§ 52.1272 Approval status.

3. Section 52.1272 is amended by adding a paragraph (d) to read as follows:

§ 52.1272 Approval status.

(d) Disapproval. Submittal from the State of Mississippi, through the Mississippi Department of Environmental Quality (MDEQ) on February 28, 2013, to address the Clean Air Act section 110(a)(2)(E)(ii) for the 2010 1-hour nitrogen dioxide (NO₂) National Ambient Air Quality Standards (NAAQS) concerning state board majority requirements respecting significant portion of income for the 2010 1-hour NO₂ NAAQS.

[FR Doc. 2016–22226 Filed 9–15–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


Aspergillus flavus strains TC16F, TC35C, TC38B, and TC46G; Temporary Exemptions From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes temporary exemptions from the requirement of a tolerance for residues of Aspergillus flavus strains TC16F, TC35C, TC38B, and TC46G in or on the food and feed commodities of corn, field; corn, pop; and corn, sweet when...
used in accordance with the terms of Experimental Use Permit (EUP) No. 91163–EUP–1. Interregional Research Project Number 4 (IR–4) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting these temporary tolerance exemptions. This regulation eliminates the need under FFDCA to establish a maximum permissible level for residues of Aspergillus flavus strains TC16F, TC35C, TC38B, and TC46G when used under the terms of EUP No. 91163–EUP–1. The temporary tolerance exemptions expire on June 30, 2020.

DATES: This regulation is effective September 16, 2016. Objections and requests for hearings must be received on or before November 15, 2016, 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–2015–0742, 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: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: BPPDFRNotices@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).

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

In the Federal Register of February 9, 2016 (81 FR 6826) (FR–9941–42), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP SEB397) by IR–4, Rutgers University, 500 College Rd. East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of Aspergillus flavus strains TC16F, TC35C, TC38B, and TC46G in or on corn. That document referenced a summary of the petition prepared by the petitioner IR–4, which is available in the docket via http://www.regulations.gov. There were no comments received in response to the notice of filing.

EPA changed the commodity name reflected in the tolerance exemption expression from “corn” to “food and feed commodities of corn, field; corn, pop; and corn, sweet” and changed “tolerance exemption” to “tolerance exemptions”. The reasons for these changes are explained in Unit III.C.

III. Final Rule

A. EPA’s Safety Determination

Section 408(r) of FFDCA authorizes EPA to establish a temporary exemption from the requirement of a tolerance for residues covered by an experimental use permit issued under the Federal Insecticide, Fungicide, and Rodenticide Act. That section states that the provisions of section 408(c)(2) of FFDCA apply to exemptions issued under FFDCA section 408(r). Section 408(c)(2)(A)(i) of 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) 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. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an
exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption 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, FFDCA section 408(b)(2)(D) requires that EPA consider “available information concerning the cumulative effects of [a particular pesticide’s] . . . residues and other substances that have a common mechanism of toxicity.”

EPA evaluated the available toxicity and exposure data on *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. A full explanation of the data upon which EPA relied and its risk assessment based on that data can be found within the August 18, 2016, document entitled “Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G.” This document, as well as other relevant information, is available in the docket for this action as described under ADDRESSES.

Based upon its evaluation, EPA concludes that *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G are not toxic, not pathogenic, and not infective. Although there may be some exposure to residues when used on corn in accordance with the terms of EUP No. 91163–EUP–1, there is a lack of concern due to the lack of potential for adverse effects. EPA also determined that retention of the Food Quality Protection Act (FQPA) safety factor was not necessary as part of the qualitative assessment conducted for *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G.

Based upon its evaluation, 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* strains TC16F, TC35C, TC38B, and TC46G. Therefore, temporary exemptions from the requirement of a tolerance are established for residues of *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G in or on the food and feed commodities of corn, field; corn, pop; and corn, sweet when used in accordance with the terms of EUP No. 91163–EUP–1.

B. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes for the reasons contained in the August 18, 2016, document entitled “Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G” and because EPA is establishing temporary exemptions from the requirement of a tolerance without any numerical limitation.

C. Revisions to the Requested Tolerance Exemption

Two modifications have been made to the requested tolerance exemption. EPA changed “corn” to “food and feed commodities of corn, field; corn, pop; and corn, sweet” to align with the Agency’s food and feed commodity vocabulary. EPA also changed “tolerance exemption” to “tolerance exemptions” as four different active ingredients are covered with this action.

IV. Statutory and Executive Order Reviews

This action establishes exemptions from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to EPA. 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 on the basis of a petition under FFDCA section 408(d), such as the tolerance exemptions in this action, 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. As a result, 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). As such, EPA 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, EPA 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 EPA’s 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).

V. 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: August 30, 2016.

Jack Housenger,
Director, 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:

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

Ammonium Persulfate; Exemption
From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of ammonium persulfate (CAS Reg. No. 7727–54–0) when used as an inert ingredient (preservative) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest, etc., at a concentration not to exceed 0.05% by weight. Exponent, Inc., on behalf of Becker Underwood, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ammonium persulfate under the approved conditions.

DATES: This regulation is effective September 16, 2016. Objections and requests for hearing must be received on or before November 15, 2016, 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–2013–0237, 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: Michael Goodis, 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

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- 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?


C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, anyone 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–2013–0237 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 November 15, 2016. 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–2013–0237, 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.
- 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. Petition for Exemption

In the Federal Register of June 5, 2013 (78 FR 33785) (FRL–9386–2), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 28E8096) by Exponent, Inc., 1150 Connecticut Ave., Suite 1100, Washington, DC 20036, on behalf of Becker Underwood, Inc., 801 Dayton Avenue, Ames, IA 50010. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of ammonium persulfate (CAS Reg. No. 7727–54–0) when used as an inert ingredient (preservative) in pesticide formulations applied to growing crops or raw agricultural commodities after harvest at a concentration not to exceed 0.05% by weight in pesticide formulations. That document referenced a summary of the petition prepared by Exponent, Inc., the