



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2023-0255; FRL-12251-02-OCSP]

#### ***Beauveria Bassiana* Strain BW149; 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 *Beauveria bassiana* strain BW149 in or on all food commodities when used in accordance with label directions and good agricultural practices. BioWorks, 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 *Beauveria bassiana* strain BW149 under FFDCA when used in accordance with good agricultural practices.

**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-2023-0255, is available online at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket in person, is 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).

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### *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. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. 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-

2023-0255, 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*]**.

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/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf>. 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).

## **II. Background**

In the *Federal Register* of July 5, 2023 (88 FR 42935 (FRL-10579-05-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 2F9027) by BioWorks, Inc., 100 Rawson Road, Suite 205, Victor, NY 14564. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the microbial pesticide *Beauveria bassiana* strain BW149 in or on all food and feed commodities. That notice referenced a summary of the petition prepared by the petitioner BioWorks, Inc., and available in the docket via <https://www.regulations.gov>. The EPA received no comments in response to the notice of filing.

## **III. Final Rule**

### A. 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 *Beauveria bassiana* strain BW149 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 the EPA relied and its risk assessment based on those data can be found within the document entitled “Human Health Risk Assessment of *Beauveria bassiana* strain BW149, a New Active Ingredient, in BW149 Technical, BW149 ESO, BW149 WPO Proposed for Registration and an Associated Petition Requesting a Tolerance Exemption” (*Beauveria bassiana* BW149 Human Health Risk Assessment). This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

The toxicological profile of *Beauveria bassiana* BW149 is described in the *Beauveria bassiana* BW149 Human Health Risk Assessment. Based upon its evaluation, EPA concludes that with regards to humans, *Beauveria bassiana* BW149 is not anticipated to be toxic, pathogenic, or infective. Significant dietary and non-occupational exposure to residues of *Beauveria bassiana* BW149 are not expected as the products will be applied in agricultural settings and has not been approved for any residential uses. Other non-occupational exposure through drift or other means is possible but considered unlikely, and toxic effects are not anticipated because drift concentrations would be below levels that would elicit effects. The active ingredient is also known to degrade in UV and sunlight and above 37°C. Even if dietary and non-occupational exposures to residues of *Beauveria bassiana* BW149 were to occur, there is no risks of concern due to the lack of adverse effects from toxicity, pathogenicity, or infectivity of *Beauveria bassiana* BW149. EPA determined that no additional margin of safety is necessary to protect infants and children as part of the qualitative assessment conducted, as data and rationale demonstrated that *Beauveria bassiana* strain BW149 is not toxic, pathogenic or infective.

Based upon its evaluation in the *Beauveria bassiana* BW149 Human Health Risk Assessment, which concludes that there are no risks of concern from aggregate exposure to *Beauveria bassiana* strain BW149, 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 *Beauveria bassiana* strain BW149.

#### *B. Analytical Enforcement Methodology*

An analytical method is not required for *Beauveria bassiana* strain BW149 because the 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

*Beauveria bassiana* strain BW149 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 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.*

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 (CRA)**

This action is subject to the CRA (5 U.S.C. 801 *et seq.*), and EPA will submit a rule report to each House of Congress and to the Comptroller General of the United States. 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: February 7, 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 § 180.1414 to subpart D to read as follows:

**§180.1414 *Beauveria bassiana* BW149; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of *Beauveria bassiana* strain BW149 in or on all food commodities when used in accordance with label directions and good agricultural practices.

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