

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 174**

[EPA-HQ-OPP-2019-0627; FRL-12149-01-OCSPP]

**Pseudomonas Chlororaphis IPD072Aa 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 *Pseudomonas chlororaphis* IPD072Aa protein in or on maize (hereafter IPD072Aa 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 IPD072Aa protein.

**DATES:** This regulation is effective August 28, 2024. Objections and requests for hearings must be received on or before October 28, 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-2019-0627, 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 (7511M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (202) 564-5754; 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 174 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-174>.

*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-2019-0627 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 28, 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-2019-0627, 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 April 15, 2020 (85 FR 20910) (FRL-10006-540), 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 9F8785) by Pioneer Hi-Bred International, Inc., 7100 NW 62nd Avenue, P.O. Box 1000, Johnston, Iowa 50131. The petition requested that 40 CFR part 174 be amended by establishing an exemption from the requirement of a tolerance for residues of IPD072Aa protein in corn. That document referenced a summary of the petition prepared by the petitioner Corteva Agriscience, 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 “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 IPD072Aa protein and considered its 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 “Human Health Risk Assessment and Review of Product Characterization of the Insecticidal Plant-Incorporated Protectants, *Pseudomonas chlororaphis* IPD072Aa protein and DvSSJ1 dsRNA Complementary to the DvSSJ1 Gene Sequence from *Diabrotica virgifera virgifera*, and the Genetic Material Necessary (vector PHP74643), for their Production in Event DP23211 Maize (OECD Unique ID DP-Ø23211-2), and Establishment of a Permanent Tolerance Exemption. Data were provided in support of a FIFRA Section 3 Seed Increase Registration.” (hereafter Human Health Risk Assessment). This document, as well as other relevant information, is available in the docket for this action EPA-HQ-OPP-2019-0627.

IPD072Aa is a modified protein derived from the bacterium *Pseudomonas chlororaphis* and is active against coleopteran pests of corn. The Agency used a “weight of evidence” approach and determined that, IPD072Aa protein represents a negligible risk to humans or livestock that consume IPD072Aa maize products. The most likely exposure to the IPD072Aa protein is dietary through consumption of food products made from corn containing the protein. Oral exposure from ingestion of drinking water is unlikely because the IPD072Aa protein is present at very low levels within the plant cells and the amounts likely to enter the water column from leaves, pollen or plant detritus are low. Additionally, proteases and nucleases found in water and the environment

would likely degrade the biological material containing the active ingredients and treatment process for municipal water plants are likely to remove IPD072Aa residues. Although there may be dietary exposure to residues of IPD072Aa protein, such exposure presents no concern for adverse effects. Submitted data show that the IPD072Aa protein is not toxic via the oral route of exposure and bioinformatics analysis did not indicate a toxigenic potential *in silico*. Likewise, the potential for allergenicity is low because: (1) The bacterium source of IPD072Aa protein, *Pseudomonas chlororaphis*, is not considered to be a source of allergenic proteins; (2) bioinformatic analysis indicates no similarity between IPD072Aa protein and known allergens; (3) IPD072Aa protein degrades rapidly when exposed to simulated gastric fluid and completely digested in simulated intestinal fluid or exposed to heat via food cooking; and (4) IPD072Aa 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.

Non-dietary non-occupational or residential exposure via pulmonary or ocular exposure is not likely since IPD072Aa protein is contained within plant cells, and corn pollen is not respirable nor is it present in commercial corn products. Exposure via the skin is somewhat more likely via the contact with corn products which might have been processed in a way that disrupts cellular structure. However, naturally occurring proteases are likely to degrade proteins in contact with the skin and, as described above, the IPD072Aa protein has little or no potential toxicity or allergenicity. Thus, adverse effects are not expected due to non-occupational and residential exposure to IPD072Aa. 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.” No risk of cumulative toxicity or effects from IPD072Aa protein has been identified as no toxicity or allergenicity has been shown for this protein in the submitted studies. Therefore, EPA has concluded that IPD072Aa 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 of IPD072Aa 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 IPD072Aa protein. Therefore, an exemption from the requirement of a tolerance is established for residues of IPD072Aa 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 was submitted for a lateral flow test strip kit to be used for the detection of IPD072Aa protein in corn grain samples. The submitted protocol adequately describes the methodology.

#### IV. Statutory and Executive Order Reviews

This action establishes 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 tolerance 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: August 19, 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 § 174.548 to subpart W to read as follows:

##### § 174.548 *Pseudomonas chlororaphis* IPD072Aa protein; exemption from the requirement of a tolerance.

Residues of *Pseudomonas chlororaphis* IPD072Aa in or on the food and feed commodities of corn: corn, field; corn, sweet; and corn, pop are exempt from the requirement when used as a plant-incorporated protectant in corn.

[FR Doc. 2024–19046 Filed 8–27–24; 8:45 am]

**BILLING CODE 6560–50–P**

#### DEPARTMENT OF COMMERCE

##### National Oceanic and Atmospheric Administration

##### 50 CFR Part 648

[Docket No. 231215–0305; RTID 0648–XE241]

##### Fisheries of the Northeastern United States; Scup Fishery; Adjustment to the 2024 Winter II Quota

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Temporary rule; in-season adjustment.

**SUMMARY:** NMFS adjusts the 2024 Winter II commercial scup quota and per-trip Federal landing limit. This action is necessary to comply with regulations implementing Framework Adjustment 3 to the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan that established the rollover of unused commercial scup quota from the Winter I to the Winter II period. This notification informs the public of the quota and trip limit changes.

**DATES:** Effective October 1, 2024, through December 31, 2024.

#### FOR FURTHER INFORMATION CONTACT:

Laura Deighan, Fishery Management Specialist, (978) 281–9184; or [Laura.Deighan@noaa.gov](mailto:Laura.Deighan@noaa.gov).

**SUPPLEMENTARY INFORMATION:** NMFS published a final rule for Framework Adjustment 3 to the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan in the **Federal Register** on November 3, 2003 (68 FR 62250), implementing a process to increase the Winter II (October 1 through December 31) commercial scup quota by the amount of the Winter I (January 1 through April 30) under-harvest and to adjust the Winter II possession limits consistent with the amount of the quota increase, based on the possession limits established through the annual specifications-setting process.

For 2024, the initial Winter II quota is 3,370,790 pounds (lb; 1,528,965 kilograms (kg)). The best available landings information through August 12, 2024, indicates that 1,703,229 lb (772,572 kg) remain of the 9,539,294 lb (4,326,951 kg) Winter I quota. Consistent with Framework 3, the full amount of unused 2024 Winter I quota is being transferred to Winter II, resulting in a revised 2024 Winter II quota 5,074,019 lb (2,301,536 kg). Because the amount transferred is between 1.5 and 2 million lb (680,389 and 907,184 kg), the Federal per-trip possession limit will increase from 12,000 lb (5,443 kg) to 16,500 lb (7,484 kg), as outlined in the final rule that established the possession limit and quota rollover procedures for this year, published on December 21, 2023 (88 FR 88266). The new possession limit will be effective October 1 through December 31, 2024. The Winter II possession limit will revert to 12,000 lb (5,443 kg) at the start of the next fishing year, which begins January 1, 2025.

#### Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 648.122(d), which was issued pursuant to section 304(b), and is exempted from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be contrary to the public interest. This action transfers unused quota from the Winter I Period to the Winter II Period to make it accessible to the commercial scup fishery and increase fishing opportunities. If the implementation of this in-season action is delayed to solicit prior public comment, the objective of the fishery