

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