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.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.2. Mail your copies, identified by docket control number OPP-301124, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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).

IV. Regulatory Assessment Requirements

This final rule extends a temporary exemption from the tolerance requirement under FFDCA section 408(d) 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) (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 FIFRA section 18 petition under FFDCA section 408, 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. 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 FFDCA section 408(n)(4).

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."

V. 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 to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: May 9, 2001.

Janet L. Anderson,
Director, Biopesticide 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 revised to read as follows:

§ 180.1206 *Aspergillus flavus* AF36.

Aspergillus flavus AF36 is temporarily exempt from the requirement of a tolerance in or on cotton when used on cotton in Arizona in accordance with the Experimental Use Permit 69224-EUP-1. The temporary exemption from a tolerance will expire on December 30, 2003.

[FR Doc. 01-12900 Filed 5-22-01; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301132; FRL-6784-7]

RIN 2070-AB78

Thiamethoxam; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of thiamethoxam and its metabolite in or on tuberous and corm vegetables crop subgroup, fruiting vegetables crop group, tomato paste, cucurbit vegetables crop group, and pome fruits crop group. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective May 23, 2001. Objections and requests for hearings, identified by docket control number OPP-301132, must be received by EPA on or before July 23, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301132 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Dani Daniel, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5409; and e-mail address: daniel.dani@epa.gov.

SUPPLEMENTARY INFORMATION: