
2. Add § 165.T08–1014 to read as follows:

§ 165.T08–1014 Security Zone; Corpus Christi Ship Channel. Corpus Christi, TX.

(a) Location. The following area is a security zone:

(1) For LNG GOLAR TUNDRA transiting shoreward of the seaward extremity of the Aransas Pass Jetties in the Corpus Christi Ship Channel and La Quinta Channel, the waters within a 500 yards of LNG GOLAR TUNDRA while transiting until moored.

(2) The mooring basin bound by 27°52′53.38″ N, 097°16′20.66″ W on the northern shoreline; thence to 27°52′45.58″ N, 097°16′19.60″ W; thence to 27°52′38.55″ N, 097°15′45.56″ W; thence to 27°52′49.30″ N, 097°15′44.44″ W; thence west along the shoreline to 27°52′3.38″ N, 097°16′20.66″ W, while LNG GOLAR TUNDRA is moored.

(b) Effective/enforcement period. This section is effective without actual notice from November 20, 2018 until November 21, 2018. For the purposes of enforcement, actual notice will be used from November 11, 2018 through November 20, 2018. Enforcement of this section began from the time LNG GOLAR TUNDRA entered the Corpus Christi Ship Channel on November 11, 2018 and will continue until LNG GOLAR TUNDRA’s departure on or about November 21, 2018.

(c) Regulations. (1) The general regulations in § 165.33 of this part apply. Entry into these zones are prohibited unless authorized by the Captain of the Port Sector Corpus Christi (COTP) or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Corpus Christi.

(2) Persons or vessels desiring to enter or pass through the zones must request permission from the COTP Sector Corpus Christi on VHF–FM channel 16 or by telephone at 361–939–0450.

(3) If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

(d) Information broadcasts. The COTP or a designated representative will inform the public through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate of the enforcement times and date for these security zones.

Dated: November 9, 2018.

J.E. Smith,
Captain, U.S. Coast Guard, Acting Captain of the Port Sector Corpus Christi.

[FR Doc. 2018–25251 Filed 11–19–18; 8:45 am]

BILLING CODE 9110–04–P

ENFORCEMENT

40 CFR Parts 51, 60, and 63

[FR Doc. 2018–24747 Filed 11–19–18; 8:45 am]

BILLING CODE 4024–01–D

ENVIROMENTAL PROTECTION AGENCY

40 CFR Part 180

[FR Doc. 2018–24747 Filed 11–19–18; 8:45 am]
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. 3466(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–2017–0460 in the subject line on your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before January 22, 2019. 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–2017–0460, 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/contact.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 December 15, 2017 (82 FR 59604) (FRL–9970–50), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 3466(d)(3), announcing the filing of a pesticide tolerance petition (PP 7F8546) by Envera, LLC, 220 Garfield Ave., West Chester, PA 19380. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the bactericide and fungicide Bacillus amyloliquefaciens strain ENV503 in or on all food commodities. That document referenced a summary of the petition prepared by the petitioner Envera, LLC and available in the docket via http://www.regulations.gov. Comments were received on the notice of filing. EPA’s response to these comments is discussed in Unit III.C.

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 amyloliquefaciens strain ENV503 and the available toxicological data on Bacillus subtilis strain GB03, a microorganism that is genetically identical to Bacillus amyloliquefaciens strain ENV503, 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 “Federal Food, Drug, and Cosmetic Act (FFDCA) Safety Determination for Bacillus amyloliquefaciens strain ENV503” (Safety Determination). This document, as well as other relevant information, is available in the docket for this action as described under ADDRESSES.

The available data demonstrated that, with regard to humans, Bacillus amyloliquefaciens strain ENV503 is not toxic, pathogenic, or infective via any route of exposure. Although there may be some exposure to residues when Bacillus amyloliquefaciens strain ENV503 is used on all food commodities in accordance with label directions and good agricultural practices, such exposure is unlikely to significantly increase exposure above the background levels of Bacillus amyloliquefaciens organisms naturally present on food commodities. EPA also determined in the Safety Determination that retention of the Food Quality Protection Act (FQPA) safety factor was not necessary as part of the qualitative assessment conducted for Bacillus amyloliquefaciens strain ENV503.

Based upon its evaluation in the Safety Determination, 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 amyloliquefaciens strain ENV503. Therefore, an exemption from the requirement of a tolerance is
established for residues of Bacillus amyloliquefaciens strain ENV503 in or on all food commodities when this pesticide chemical is used in accordance with label directions and good agricultural practices.

B. Analytical Enforcement Methodology

An analytical method is not required because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Response to Comments

Four comments were received in response to the notice of filing. EPA reviewed the comments and determined that they are irrelevant to the tolerance exemption in this action.

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), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). 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.).

A. Analytical Enforcement Methodology

An analytical method is not required because EPA is establishing an exemption from the requirement of a tolerance.

B. Response to Comments

Four comments were received in response to the notice of filing. EPA reviewed the comments and determined that they are irrelevant to the tolerance exemption in this action.

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), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). 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.).

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. Add § 180.1363 to subpart D to read as follows:

§ 180.1363 Bacillus amyloliquefaciens strain ENV503; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of Bacillus amyloliquefaciens strain ENV503 in or on all food commodities when used in accordance with label directions and good agricultural practices.

[Dated: November 5, 2018.

Richard P.Keigwin, Jr.,
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:


2. Add § 180.1363 to subpart D to read as follows:

§ 180.1363 Bacillus amyloliquefaciens strain ENV503; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of Bacillus amyloliquefaciens strain ENV503 in or on all food commodities when used in accordance with label directions and good agricultural practices.

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