Judicial challenges to the EPA's denials of petitions for reconsideration of CAA actions belong in the same venue as any challenge to the action that such petitions request the agency to reconsider.[1]

The D.C. Circuit is the only appropriate venue for both challenges to the final action titled, ''Air Quality Designations for the 2010 Sulfur Dioxide (SO_2) Primary National Ambient Air Quality Standard—Supplement to Round 2 for Four Areas in Texas: Freestone and Anderson Counties, Milam County, Rusk and Panola Counties, and Titus County,'' 81 FR 89870 (December 13, 2016) (''Round 2 Supplement'') and challenges to these actions denying administrative petitions on the Round 2 Supplement. The EPA made a finding in the Round 2 Supplement, that the Round 2 Supplement is based on a determination of ''nationwide scope or effect'' within the meaning of CAA section 307(b)(1). *See* 81 FR at 89874–75. That action is currently being challenged in the Court of Appeals for the Fifth Circuit; however, the EPA maintains that the proper venue for that action is the D.C. Circuit.[2] Thus, judicial challenges to the actions noticed here, denying administrative petitions for reconsideration and/or stay of the Round 2 Supplement, also belong in the D.C. Circuit.

To the extent a court finds these actions denying the administrative petitions on the Round 2 Supplement to be locally or regionally applicable, the Administrator is exercising the complete discretion afforded to him under the CAA to make and publish a finding that each of these actions are based on a determination of ''nationwide scope or effect'' within the meaning of CAA section 307(b)(1).[3] Both the Round 2 Supplement and these final actions noticed here are finalized pursuant to a common, uniform nationwide analytical method and interpretation of CAA section 107(d). In denying the petitions for reconsideration and administrative stay of the Round 2 Supplement, these final actions apply the same common, uniform nationwide analytical method and interpretation of CAA section 107(d) that the EPA applied across the country in designations for the SO_2 Primary National Ambient Air Quality Standard (NAAQS), including the EPA's nationwide approach to and technical evaluation of air quality modeling and monitoring data within the EPA's interpretation of statutory terms under section 107(d)(1) of the CAA.[4] These final actions are based on this same common core of determinations regarding the nationwide analytical method and interpretation of CAA section 107(d), determinations that specific methodologies are appropriate or preferable for assessing sulfur dioxide levels nationwide.[5] More specifically, these final actions are based on a determination by the EPA to evaluate areas nationwide using a common five-factor analysis in determining whether areas are in violation of or contributing to an area in violation of the 2010 SO_2 NAAQS at the time of the designations final action. The actions denying the petitions for reconsideration explained, for example, that the EPA's designations and the denials for reconsideration are based on the EPA's determination to consider and assess the technical representativeness of all available information regarding then-current air quality at the time of designations *(e.g.,* to consider third party modeling submitted to the EPA of the then-most recent years of air quality and then-currently available monitoring information, and not to consider projections or intended monitoring of future years' emissions, for SO_2 designations under the CAA). For these reasons, the Administrator is exercising the complete discretion afforded to him by the CAA and hereby finds that each of these final actions is based on a determination of nationwide scope or effect for purposes of CAA section 307(b)(1) and is hereby publishing those findings in the **Federal Register**.

Under CAA section 307(b), any petition for review of these actions denying the petitions for reconsideration and/or stay must be filed in the Court of Appeals for the District of Columbia Circuit within 60 days from the date this notice is published in the **Federal Register**. Filing a petition for reconsideration by the Administrator of these final actions does not affect the finality of the actions for the purposes of judicial review, nor does it extend the time within which a petition for judicial review must be filed, and shall not postpone the effectiveness of such actions.

Michael S. Regan,

Administrator.

[FR Doc. 2021–13938 Filed 6–28–21; 8:45 am]

BILLING CODE 6560–50–P

[1] *Cf. Natural Res. Def. Council, Inc.* v. *Thomas,* 838 F.2d 1224, 1249 (D.C. Cir. 1988) (the clause in CAA section 307(b) governing ''nationally applicable regulations'' provides jurisdiction over both the direct challenge to the regulations and the petition for reconsideration).

[2] The EPA intends to maintain this position in merits briefing in the 5th Circuit, as the 5th Circuit's venue decision denied the EPA's motion to dismiss or transfer the case to the D.C. Circuit without prejudice to reconsideration of the issue by the merits panel. Texas v. EPA, 706 Fed. Appx. 159, 161, 165 (5th Cir. 2017) (''EPA's motion therefore is denied without prejudice to reconsideration by the merits panel . . . merits briefing will provide greater clarity on what determinations lie at the [Round 2] Supplement's core, by, for example, illuminating that the key determinations in the rule are determinations that specific methodologies are appropriate or preferable for assessing sulfur dioxide levels nationwide, as opposed to fact-specific assessments of sulfur dioxide levels in the four Texas regions. In that case, the merits panel should not be constrained from revisiting the issue.'').

[3] In deciding whether to invoke the exception by making and publishing a finding that this final action is based on a determination of nationwide scope or effect, the Administrator has also taken into account a number of policy considerations, including his judgment balancing the benefit of obtaining the D.C. Circuit's authoritative centralized review versus allowing development of the issue in other contexts and the best use of agency resources.

[4] In the report on the 1977 Amendments that revised section 307(b)(1) of the CAA, Congress noted that the Administrator's determination that the ''nationwide scope or effect'' exception applies would be appropriate for any action that has a scope or effect beyond a single judicial circuit. See H.R. Rep. No. 95–294 at 323, 324, reprinted in 1977 U.S.C.C.A.N. 1402–03.

[5] *See, supra,* n.2.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0474; FRL–10025–18]

Bacillus subtilis Strain RTI477; 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 subtilis* strain RTI477 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 subtilis* strain RTI477 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–2019–0474, 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 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.*

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?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Publishing 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 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–2019–0474 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_urging_electronic_service_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 shall notify the Hearing Clerk every time it files a document in such a manner. The address for mailing documents is U.S. Environmental Protection Agency, Office of Administrative Law Judges, Mail Code 1900R, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

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–2019–0474, 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

In the **Federal Register** of February 4, 2020 (85 FR 6129) (FRL–10003–17), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance exemption petition (PP 9F8749) 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 subtilis* strain RTI477 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.* No comments were received on the notice of filing.

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 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 subtilis* strain RTI477 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–OAUI and End-use Products 279–OAUO, 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 subtilis* strain RTI477 is not toxic via the pulmonary, oral, or dermal routes of exposure and is not pathogenic or infective via the pulmonary route of exposure. Although there may be some dietary and non-occupational exposures to residues of *Bacillus subtilis* strain RTI477 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 subtilis* strain RTI477, 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 subtilis* strain RTI477, 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 RTI477.

B. Analytical Enforcement Methodology

An analytical method is not required for *Bacillus subtilis* strain RTI477 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 subtilis* strain RTI477 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 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, 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 (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 (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 (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: 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:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 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

[EPA–HQ–OPP–2019–0475; FRL–10025–21]

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.

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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?

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

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