

about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132. Federalism, if it has a substantial direct effect 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone on the Upper Mississippi River from MM 497.6 to 497.2 for short periods of time over two days. It is

categorically excluded from further review under paragraph L60(a) of appendix A, table 1 of DHS Instruction Manual 023–01–001–01, Rev. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

- 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

- 2. Add § 165.T08–0695 to read as follows:

§ 165.T08–0695 Safety Zone; Upper Mississippi River, Mile Markers 497.6 to 497.2 LeClaire, IA and Port Byron, IL.

(a) *Location.* The following area is a safety zone: all navigable waters within the Upper Mississippi River from Mile Marker 497.6 to 497.2.

(b) *Enforcement period.* This section will be subject to enforcement from 8:30 p.m. to 11 p.m. on August 9, 2024, from 10:30 a.m. to 4 p.m. on August 10, 2024, and from 8:30 p.m. to 11 p.m. on August 10, 2024.

(c) *Regulations.* (1) In accordance with the general safety zone regulations in § 165.23, entry of persons or vessels into this safety zone described in paragraph (a) of this section is prohibited unless authorized by the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Upper Mississippi River.

(2) To seek permission to enter, contact the COTP or a designated

representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative.

(d) *Informational broadcasts.* The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement, as well as reductions in size or scope of the safety zone, through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Safety Marine Information Broadcast (SMIB) as appropriate.

Dated: July 31, 2024.

A.R. Bender,

Captain, U.S. Coast Guard, Captain of the Port, Sector Upper Mississippi River.

[FR Doc. 2024–17368 Filed 8–7–24; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2022–0939; FRL–11911–01–OCSPP]

Ophioglossum pendulum IPD079Ea Protein; 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 *Ophioglossum pendulum* IPD079Ea protein (hereafter IPD079Ea protein) when used as a plant incorporated protectant (PIP) in or on the food and feed commodities of corn: corn, field; corn, sweet, and corn, pop. Pioneer Hi-Bred International, 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 IPD079Ea protein.

DATES: This regulation is effective August 8, 2024. Objections and requests for hearings must be received on or before October 7, 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–2022–0939, 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. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Madison Le, Biopesticides and Pollution Prevention Division (7511P), 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, 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–2022–0939 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 October 7, 2024. 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–2022–0939, 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 and Statutory Findings

In the **Federal Register** of January 3, 2023 (88 FR 38) (FRL–9410–08), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 2F9010 by Pioneer Hi-Bred International, Inc., 7100 NW 62 Avenue, P.O. Box 1000, Johnston, IA 50131–1000). The petition requested that 40 CFR part 174 be amended by establishing an exemption from the requirement of a tolerance for residues of *Ophioglossum pendulum* IPD079Ea insecticidal protein in or on corn. That document referenced a summary of the petition prepared by the petitioner Pioneer Hi-Bred International, Inc., which is available in the docket, <https://www.regulations.gov>. There were no comments received in response to 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 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.” 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 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 factors, “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 toxicity and exposure data on IPD079Ea protein and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. A summary of the data upon which EPA relied and its risk assessment based on those data can be found within the document entitled “Product Characterization Review and Human Health Risk Assessment of the Insecticidal Plant-Incorporated Protectant Active Ingredient *Ophioglossum pendulum* IPD079Ea Protein and the Genetic Material Necessary (PHP83175) for its Production in DP–915635–4 maize and Establishment of a Permanent Tolerance Exemption” (hereafter Human Health Risk Assessment). This document, as well as other relevant information, is available in the docket for this action EPA–HQ–OPP–2022–0939.

The IPD079Ea protein, encoded by the *ipd079Ea* gene from *Ophioglossum pendulum* (common name: ribbon fern), a Southeast Asian epiphyte, confers control of *Diabrotica virgifera virgifera* (Western Corn Rootworm) when expressed in corn plants. An assessment of the toxic and allergenic potential of the IPD079Ea protein indicates that the IPD079Ea protein is not likely to be a potential toxin or allergen by any route of exposure. Dietary exposure is deemed the most relevant route for assessing human health risk of IPD079Ea protein, as corn products are made from grains and are consumed regularly by the American public. However, exposure to IPD079Ea protein through consumption of corn products containing the protein is expected to be very low given its very low levels of expression in grain. Oral exposure to IPD079Ea protein via drinking water is considered unlikely because the protein is already expressed at very low levels in the whole corn plant. Further, leaching into the soil and groundwater, combined with environmental conditions and microbial activity, is expected to further reduce its presence in drinking water. Although there may be dietary exposure to residues of IPD079Ea protein, such exposure presents no concern for adverse effects. Acute oral toxicity data demonstrated a lack of mammalian toxicity at high levels of exposure to pure IPD079Ea protein, and a bioinformatics analysis showed no similarities between the IPD079Ea protein and known toxic proteins that would raise a safety concern. Likewise, the potential for allergenicity is low because (1) there is no information in the literature indicating that *Ophioglossum pendulum* is a known source of allergenic proteins, (2) a bioinformatics analysis showed that the IPD079Ea protein does not have significant homology with known or putative allergens, (3) the IPD079Ea protein degrades rapidly (within 30 seconds) in the presence of simulated gastric fluid, indicating the protein will not be intact after stomach digestion, (4) the IPD079Ea protein is inactivated at high temperatures (50 °C/122 °F), such as those experienced by cooking corn products, and (5) the protein is not glycosylated, which further reduces its allergenicity potential. Glycosylation is an enzymatic post-translational process in which carbohydrates (glycans) link to proteins, creating structures which could lead to an immune response in humans.

Residential and non-occupational exposures are expected to be minimal given that the IPD079Ea protein is a

plant-incorporated protectant in corn. The only possible route of non-occupational exposure other than dietary is via handling of the plants and plant products. Exposures via the skin or inhalation are expected to be minimal given that the IPD079Ea protein is embedded in the matrix of the plant, which essentially eliminates or reduces dermal and inhalation routes of exposure to negligible levels. Furthermore, IPD079Ea protein expression in leaf tissue, forage, and pollen is very low. Together, there are no risks associated with these exposure routes because IPD079Ea protein is present in the plant at low levels and is not toxic or allergenic. These findings are discussed in more detail in the Human Health Risk Assessment.

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.” EPA has not found the IPD079Ea protein to share a common mechanism of toxicity with any other substances, and the IPD079Ea protein does not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has assumed that IPD079Ea protein does not have a common mechanism of toxicity with other substances.

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 and allergenicity of the IPD079Ea protein. As a result, an additional margin of safety for the protection of infants and children is unnecessary.

Based upon its evaluation described above and in the Human Health Risk Assessment, 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 the IPD079Ea protein. Therefore, an exemption from the requirement of a tolerance is established for residues of the IPD079Ea protein in or on the food and feed commodities of corn: corn, field; corn, sweet; and corn, pop when used as a plant-incorporated protectant in corn.

B. Analytical Enforcement Methodology

EPA has determined that an analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any

numerical limitation. Nonetheless, a protocol for a lateral flow test kit was submitted for detection of IPD079Ea protein. The submitted protocol adequately describes the methodology.

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 the Agency. 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 (PRA), 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 exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (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, nor does this action 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 Agency 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 Agency 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 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (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 174

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 25, 2024.

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 174—PROCEDURES AND REQUIREMENTS FOR PLANT-INCORPORATED PROTECTANTS

- 1. The authority citation for part 174 continues to read as follows:

Authority: 7 U.S.C. 136–136y; 21 U.S.C. 321(q), 346a and 371.

- 2. Add § 174.547 to subpart W to read as follows:

§ 174.547 *Ophioglossum pendulum* IPD079Ea protein; exemption from the requirement of a tolerance.

Residues of *Ophioglossum pendulum* IPD079Ea protein in or on the food and feed commodities of corn: corn, field; corn, sweet; and corn, pop are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in corn.

[FR Doc. 2024–17419 Filed 8–7–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2023–0079; FRL–11964–01–OCSPJ]

Indoxacarb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of indoxacarb in or on multiple crops listed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 8, 2024. Objections and requests for hearings must be received on or before October 7, 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–2023–0079, 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 the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: RDFRNotices@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 EPA’s tolerance regulations at 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–2023–0079 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 October 7, 2024. 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–2023–0079, by one of the following methods:

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- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

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