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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2023-0503; FRL-12664-01-OCSPP]

***Pseudomonas Oryzihabitans* Strain SYM23945; 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 *Pseudomonas oryzihabitans* strain SYM23945 in or on all food commodities when used in accordance with label directions and good agricultural practices. Indigo Ag, 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 *Pseudomonas oryzihabitans* strain SYM23945 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- 2023-0503, is available 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*.

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 action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. *What is EPA's authority for taking this action?*

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(c)(2)(A)(i) allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." FFDCA section 408(c)(2)(A)(ii) 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 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 Agency consider, among other things, "available information concerning the cumulative effects of a particular pesticide's residues" and "other substances that have a common mechanism of toxicity."

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-2023-0503 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*].**

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 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; therefore, 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*.

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 at *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. If you wish to include CBI in your request, please follow the applicable instructions at *https://*www.epa.gov/dockets/commenting-epa-dockets#rules and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

II. Petitioned-for Exemption

In the **Federal Register** of February 9, 2024 (89 FR 9103) (FRL-10579-12-OCSPP), 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 2F9043) by Indigo Ag, Inc., 500 Rutherford Ave., Charlestown, MA 02129. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the nematicide *Pseudomonas oryzihabitans* strain SYM23945 in or on all food commodities. That notice referenced a summary of the petition prepared by the petitioner Indigo Ag, Inc. and is available in the docket. EPA received two comments in response to the notice of filing. EPA's response to these comments is discussed in Unit III.C.

EPA has omitted the term "nematicide" from the exemption established in this action. The reason for this change is explained in Unit III.D.

III. Final Tolerance Actions

A. *EPA's Safety Determination*

EPA evaluated the available toxicological and exposure data on *Pseudomonas oryzihabitans* strain SYM23945 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 *Pseudomonas oryzihabitans* strain SYM23945, a New Active Ingredient in *Pseudomonas oryzihabitans* strain SYM23945 Technical, *Pseudomonas oryzihabitans* strain SYM23945 MUP, and Indigo 407 FP Proposed for Registration and an Associated Petition Requesting a Tolerance Exemption" (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 *Pseudomonas oryzihabitans* strain SYM23945 is described in the *Pseudomonas oryzihabitans* strain SYM23945 Human Health Risk Assessment. Based upon its evaluation, EPA concludes that with regards to humans, *Pseudomonas oryzihabitans* strain SYM23945 is not toxic, pathogenic, or infective via the oral, pulmonary, or injection routes of exposure. Additionally, a pattern of clearance was demonstrated from the test animals indicating a lack of pathogenicity or infectivity of *Pseudomonas oryzihabitans* strain SYM2394. Significant dietary and non-occupational exposures to residues of *Pseudomonas oryzihabitans* strain SYM23945 are not expected as the pesticide will be applied as a seed treatment only, reducing the likelihood of pesticide residues on food crops or of off-site, airborne or runoff movement of this active ingredient. However, if this active ingredient were to enter the environment, it would likely be present at levels below those of naturally occurring *Pseudomonas oryzihabitans* due to relatively low application rates and use patterns. Further, because food crops undergo postharvest washing, it is unlikely that significant residues of *Pseudomonas oryzihabitans* strain SYM23945 would remain on treated crops. Municipal water treatment practices are also likely to eliminate any residues in drinking water. Even if dietary and non-occupational exposures to residues of *Pseudomonas oryzihabitans* strain SYM23945 were to occur, there are no risks of concern due to

the lack of adverse effects from toxicity, pathogenicity, or infectivity of *Pseudomonas oryzihabitans* strain SYM23945. Because there are no threshold levels of concern with the toxicity, pathogenicity, or infectivity of *Pseudomonas oryzihabitans* strain SYM23945, 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 Human Health Risk Assessment, which concludes that there are no risks of concern from aggregate exposure to *Pseudomonas oryzihabitans* strain SYM23945, 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 *Pseudomonas oryzihabitans* strain SYM23945.

B. *Analytical Enforcement Methodology*

An analytical method is not required for *Pseudomonas oryzihabitans* strain SYM23945 because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. *Response to Comments*

The Agency received two identical comments that expressed concern with *Pseudomonas oryzihabitans* being a pathogenic bacterium causing sickness, cancer, and being overall harmful to humans. The Agency's literature review showed that rare cases of human infection have been documented with *Pseudomonas oryzihabitans* in immunocompromised individuals and/or individuals that have experienced injury or recent medical procedure. No instances of human infection have been documented for *Pseudomonas oryzihabitans* strain SYM23945. Additionally, EPA concluded that *Pseudomonas oryzihabitans* strain SYM23945 is not toxic, pathogenic, and/or infective to mammals. The Agency has evaluated the aggregate risk of *Pseudomonas oryzihabitans* strain SYM23945 and has determined that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to residues of *Pseudomonas oryzihabitans* strain SYM23945. The Agency is

aware of no evidence indicating that Pseudomonas oryzihabitans strain SYM23945 is carcinogenic. The comments offered no relevant information that would warrant a reconsideration of the Agency's determination.

D. *Revisions to the requested tolerance exemption*

The petition requested an exemption from the requirement of a tolerance for residues of the nematicide *Pseudomonas oryzihabitans* strain SYM23945 in or on all food commodities. The Agency has omitted the term "nematicide" from the exemption established in this action to reduce any unnecessary restrictions therein.

E. *Conclusion*

Therefore, an exemption from the requirement of a tolerance is established for residues of *Pseudomonas oryzihabitans* strain SYM23945 in or on all food commodities when used in accordance with label directions and good agricultural practices.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. *Executive Order 12866: Regulatory Planning and Review*

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866.

B. *Paperwork Reduction Act (PRA)*

This action does not impose an information collection burden under the PRA, 44 U.S.C. 3501 *et seq*., because it does not contain any information collection activities.

C. *Regulatory Flexibility Act (RFA)*

This action is not subject to the RFA, 5 U.S.C. 601 *et seq.* The RFA applies only to rules

subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule is not subject to the APA but is subject to FFDCA section 408(d), which does not require notice and comment rulemaking to take this action in response to a petition.

D. *Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of $100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. *Executive Order 13132: Federalism*

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. *Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

G. *Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866 (See Unit IV.A.), and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. However, EPA's 2021 Policy on Children's Health applies to this action. This rule finalizes an exemption from the requirement

of a tolerance under the FFDCA, which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance 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 ..." (FFDCA 408(b)(2)(C)). The Agency's consideration is documented in Unit III.A.

H. *Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. *National Technology Transfer Advancement Act (NTTAA)*

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

J. *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 the Congress and to the Comptroller General of the United States. This action 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: March 19, 2025.

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 § 180.1416 to subpart D to read as follows:

§180.1416 *Pseudomonas oryzihabitans* strain SYM23945; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Pseudomonas oryzihabitans* strain SYM23945 in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2025-05173 Filed: 3/26/2025 8:45 am; Publication Date: 3/27/2025]