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 202)
- 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(g), 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–2010–0099, 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. Background

An exemption from the requirement of a tolerance for residues of the Aureobasidium pullulans strains DSM 14940 and DSM 14941 in or on all food commodities when applied pre-harvest and used in accordance with good agricultural practices was established and published in the Federal Register of February 15, 2012 (77 FR 8731) (FRL–9337–3). In the Federal Register of July 17, 2015 (80 FR 42462) (FRL–9929–13), 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 4F8342) by bio-ferm GmbH, Technologiezentrum Tulln, Technopark 1, Tulln, 3430, Austria. The petition requested that 40 CFR 180.1312 be amended by expanding the current exemption to also include food commodities that are treated post-harvest. Therefore an exemption from the requirement of a tolerance for residues of Aureobasidium pullulans strains DSM 14940 and DSM 14941 in or on all food commodities was proposed. The Notice of Filing referenced a summary of the petition prepared by the petitioner bio-ferm GmbH, which is available in the docket referenced a summary of the petition.

III. Final Rule

A. EPA’s Safety Determination

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(e)(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(e)(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 Aureobasidium pullulans strains DSM 14940 and DSM 14941 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 October 15, 2015, document entitled “Federal Food, Drug, and Cosmetic Act (FFDCA) considerations for Aureobasidium pullulans strains DSM 14940 and DSM 14941”. 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 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 Aureobasidium pullulans strains DSM 14940 and DSM 14941. Therefore, an exemption from the requirement of a tolerance is established for residues of Aureobasidium pullulans strains DSM 14940 and DSM 14941 in or on all food commodities when used in accordance with label directions and good agricultural practices.

B. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes for the reasons contained in the October 15, 2015, document entitled “Federal Food, Drug, and Cosmetic Act (FFDCA) considerations for Aureobasidium pullulans strains DSM 14940 and DSM 14941” and because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

IV. Statutory and Executive Order Reviews

This action establishes a tolerance exemption under FFDCA section 408(d) in response to a petition submitted by 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 exemption 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: November 5, 2015.

Robert McNally,
Director, Biopesticides and Pollution Prevention 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:


■ 2. Revise § 180.1312 to read as follows:

§ 180.1312 Aureobasidium pullulans strains DSM 14940 and DSM 14941; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of Aureobasidium pullulans strains DSM 14940 and DSM 14941 in or on all food commodities when used in accordance with label directions and good agricultural practices.