Dated: June 21, 2021.
Edward Messina,
Acting Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

2. Add § 180.1384 to subpart D to read as follows:

§ 180.1384 Bacillus subtilis strain RTI477; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of Bacillus subtilis strain RTI477 in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2021–13804 Filed 6–28–21; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


Bacillus velezensis Strain RTI301; 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 Bacillus velezensis strain RTI301 in or on all food commodities when used in accordance with label directions and good agricultural practices. FMC Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of Bacillus velezensis strain RTI301 under FFDCA when used in accordance with this exemption.

DATES: This regulation is effective June 29, 2021. Objections and requests for hearings must be received on or before August 30, 2021 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–2019–0475, 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.

Due to the public health concerns related to COVID–19, the OPP Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit https://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT:
Charles Smith, 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).

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–2019–0475 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 August 30, 2021. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b), although EPA strongly encourages those interested in submitting objections or a hearing request, to submit objections and hearing requests electronically. See Order Urging Electronic Service and Filing (April 10, 2020), https://www.epa.gov/sites/production/files/2020-05/documents/2020-04-10_-_order_uring電子ian服务_and_filing.pdf. At this time, because of the COVID–19 pandemic, the judges and staff of the Office of Administrative Law Judges are working remotely and not able to accept filings or correspondence by courier, personal delivery, or commercial delivery, and the ability to receive filings or correspondence by U.S. Mail is similarly limited. When submitting documents to the U.S. EPA Office of Administrative Law Judges (OALJ), a person should utilize the OALJ e-filing system, at https://yosemite.epa.gov/OA/EAB/EAB-ALJ-upload.nsf.

Although EPA’s regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions during this time that the Agency continues to maximize telework due to the pandemic; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. If it is impossible for a person to submit documents electronically or receive service electronically, e.g., the person does not have any access to a computer, the person shall so advise OALJ by contacting the Hearing Clerk at (202) 564–6281. If a person is without access to a computer and must file documents by U.S. Mail, the person may use the OALJ e-filing system, at https://yosemite.epa.gov/OA/EAB/EAB-ALJ-upload.nsf.

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–2019–0475, 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 docket generally, is available at http://www.epa.gov/dockets.

II. Background

In the **Federal Register** of February 4, 2020 (85 FR 6129) (FRL–10003–17), EPA issued a notice pursuant to FFDCA section 406(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance exemption petition (PP 9F8750) by FMC Corporation, 2929 Walnut St., Philadelphia, PA 19104. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the fungicide *Bacillus velezensis* strain RTI301 in or on all food commodities. That notice referenced a summary of the petition prepared by the petitioner FMC Corporation and available in the docket via http://www.regulations.gov. Although one comment was submitted to the docket for this notice of filing, it was unrelated to this tolerance exemption rulemaking.

III. Final Rule

A. **EPA’s Safety Determination**

Section 408(c)(2)(A)(ii) 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. 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 toxicological and exposure data on *Bacillus velezensis* strain RTI301 and considered their 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 those data can be found within the document entitled “Human Health Risk Assessment for the New Active Ingredients *Bacillus subtilis* strain RTI477 and *Bacillus velezensis* strain RTI301 in the Proposed Manufacturing-use Products 279–OAUT, 279–OAU1 and End-use Products 279–OAU2, 279–OALN and 279–OALR for FIFRA Section 3 Registration with Tolerance Exemption Petitions” ( *Bacillus subtilis* strain RTI477 and *Bacillus velezensis* strain RTI301 Human Health Assessment).

This document, as well as other relevant information, is available in docket for this action as described under ADDRESSES.

The available data demonstrated that, with regard to humans, *Bacillus velezensis* strain RTI301 is not toxic via the pulmonary, oral, or dermal routes of exposure and is not pathogenic or infective via the pulmonary or oral routes of exposure. Although there may be some dietary and non-occupational exposure to residues of *Bacillus velezensis* strain RTI301 when used in accordance with label directions and good agricultural practices, there is not a concern due to the lack of potential for adverse effects. Because there are no threshold levels of concern with the toxicity, pathogenicity, or infectivity of *Bacillus velezensis* strain RTI301, EPA determined that no additional margin of safety is necessary to protect infants and children as part of the qualitative assessment conducted. Based upon its evaluation in the *Bacillus subtilis* strain RTI477 and *Bacillus velezensis* strain RTI301 Human Health Assessment, which concludes that there are no risks of concern from aggregate exposure to *Bacillus velezensis* strain RTI301, 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 velezensis* strain RTI301.

B. **Analytical Enforcement Methodology**

An analytical method is not required for *Bacillus velezensis* strain RTI301 because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. **Conclusion**

Therefore, an exemption from the requirement of a tolerance is established for residues of *Bacillus velezensis* strain RTI301 in or on all food commodities when used in accordance with label directions and good agricultural practices.

IV. **Statutory and Executive Order Reviews**

This action establishes a tolerance exemption 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 28335, 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, 44 U.S.C.
Agricultural Commodities, Pesticides

This action is not a "major
Register General of the United States prior to
Representatives, and the Comptroller
Senate, the U.S. House of
other required information to the U.S.
seq.

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: June 21, 2021.

Edward Messina,
Acting Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:


2. Add § 180.1383 to subpart D to read as follows:

§ 180.1383 Bacillus velezensis strain RT301; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of Bacillus velezensis strain RT301 in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2021-13806 Filed 6-28-21; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 716


RIN 2070–AB11

Health and Safety Data Reporting;
Addition of 20 High-Priority Substances and 30 Organohalogen Flame Retardants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule, issued pursuant to the Toxic Substances Control Act (TSCA) and the TSCA Health and Safety Data Reporting rule, requires manufacturers (including importers) of 50 specified chemical substances to report certain lists and copies of unpublished health and safety studies to EPA. The chemical substances subject to this rule are listed in this document and consist of the 20 designated by EPA as High-Priority Substances and the 30 organohalogen flame retardants being evaluated for risks by the Consumer Product Safety Commission (CPSC) under the Federal Hazardous Substances Act (FHSA). EPA is taking this action because the TSCA Interagency Testing Committee (ITC) added these chemical substances to the Priority Testing List through its 69th and 74th Reports and EPA will use this information to inform the risk evaluations currently underway for 20 High-Priority Substances and for future prioritization.

DATES: This final rule is effective July 29, 2021. For purposes of judicial review, this final rule shall be promulgated at 1 p.m. eastern daylight/standard time July 13, 2021.

A request to withdraw a chemical substance from this final rule pursuant to 40 CFR 716.105(c) must be received on or before July 13, 2021. (See Unit IV. of the SUPPLEMENTARY INFORMATION.)

Dates for the reporting requirements are enumerated in Unit III.B. of the SUPPLEMENTARY INFORMATION.

ADDRESSES:

Comments. Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2020–0474, by using the Federal eRulemaking Portal at http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit https://www.epa.gov/dockets.

Withdrawal requests. For submission of a withdrawal request, see Unit IV. of this document. Each withdrawal request must be identified by docket ID number EPA–HQ–OPPT–2020–0474.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Diana Fahning, Data Gathering and Analysis Division (7410M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8621; email address: fahning.diana@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION: