List of Subjects in 40 CFR Part 174

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

Dated: December 4, 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 § 174.549 to subpart W to read as follows:

§ 174.549 *Bacillus thuringiensis* Cry1Da2 protein; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1Da2 protein in or on the food and feed commodities of corn, including 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. 2024–29132 Filed 12–12–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2022–0990; FRL–12381–01–OCSPP]

Streptomyces Sviceus DGT–28 EPSPS (5-Enolpyruvylshikimate-3-Phosphate Synthase) 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 the *Streptomyces sviceus* DGT–28 EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) protein (hereafter DGT–28 EPSPS 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 (PIP) inert ingredient. Pioneer Hi-Bred International, Inc., (Pioneer) 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 DGT–28 EPSPS protein.

DATES: This regulation is effective December 13, 2024. Objections and requests for hearings must be received on or before February 11, 2025, 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–2022–0990, 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) 564–5754; 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 174 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–2022–0990, 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 February 11, 2025. 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–2022–0990, 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 March 24, 2023 (88 FR 17778) (FRL–10579–02–OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of an FFDCA petition (IN 11746) 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 DGT–28 EPSPS protein derived from *Streptomyces sviceus* when used as an inert ingredient in a plant-incorporated protectant in or on maize. 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 ''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 DGT–28 EPSPS 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 ''Product Characterization Review and Human Health Risk Assessment of the Insecticidal Plant-Incorporated Protectant Active Ingredient, *Bacillus thuringiensis* Cry1Da2 and Plant-Incorporated Inert Ingredient DGT–28 EPSPS, and the Genetic Material Necessary (PHP88492) for their Production in Event DAS–1131–3 Maize, and Establishment of a Permanent Tolerance Exemption for Residues of these Proteins when used as a Plant-incorporated protectant in corn.'' (hereafter Human Health Risk Assessment). This document, as well as other relevant information, is available in the docket for this action EPA–HQ–OPP–2022–0990.

The gene for the inert plant-incorporated protectant protein DGT–28 EPSPS was derived from the soil bacterium *Streptomyces sviceus* and is intended to confer tolerance to glyphosate herbicides. The Agency used a ''weight of evidence'' approach and determined that DGT–28 EPSPS protein is not expected to pose any risk of toxicity to humans and the likelihood of the protein to be a food allergen is minimal. Submitted data show that the DGT–28 EPSPS protein is not toxic via the oral route of exposure and bioinformatics analysis did not indicate any homology to known toxins. Likewise, the potential for allergenicity is low because: (1) A literature search for the bacterium source of DGT–28 EPSPS protein, *Streptomyces sviceus,* did not yield any results that would indicate that *S. sviceus* is a known source of mammalian toxic or allergenic proteins; (2) DGT–28 EPSPS has been demonstrated to catalyze the same reaction as other EPSPS enzymes covered under current tolerance exemptions and have not been found to be associated with adverse health effects; (3) bioinformatic analysis indicates no biologically relevant similarity between DGT–28 EPSPS protein and known allergens; (4) DGT–28 EPSPS protein degrades rapidly when exposed to simulated gastric fluid and is completely digested in simulated intestinal fluid; DGT–28 EPSPS is heat labile at temperatures exceeding 50 °C, indicating that it will likely denature in the course of normal thermal treatment during food preparation; and (5) DGT–28 EPSPS 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.

The most likely exposure to the DGT–28 EPSPS 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 DGT–28 EPSPS 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 DGT–28 EPSPS residues. While dietary exposure is expected to be limited, even if there is dietary exposure to residues of DGT–28 EPSPS protein, such exposure presents no concern for adverse effects due to the lack of toxicity or allergenicity.

Non-dietary, non-occupational or residential exposure via pulmonary or ocular exposure is not likely since DGT–28 EPSPS protein is contained within plant cells, and corn pollen is not respirable. 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 DGT–28 EPSPS protein has little or no potential toxicity to mammals and minimal potential for allergenicity. Thus, adverse effects are not expected due to non-occupational and residential exposure to DGT 28–EPSPS protein. 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 DGT–28 EPSPS protein has been identified as no toxicity or allergenicity has been shown for this protein in the submitted studies. Therefore, EPA has concluded that DGT–28 EPSPS 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

DGT–28 EPSPS 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 DGT–28 EPSPS protein. Therefore, an exemption from the requirement of a tolerance is established for residues of DGT–28 EPSPS 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 inert ingredient in corn.

B. Analytical Enforcement Methodology

Validated enzyme linked immunosorbent assays (ELISAs) are available analytical methods for detection of DGT–28 EPSPS protein. These ELISAs have been demonstrated to reliably detect the levels of protein in the tissues of corn.

C. Conclusion

Therefore, an exemption from the requirement of a tolerance is established for residues of the *Streptomyces sviceus* DGT–28 EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) protein in or on the food and feed commodities of corn: corn, field; corn, sweet; and corn, pop when used as an inert ingredient in a plant-incorporated protectant (PIP) in corn.

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 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 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: December 5, 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 § 174.550 to subpart W to read as follows:

§ 174.550 Streptomyces sviceus DGT–28 EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) protein; exemption from the requirement of a tolerance.

Residues of *Streptomyces sviceus* DGT–28 EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) 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 an inert ingredient in a plant-incorporated protectant in corn.

[FR Doc. 2024–29362 Filed 12–12–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–OLEM–2024–0068; FRL–11724–02–OLEM]

National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (''CERCLA'' or ''the Act''), as amended, requires that the National Oil and Hazardous Substances Pollution Contingency Plan (''NCP'') include a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants or contaminants throughout the United States. The National Priorities List (''NPL'') constitutes this list. The NPL is intended primarily to guide the Environmental Protection Agency (''the EPA'' or ''the agency'') in determining which sites warrant further investigation. These further investigations will allow the EPA to assess the nature and extent of public health and environmental risks