(2) February 3, 2025 through February 28, 2025: No transit restrictions required due to lack of anticipated vessel traffic.

(3) March 3, 2025 through March 28, 2025: 8 a.m. though 4 p.m. each Monday through Friday.

(4) March 31, 2025 through Jul 11, 2025: 7 a.m. each Tuesday through 7 a.m. each Thursday.

(e) If the COTP determines this section need not be enforced during these times on a given day, marine broadcast notices to mariners will be used to announce the specific periods when this section will not be subject to enforcement. For information on radio stations broadcasting BNMs, see 33 CFR 72.01–25 and check the latest Local Notice to Mariners (LNM) for Coast Guard District 9 on *https://www.navcen.uscg.gov.*

Dated: February 19, 2025.

J.P. Hickey,

Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District

[FR Doc. 2025–03021 Filed 2–24–25; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2022–0988; FRL–12514–01–OCSPP]

Bacillus Thuringiensis Cry1B.34 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 *Bacillus thuringienisis* Cry1B.34 protein (hereafter Cry1B.34 protein) in or on the food and feed commodities of corn, field; corn, sweet; and corn, pop when used as a Plant-Incorporated Protectant (PIP). 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 Cry1B.34 protein.

DATES: This regulation is effective February 25, 2025. Objections and requests for hearings must be received on or before April 28, 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–2022–0988, is available online at *https://www.regulations.gov.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is 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).

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. 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. 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 EPA, you must identify docket ID number EPA–HQ–OPP–2022–0988, 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 April 28, 2025. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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.*

II. Background and Statutory Findings

In the **Federal Register** of February 23, 2023 (88 FR 11401 (FRL–10579–01–OCSPP)), 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 by Pioneer Hi-Bred International, Inc., requesting that 40 CFR part 174 be amended by establishing an exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis* Cry1B.34 protein in maize. That document incorrectly noted the petition number as PP 2F29001 and the address of Pioneer as 8325 NW 62nd Avenue, Johnston, IA 50131. The correct petition number is PP 2F9001, and the correct address is 7100 NW 62nd Avenue, P.O. Box 1000, Johnston, Iowa 50131. 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.* One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit III.C.

III. Final Rule

A. EPA's Safety Determination

Section 408(c)(2)(A)(i) of the 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 things, ''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 Cry1B.34 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, Cry1B.34, and the Genetic Material Necessary (PHP79620) for its Production in Event DP910521 maize (OECD Unique Identifier: DP–91Ø521–2), and in Support of a Permanent Tolerance Exemption for Residues of this Protein 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–2022–0988.

Cry1B.34 is a modified protein derived from the bacterium *Bacillus thuringiensis* (Bt) and, when expressed in corn plants, provides protection against feeding damage caused by certain susceptible lepidopteran insect pests. Cry1B.34 is a chimeric protein comprising sequences from the Bt *cry*1B-class, *cry*1Ca1, and *cry*9Db1 genes. The Agency used a ''weight of evidence'' approach and determined that, Cry1B.34 protein represents a negligible risk to humans that consume Cry1B.34 maize products. Although there may be dietary exposure to residues of Cry1B.34 protein, such exposure presents no concern for adverse effects. Submitted data showed that no adverse toxic effects were observed in acute oral toxicity studies conducted with Cry1B.34 protein in mice. Additionally, a bioinformatics analysis found that Cry1B.34 protein does not exhibit homology to any known mammalian toxins. Likewise, the potential for allergenicity is low because: (1) the Cry1B.34 protein is a novel protein that was derived via biotechnology from the encoding genes of three other proteins. The bacterial source of those proteins is *Bacillus thuringiensis,* which has a long history of safe use, including use as a pesticide, and is not considered to be a source of allergenic proteins; (2) bioinformatic analysis indicates no similarity between Cry1B.34 protein and any known allergens; (3) Cry1B.34 protein is rapidly digested when exposed to gastric proteases; (4) Cry1B.34 protein shows loss of function under high temperatures (≥75 °C), indicating that it is heat labile and will likely denature in the course of normal thermal treatment during food preparation; and (5) Cry1B.34 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 Cry1B.34 protein is dietary through consumption of food products made from corn containing the protein. However, such exposure is expected to be very low given the very low level of expression of Cry1B.34 protein in grain (7.7 nanograms (ng)/milligrams (mg) dry weight). Oral exposure to the Cry1B.34 protein via drinking water specifically is considered unlikely. When a plant dies or a part is removed from the living plant, microorganisms colonize the tissue immediately and begin to degrade it. Microorganisms utilize the plant components, including any residues of Cry1B.34 that are the subject of the tolerance exemption, as building blocks for their own metabolisms. This biodegradation is expected to occur in rapid fashion and is likely to preclude residues of Cry1B.34, which is already present only at low levels within the whole corn plant (320ng/mg dry weight), from persisting in the environment long enough to reach the drinking water supply. Importantly, in the unlikely event that Cry1B.34 does enter drinking water, exposure to this protein would not be expected to result in a human health risk based on the lack of toxicity and minimal potential for allergenicity.

The Cry1B.34 protein is not proposed for use in residential settings; therefore, EPA does not expect much, if any, residential exposures. The most likely non-dietary, non-occupational route of exposure is through the inhalation of corn pollen; however, since corn pollen is typically many sizes greater than respirable particles, it is unlikely that people living in residential areas around commercial corn fields will inhale corn pollen containing the Cry1B.34 protein. Even if inhalation of dust-like particles were to occur, the protein is contained within plant cells, which essentially eliminates the likelihood of any actual exposure to the protein itself. 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 Cry1B.34 protein has been identified as no toxicity or allergenicity has been shown for this protein in the submitted studies. Therefore, EPA has concluded that Cry1B.34 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 Cry1B.34 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 Cry1B.34 protein. Therefore, an exemption from the requirement of a tolerance is established for residues of Cry1B.34 protein in or on the food and feed commodities of 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 method was submitted for an enzyme-linked immunosorbent assay (ELISA) to detect the presence of Cry1B.34 protein in extracts from different plant parts. The submitted ELISA methodology was determined to be a valid method of detecting Cry1B.34 protein in the tissues of corn.

C. Response to Comment

One comment was received during the public comment period for the notice of filing. The commentor provided general objections to EPA establishing exemptions from the requirement of a tolerance for pesticides but did not provide any specific or substantive objections to the petition to exempt the Cry1B.34 protein. Based on its review of the data and other information submitted in support of the tolerance exemption petition (as described above in Unit III.A), EPA has determined that a tolerance exemption for Cry1B.34 protein is safe under the FFDCA. Therefore, EPA is establishing an exemption from the requirement of a tolerance for residues of Cry1B.34 protein in or on the feed and food commodities of corn.

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.*

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 (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 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 174

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

Dated: February 11, 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 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 § 174.553 to subpart W to read as follows:

§ 174.553 *Bacillus thuringiensis* Cry1B.34 protein; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1B.34 protein in or on the food and feed commodities of corn, field; corn, sweet; and corn, pop are exempt from the requirement when used as a plant-incorporated protectant in corn.

[FR Doc. 2025–02997 Filed 2–24–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0572; FRL–12526–01–OCSPP]

Bacillus Thuringiensis Strain EX 297512 in Pesticide Formulations; 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 *Bacillus thuringiensis* strain EX 297512, when used as an inert ingredient (diluent and/or carrier) in pesticide formulations applied for seed treatment purposes. BASF Corporation, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *B. thuringiensis* strain EX 297512, when used in accordance with the terms of this exemption.

DATES: This regulation is effective February 25, 2025. Objections and requests for hearings must be received on or before April 28, 2025 and must be