established for residues of Bacillus licheniformis strain FMCH001 in or on all food commodities when used in accordance with label directions and good agricultural practices.

B. Analytical Enforcement Methodology

EPA is establishing an exemption from a tolerance on all food commodities without any numerical limitation and thus an analytical method is not required for enforcement purposes.

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 (5 U.S.C. 3501 et seq.) nor does it require any special considerations under Executive Order 12998, 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 406(n)(4). As such, EPA has determined that this action will not have a substantial direct effect on State 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: March 16, 2018.

Richard P. Keigwin, Jr.,
Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

§ 180.1350 Bacillus licheniformis strain FMCH001; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of Bacillus licheniformis strain FMCH001 in or on all food commodities when used in accordance with label directions and good agricultural practices.
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).

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–2017–0186 in the subject line on all food commodities. That document referenced FMCH002 in or on all food commodities. This document referenced FMCH002 in or on all food commodities. This document referenced FMCH002 in or on all food commodities. That document referenced FMCH002 in or on all food commodities. This document referenced FMCH002 in or on all food commodities. This document referenced FMCH002 in or on all food commodities. This document referenced FMCH002 in or on all food commodities. That document referenced FMCH002 in or on all food commodities. That document referenced FMCH002 in or on all food commodities.

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(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 “additional 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 Bacillus subtilis strain FMCH002 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 document entitled “Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Bacillus subtilis strain FMCH002.” 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 Bacillus subtilis strain FMCH002 is not toxic, not pathogenic, and not infective. Although there may be some exposure to residues when used on all food commodities in accordance with label directions and good agricultural practices, such exposure is unlikely to cause any 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 Bacillus subtilis strain FMCH002.

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 Bacillus subtilis strain FMCH002. Therefore, an exemption from the requirement of a tolerance is established for residues of Bacillus subtilis strain FMCH002 in or on all food commodities when used in....
accordance with label directions and good agricultural practices.

B. Analytical Enforcement Methodology

EPA is establishing an exemption from a tolerance on all food commodities without any numerical limitation, and thus an analytical method is not required for enforcement purposes.

C. Response to Comments

One comment on the Notice of Filing was received. That comment opposed allowing residues of this pesticide on food but provided no additional information to support a conclusion that the substance is unsafe. EPA evaluated the available information on Bacillus subtilis strain FMCH002, including toxicity and potential exposure, and concluded, in accordance with the statutory requirements of the FFDCA, that the exemption would be safe. The commenter has provided no basis for a different conclusion.

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: March 16, 2018.

Richard P. Keigwin, Jr.,
Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

§ 180.1351 Bacillus subtilis strain FMCH002; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of Bacillus subtilis strain FMCH002 in or on all food commodities when used in accordance with label directions and good agricultural practices.

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