



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2023-0143; FRL-12383-01-OCSP]

Inactivated *Burkholderia Rinojensis* Strain A396 Cells and Spent Fermentation Media; 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 Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media in or on all food commodities when used in accordance with label directions and good agricultural practices. Marrone Bio Innovations, Inc., 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 Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media under FFDCA when used in accordance with this exemption.

DATES: This regulation is effective **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Objections and requests for hearings must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** 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-2023-0143, 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 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, and for the OPP Docket is (202) 566-1744. For the latest status information on EPA/DC services and docket access, visit <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.

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://www.ecfr.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 EPA, you must identify docket ID number EPA-HQ-OPP-2023-0143, 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 **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. 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-2023-0143, 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), EPA issued a notice pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance exemption petition (PP 1F8955) by Marrone Bio Innovations, Inc., 1540

Drew Ave., 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 insecticide, fungicide, miticide, and nematocide Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media in or on all agricultural commodities. That notice referenced a summary of the petition prepared by the petitioner Marrone Bio Innovations, Inc., and is available in the docket via <https://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.”

Consistent with FFDCA section 408(b)(2)(D), EPA has evaluated the available

toxicological and exposure data on Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media 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 “Microbial Human Health Risk Assessment for Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media”. This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

The available data and rationale demonstrated that, with regard to humans, Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media has low toxicity via oral, dermal, or inhalation routes of exposure. Additionally, it was found to be minimally irritating to the skin and to the eye and is not a skin sensitizer. In a 90-day oral toxicity study conducted with Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media, there were no adverse effects observed at the maximum dose of 900mg/kg/day. The 90-day dermal, 90-day inhalation, prenatal developmental toxicity, and genotoxicity data requirements were addressed with rationale using a weight of the evidence (WOE) approach that considered the lack of adverse effects in the toxicity data, among other considerations. Based on the lack of adverse effects seen in the available toxicity/pathogenicity data, EPA did not identify any points of departure for assessing risk; thus, no quantitative risk assessment was conducted. Significant dietary and non-occupational exposures to residues of Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media are not anticipated because of its rapid biodegradability and it is not expected to remain at high levels on plant surfaces or readily percolate through soil before reaching ground water. Even if dietary and non-occupational exposures to residues of Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media were to occur, there is no risk of concern due to the lack of potential for adverse effects.

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the

cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." No risk of cumulative toxicity/effects from Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media has been identified as no toxicity has been shown for Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media in the submitted studies. Therefore, EPA has not assumed that Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media has a common mechanism of toxicity with other substances.

Additionally, although FFDCA section 408(b)(2)(C) provides for an additional tenfold margin of safety for infants and children in the case of threshold effects, EPA has determined that there are no such effects due to the lack of toxicity of Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media. Because there are no threshold levels of concern with the toxicity of Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media, 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 described above and in the Microbial Human Health Risk Assessment for Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media, which concludes that there are no risks of concern from aggregate exposure to Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media, 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 Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media.

B. Analytical enforcement methodology

An analytical method is not required for Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media 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 Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media in or on all agricultural food commodities when used in accordance with label directions and good agricultural practices.

IV. Statutory and Executive Order Reviews

This action establishes an exemption 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, 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: January 8, 2025.

Edward Messina,

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 § 180.1415 to subpart D to read as follows:

§180.1415 Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of Inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media in or on all agricultural commodities when used in accordance with label directions and good agricultural practices.

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