

regulations for recurring marine events taking place in August and September of 2024. This action is necessary and intended for the safety of life and property on navigable waters during these events. During the enforcement periods, no person or vessel may enter the respective safety zone without the permission of the Captain of the Port Eastern Great Lakes or a designated representative.

**DATES:** The regulations listed in 33 CFR 165.939 Table 165.939, will be enforced for the following events during the dates and times indicated in the

**SUPPLEMENTARY INFORMATION SECTION.**

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notice of enforcement, call or email MST1 Cody Mayrer, Waterways Management Division, U.S. Coast Guard Marine Safety Unit Cleveland; telephone 216-937-6007, email *D09-SMB-MSUCLEVELAND-WWM@uscg.mil*.

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce multiple safety zones for annual events in the Captain of the Port Eastern Great Lakes Zone listed in 33 CFR 165.939, Table 165.939 for events occurring in the months of August and September as listed in the **DATES** section above. Pursuant to 33 CFR 165.23, entry into, transiting, or anchoring within these safety zones during an enforcement period is prohibited unless authorized by the Captain of the Port Eastern Great Lakes or his designated representative. Those seeking permission to enter the safety zone may request permission from the Captain of Port Eastern Great Lakes via channel 16, VHF-FM. Vessels and persons granted permission to enter the safety zone shall obey the directions of the Captain of the Port Eastern Great Lakes or his designated representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

The safety are listed in 33 CFR 165.939 in Table 165.939. The specific zones and the Coast Guard plans to enforce are:

(c)(1) Whiskey Island Paddlefest—from 7 a.m. through 1:30 p.m. on August 17, 2024, in Cleveland Harbor, Lake Erie.

(c)(2) D-Day Conneaut—from 12:30 p.m. through 5:30 p.m. on August 15 through August 17, 2024, in U.S. waters of Lake Erie adjacent to Conneaut Township Park, Ohio.

(d)(1) Madison Light Up the Park (Madison Township Light Up the Park)—from 9 p.m. through 10:30 p.m. on August 10, 2024, in U.S. waters of Lake Erie adjacent to Madison Township, Ohio.

(d)(2) Cleveland National Air Show—from 11 a.m. through 5:30 p.m. on August 29, 2024; from 7 a.m. through 5:30 p.m. on August 30, 2024; and from 7:30 a.m. through 6:30 p.m. August 31 through September 2, 2024, in Cleveland Harbor, Lake Erie.

This notice of enforcement is issued under authority of 33 CFR 165.939 and 5 U.S.C. 552 (a). In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via Broadcast Notice to Mariners or Local Notice to Mariners. If the Captain of the Port Eastern Great Lakes determines that the safety zone need not be enforced for the full duration stated in this notice, he may use a Broadcast Notice to Mariners to grant general permission to enter the respective safety zone. This notification is being issued by the Coast Guard Sector Eastern Great Lakes Prevention Department Head at the direction of the Captain of the Port.

Dated: June 26, 2024.

**J.B. Bybee,**

*Commander, U.S. Coast Guard, Sector Eastern Great Lakes Prevention Department Head.*

[FR Doc. 2024-14432 Filed 7-1-24; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2023-0083; FRL-11889-01-OCSPJ]

### B.F. Strain 11604; 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 11604 in or on all food and feed commodities when used in accordance with label directions and good agricultural practices. BioConsortia, Inc., submitted a petition to the 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 11604 under FFDCA when used in accordance with this exemption.

**DATES:** This regulation is effective July 2, 2024. Objections and requests for

hearings must be received on or before September 3, 2024 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-2023-0083, is available at <https://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 20004. 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 and OPP Docket is (202) 566-1744. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:**

Madison H. Le, Biopesticides and Pollution Prevention Division (7511M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (202) 566-1400; email address: [BPPDFRNotices@epa.gov](mailto: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 Office of the Federal Register's e-CFR site at <https://ecfr.federalregister.gov/current/title-40>.

### 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 the EPA, you must identify docket ID number EPA-HQ-OPP-2023-0083 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 September 3, 2024.

The EPA's Office of Administrative Law Judges (OALJ), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. See "Revised Order Urging Electronic Filing and Service," dated June 22, 2023, which can be found at <https://www.epa.gov/alj/revised-order-urging-electronic-filing-and-service>. Although the EPA's regulations require submission via U.S. Mail or hand delivery, the EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, the EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at [https://yosemite.epa.gov/OA/EAB/EAB-ALJ\\_upload.nsf](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 the EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2023-0083, by one of the following methods:

- **Federal eRulemaking Portal:** <https://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 <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

## II. Background

In the **Federal Register** of March 24, 2023 (88 FR 17778) (FRL-10579-02-OCSP), the 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 2F8991) by BioConsortia, Inc., 279 Cousteau Place, Davis, CA 95618. 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 and bactericide *Bacillus velezensis* strain 11604 in or on all food and feed commodities. That notice referenced a summary of the petition prepared by the petitioner BioConsortia, Inc., and available in the docket via <https://www.regulations.gov>. The EPA received two comments on the notice of filing. The EPA's response to these comments is discussed in Unit III.C.

Based upon review of data and other information supporting the petition, the EPA modified the active ingredient name. In addition, the EPA also changed the commodity to be reflected in the tolerance exemption expression from "in or on all raw agricultural crops" to "in or on all food and feed commodities." The reason for this change is explained in Unit III.D.

## III. Final Rule

### A. The EPA's Safety Determination

Section 408(c)(2)(A)(i) of FFDCA allows the 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 the 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, the EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require the 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 the EPA consider "available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity."

The EPA evaluated the available toxicological and exposure data on *Bacillus velezensis* strain 11604 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 the EPA relied, and its risk assessment based on those data can be found within the document entitled "Human Health Risk Assessment of *Bacillus velezensis* strain 11604, a New Active Ingredient, in Crimson (End-use Product) Proposed for Registration and an Associated Petition Requesting a Tolerance Exemption" (Human Health Risk Assessment of *Bacillus velezensis* strain 11604). This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

Based on its evaluation, EPA concludes that *Bacillus velezensis* strain 11604 is not toxic, pathogenic, or infective via the injection route of exposure. *Bacillus velezensis* strain 11604 is not anticipated to be toxic, pathogenic, or infective via the oral or pulmonary routes of exposure based on rationale supported by acute toxicity data conducted with a mixture of *Bacillus velezensis* strain 11604 and other (inert) ingredients. Additionally, the acute injection toxicity/pathogenicity study demonstrated a pattern of clearance of *Bacillus velezensis* strain 11604 from the test animals. Significant dietary and non-occupational exposures to residues of *Bacillus velezensis* strain 11604 are not anticipated because levels of *Bacillus velezensis* strain 11604 after application on food and feed commodities will rapidly decrease to naturally occurring background levels. Furthermore, *Bacillus velezensis* is naturally present in the soil, on the surface of a variety of plant-based foods, and in water processed through water treatment facilities with no reported human

disease or illness. Even if dietary and non-occupational exposures to residues of *Bacillus velezensis* strain 11604 were to occur, there is not a concern due to the lack of potential for adverse effects. EPA determined that the additional margin of safety referred to as the Food Quality Protection Act Safety Factor is not necessary to protect infants and children as part of the qualitative assessment conducted.

Based upon its evaluation in the Human Health Risk Assessment of *Bacillus velezensis* strain 11604, which concludes that there are no risks of concern from aggregate exposure to *Bacillus velezensis* strain 11604, the 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 11604.

#### *B. Analytical Enforcement Methodology*

An analytical method is not required for *Bacillus velezensis* strain 11604 because the EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

#### *C. Response to Comments*

Comments were not directly related to the petition for a tolerance exemption for *Bacillus velezensis* strain 11604 and have been acknowledged. The comments received were unrelated to *Bacillus velezensis* strain 11604 and did not relate to the protection of human health and the environment.

#### *D. Revisions to the Requested Tolerance Exemption*

EPA Revised the tolerance exemption expression to specifically include the establishment of the exemption from the requirement of a tolerance for residues of the microbial pesticide *Bacillus velezensis* strain 11604 in or on all food and feed commodities. Although not expressly stated in the petition, EPA interpreted the petition as requesting an exemption covering all food and feed commodities.

#### *E. Conclusion*

Therefore, an exemption from the requirement of a tolerance is established for residues of *Bacillus velezensis* strain 11604 in or on all food and feed 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 the 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, the 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, the 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 the 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.*), the 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 24, 2024.

**Edward Messina,**

*Director, Office of Pesticide Programs.*

Therefore, for the reasons stated in the preamble, the 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 § 180.1408 to subpart D to read as follows:

#### **§ 180.1408 *Bacillus velezensis* strain 11604; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of *Bacillus velezensis* strain 11604 in or on all food and feed commodities when used in accordance with label directions and good agricultural practices.

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