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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,