

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and record keeping requirements.

Dated: February 6, 2003.

Phil Hutton,

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

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Interregional Research Project Number 4 and The Arizona Cotton Research and Protection Council

PP 8E5001

EPA has received a pesticide petition (PP 8E5001) from Interregional Research Project Number 4 (IR-4), New Jersey

Agricultural Experiment Station, Technology Center, 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, Arizona 85040–2933 proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.1206 by establishing an amendment/expansion of an existing tolerance exemption for the microbial pesticide *Aspergillus flavus* AF36 in or on the food and feed commodity cotton and its by products.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, the aforesaid Interregional Research Project Number 4 (IR-4), has submitted the following summary of information, data, and arguments in support of the pesticide petition on behalf of the Arizona Cotton Research and Protection Council, however EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product name and Proposed Use Practices

Aspergillus flavus AF36, a non-aflatoxin-producing strain of *Aspergillus flavus*, is proposed for application to cotton to reduce the incidence of aflatoxin producing strains of *Aspergillus flavus* and thereby reduce aflatoxin contamination of cottonseed. When applied just prior to flowering, *Aspergillus flavus* AF36 which does not produce aflatoxin, competitively excludes aflatoxin producing *Aspergillus flavus* strains without increasing *Aspergillus flavus* in the environment in the long term. Sterile wheat seed colonized with *Aspergillus flavus* AF36 is applied at 10 lb of end-use product (total amount of active ingredient less than 0.01 lb/acre) per acre. The pesticide is currently being used in certain counties in the States of Arizona and Texas under an Experimental Use Permit (EPA Reg. No. 69224–EUP–1). The current submission proposes to establish a permanent exemption from tolerance for residues of *Aspergillus flavus* AF36 on cotton and its byproducts.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* The pesticide and corresponding residues are identified as *Aspergillus flavus* AF36, a

non-aflatoxin-producing strain of *Aspergillus flavus*.

2. *Magnitude of residue at the time of harvest and method used to determine the residue.* *Aspergillus flavus* AF36 is a naturally occurring fungus isolated from cottonseed produced in the Yuma Valley of Arizona. *Aspergillus flavus* AF36 has been shown to be naturally and consistently associated with commercial cotton grown in Arizona. Other than immediately after application, the overall quantity of *Aspergillus flavus* at time of harvest on cottonseed grown in fields where *Aspergillus flavus* AF36 has been applied and has been shown to be similar to levels on cottonseed grown in fields where no application was made. *Aspergillus flavus* is a widespread fungus. It is particularly well adapted to the hot desert regions of Arizona where it is widespread in the environment. The communities of *Aspergillus flavus* in the desert and in agricultural fields are naturally composed of both aflatoxin producing (toxigenic) and aflatoxin non-producing (atoxigenic) strains. Both atoxigenic and toxigenic strains have been found on essentially all plant material and soils in the desert valleys of Arizona. The goal of applications is to increase the percent of the *Aspergillus flavus* community composed of the atoxigenic strain AF36 and to decrease the percent of *Aspergillus flavus* that produces aflatoxins on the crop and in the fields.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* An exemption from the requirement of a tolerance for residues of the microbial pesticide *Aspergillus flavus* AF36 in/on cotton is being proposed for cotton treated in Arizona and Texas. *Aspergillus flavus* isolate AF36, when applied to the soil just prior to bloom has been shown to significantly reduce the levels of aflatoxin in cottonseed at harvest. Aflatoxin levels in cottonseed products are regulated by the Food and Drug Administration (FDA). 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. All lots of the active ingredient (*Aspergillus flavus* isolate AF36) and the formulated products are monitored for aflatoxin production as part of a rigorous quality control program. Starter cultures of *Aspergillus flavus* isolate AF36 used in the production of the end-use product are always screened for strain identity by vegetative