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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0538; FRL-9939-53]

Aspergillus flavus AF36; Time Limited Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited exemption from the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(a) requirement of a tolerance for residues of the pesticide *Aspergillus flavus* AF36 in or on dried figs resulting from use in accordance with the terms of an emergency exemption issued under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This action is in response to the issuance of a crisis emergency exemption under FIFRA section 18 authorizing use of the pesticide on dried figs. The time-limited exemption from the requirement of a tolerance expires on December 31, 2017.

DATES: This regulation is effective [insert date of publication in the **Federal Register**].

Objections and requests for hearings must be received on or before [insert date 60 days after date of publication in the **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0538, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to

4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan T. Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2015-0538 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the Federal Register]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0538, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6), 21 U.S.C. 346a(e) and 346a(1)(6), is establishing a time-limited exemption from the requirement of a tolerance for residues of *Aspergillus flavus* AF36, in or on dried figs. This time-limited exemption from the requirement of a tolerance expires on December 31, 2017.

Section 408(l)(6) of 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 FIFRA section 18. Such tolerances or exemptions from the requirement of a tolerance must be consistent with the safety standard in 408(b)(2) and (c)(2), respectively, and can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances or exemptions from the requirement of a tolerance to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(c)(2)(A)(i) of 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 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. In evaluating the safety of an exemption, section 408(c)(2)(B) requires EPA to take into account the considerations set forth in 408(b)(2)(C) and (D). Section 408(b)(2)(C) of 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. . . .”

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for *Aspergillus flavus* AF36 on Dried Figs and FFDCA Tolerances

The California Department of Pesticide Regulation asserted that an emergency condition, brought on by an ongoing drought in California, existed in accordance with the criteria for approval of an emergency exemption, and utilized a crisis exemption under FIFRA section 18 to allow the use of *Aspergillus flavus* AF36 to reduce aflatoxin-producing fungi on dried figs in California. The California Department of Pesticide Regulation invoked the crisis exemption provision on June 15, 2015. After having reviewed the crisis exemption, EPA concurred on the emergency action in order to meet the emergency needs of fig growers in California. The crisis exemption program expired on July 31, 2015.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of *Aspergillus flavus* AF36 in or on dried figs. In doing so, EPA considered the safety standard in FFDCA section 408(c)(2), and EPA decided that the necessary exemption from the requirement of a tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to

move quickly on the crisis exemption in order to address an urgent, non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this exemption from the requirement of a tolerance without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). This time-limited exemption from the requirement of a tolerance expires on December 31, 2017. EPA will take action to revoke the time-limited exemption from the requirement of a tolerance earlier if any experience with scientific data, or other relevant information on this pesticide indicates that the residues are not safe.

Because this time-limited exemption from the requirement of a tolerance is being approved under emergency conditions, EPA has not made any decisions about whether *Aspergillus flavus* AF36 meets FIFRA's registration requirements for use on dried figs or whether permanent tolerances or exemption from the requirement of a tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited exemption from the requirement of a tolerance serves as a basis for registration of *Aspergillus flavus* AF36 by a State for special local needs under FIFRA section 24(c). Nor does this exemption from the requirement of a tolerance by itself serve as the authority for persons in any State other than California to use this pesticide on the applicable crop under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the crisis exemption for *Aspergillus flavus* AF36, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Toxicological Profile

Consistent with the FFDCA section 408(b)(2)(D), the EPA reviewed the available scientific data and other relevant information for *Aspergillus flavus* AF36, and considered its validity, completeness, and reliability, as well as the relationship of this information to human

risk. The EPA also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Aspergillus flavus refers to a diverse group of saprophytic soil fungi strains, which are ubiquitously distributed throughout the United States. This fungal group includes strains that produce aflatoxin (i.e., toxigenic strains) and strains that do not produce aflatoxins (i.e., atoxigenic strains). The toxigenic strains can cause aflatoxin contamination in seed, nut, and grain crops pre- and postharvest. In addition, toxigenic strains of several *Aspergillus* spp. can cause aspergillosis disease in humans (Ref. 1, 2).

Aspergillus flavus AF36 is an atoxigenic strain registered as a microbial pesticide for use on cotton, corn, and pistachios. The AF36 strain is a soil colonizing fungus and displaces toxigenic strains through competition, thereby reducing aflatoxin levels on crops contaminated with toxigenic strains of *Aspergillus* spp. (Ref. 3).

The toxicological profile of *Aspergillus flavus* were previously described in the **Federal Register** July 14, 2003 (68 FR 41535) (FRL-7311-6) and the data were used to establish the tolerance exemption for *Aspergillus flavus* AF36 in or on cotton (see the **Federal Register** of July 14, 2003), corn (see the **Federal Register** of March 23, 2011 (76 FR 16297) (FRL-8868-7)), and pistachio (see the **Federal Register** of March 9, 2012 (77 FR 14287) (FRL-9341-5)). The studies used to establish the tolerance exemptions in or on cotton, corn, and pistachio tested the toxicity/pathogenicity of *Aspergillus flavus* AF36 to rats through acute oral and pulmonary exposures and did not find any evidence of toxicity or infection (Ref. 1). Further, when exposed through intratracheal dosing, rats cleared *Aspergillus flavus* AF36 from their systems within 8 days. Moreover, rats exposed to *Aspergillus flavus* AF36 cleared the fungus from their body without compromising their immune system. After more than a decade of agricultural use in cotton and several years of use in corn and pistachio, there have not been any reports of

hypersensitivity or other problems from workers exposed to *Aspergillus flavus* AF36. Therefore, based on the atoxigenic profile of *Aspergillus flavus* AF36, and previous toxicological evaluations to establish tolerance exemptions in or on cotton (see the **Federal Register** of July 14, 2003), corn (see the **Federal Register** of March 23, 2011), and pistachio (see the **Federal Register** of March 9, 2012), EPA concludes that there are no toxicological endpoints of concern for *Aspergillus flavus* AF36 and that there are no hazards associated with this particular isolate; therefore, any expected residues on food would be safe to consume.

V. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 directs the 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).

Food exposure: *Aspergillus flavus* AF36 will be applied as a single broadcast application to soil in California fig orchards from mid-June to mid-July 2015. The proposed method of application is by grain seed (wheat-infested *Aspergillus flavus* AF36 inoculum) applied to the orchard floor by ground. Grain seed inoculum is directed under the fig tree canopy where soil is wetted before and after the application. After application, *Aspergillus flavus* AF36 germinates using a grain carrier as a nutrient source and displaces aflatoxin-producing strains of *Aspergillus flavus*. Thus, the use of *Aspergillus flavus* AF36 in fig orchards should not increase the total *Aspergillus flavus* population in the environment (Ref. 1). Although, total *Aspergillus flavus* populations may increase immediately after applying *Aspergillus flavus* AF36, populations of *Aspergillus flavus* AF36 decline by spring of the year after application and there is no evidence of long term increases in populations of *Aspergillus flavus* resulting from application of *Aspergillus*

flavus AF36. In addition, levels of natural *Aspergillus flavus* populations can fluctuate greatly over the course of a year (Ref. 1). Therefore, a temporary increase in *Aspergillus flavus* populations resulting from an application of *Aspergillus flavus* AF36 are not expected to produce effects that do not already occur from exposure to natural *Aspergillus flavus* populations.

Drinking water exposure: Similar to previous drinking water exposures for cotton and corn uses (see **Federal Register** of July 14, 2003 and March 23, 2011) exposure to residues of *Aspergillus flavus* AF36 ensuing from application in fig orchards is possible as a result of consuming drinking water, but it is not likely to be greater than existing exposures to naturally occurring strains of *Aspergillus flavus* AF36. This time-limited exemption from the requirement of a tolerance will only allow for applications in California in an area where the climate is arid, which minimizes the potential for contamination of surface or ground water that may serve as a source of drinking water. Further, because *Aspergillus flavus* AF36 will only be applied as a granular formulation to terrestrial sites, offsite movement into water is not anticipated. If *Aspergillus flavus* AF36 residues should be present in drinking water, the results of a study assessing acute oral toxicity and pathogenicity found that no toxicity, pathogenicity, and/or infectivity is likely to occur from exposure to any level of *Aspergillus flavus* AF36 resulting from an application of *Aspergillus flavus* AF36 made in accordance with good agricultural practice.

Other non-occupational exposure: Non-occupational dermal and inhalation exposure is expected to be minimal to non-existent for the use of *Aspergillus flavus* AF36 on figs. As previously described in the **Federal Register** of July 14, 2003, March 23, 2011, and March 9, 2012; *Aspergillus flavus* AF36 will be applied to agricultural sites and not in the proximity of schools, residential areas, nursing homes, or daycare facilities. Moreover, *Aspergillus flavus* AF36 will be applied in a granular form which will minimize drift and exposure.

VI. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the EPA consider “available information concerning the cumulative effects of a particular pesticide’s . . . residues and other substances that have a common mechanism of toxicity.”

The EPA has not found *Aspergillus flavus* AF36 to share a common mechanism of toxicity with any other substances, and *Aspergillus flavus* AF36 does not appear to produce a toxic metabolite produced by other substances. For the purposes of this exemption from the requirement of a tolerance action, therefore, the EPA has assumed that *Aspergillus flavus* AF36 does not have a common mechanism of toxicity with other substances since there is no indication of mammalian toxicity or pathogenicity resulting from exposure to *Aspergillus flavus* AF36. For information regarding the EPA’s efforts to determine chemicals that have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

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

In considering the establishment of a time-limited exemption from the requirement of a tolerance for a pesticide chemical residue, FFDCA section 408(b)(2)(C) requires that EPA assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of exposure (safety) will be safe for

infants and children. This additional margin of exposure (safety) is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

In this instance, based on all the available information, EPA concludes that there are no effects of concern to infants, children, or adults when *Aspergillus flavus* AF36 is used in accordance with the crisis exemption. As a result, EPA concludes that no additional margin of exposure (safety) is necessary to protect infants and children.

Moreover, based on the data and EPA analysis presented in this document, the Agency is able to conclude that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of *Aspergillus flavus* AF36 when it is used as an antifungal agent in accordance with the crisis exemption. Such exposure includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, there is reasonable certainty of no harm via dietary exposure from this fungus when used as an antifungal agent because the microorganism is non-toxic and non-pathogenic to animals and humans. EPA arrived at this conclusion based on the very low levels of mammalian toxicity for acute oral and pulmonary effects with no toxicity or infectivity at the doses tested (see Unit IV. of this document).

VIII. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

IX. Conclusion

The EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Aspergillus flavus* AF36. Therefore, a time-limited exemption from the requirement of a tolerance is established for residues of *Aspergillus flavus* AF36 in or on dried figs when used in accordance with the crisis exemption. This time-limited exemption from the requirement of a tolerance for residues of *Aspergillus flavus* AF36 in or on dried figs will expire and is revoked on December 31, 2017.

X. References

1. U.S. EPA. 2015. Human Health and Environmental Assessment for the California Section 18 (Emergency Exemption) request for the use of AF36, an end use formulation containing the active ingredient, *Aspergillus flavus* Strain AF36. Memorandum from G. Tomimatsu, Ph.D. and M. Djurickovic, M.S. to S. Borges.
2. Jensen, A.B., K. Aronstein, J.M. Flores, S. Vojvodic, M.A. Palacio and M. Spivak. 2013. Standard methods for fungal brood disease research. *J. Apic. Res.* 52 (1).
3. Ehrlich, K.C. 2014. Non-aflatoxigenic *Aspergillus flavus* to prevent aflatoxin contamination in crops: advantages and limitations. *Front. Micro.* <http://dx.doi.org/10.3389/fmicb.2014.00050>.

XI. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA sections 408(e) and 408(l)(6). 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). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or

Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, 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).

Since tolerances and exemptions that are established in accordance with FFDCA sections 408(e) and 408(l)(6), such as the 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.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

XII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 action 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: December 18, 2015.

Susan Lewis,
Director, Registration Division, Office of Pesticide Programs.

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), 346a and 371.

2. In § 180.1206, add a new paragraph (d) to read as follows:

§ 180.1206 *Aspergillus flavus* AF36; exemption from the requirement of a tolerance.

* * * *

(d) *Section 18 emergency exemptions.* A time-limited exemption from the requirement of a tolerance is established for residues of *Aspergillus flavus* AF36, in or on dried figs, resulting from use of the pesticide pursuant to a FIFRA section 18 emergency exemption. This time-limited exemption from the requirement of a tolerance for residues of *Aspergillus flavus* AF36 in or on dried figs will expire and is revoked on December 31, 2017.

[FR Doc. 2016-665 Filed: 1/13/2016 8:45 am; Publication Date: 1/14/2016]