



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA-HQ-OPP-2020-0546; FRL-11674-01-OCSP]

***Bacillus Thuringensis* Cry1B.868 and Cry1Da_7 Proteins; 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 thuringensis* Cry1B.868 and Cry1Da_7 proteins (hereafter Cry1B.868 and Cry1Da_7) 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. Bayer U.S. – Crop Science 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.868 and Cry1Da_7 proteins.

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-2020-0546, is available at <https://www.regulations.gov>. 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.

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(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-2020-0546 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*]**.

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-2020-0546, 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>.

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 December 23, 2020 (85 FR 83880) (FRL-10017-71), 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 0F8839) by Bayer Crop Science LP, 800 N. Lindbergh Blvd., St. Louis, Missouri 63167. The petition requested that 40 CFR part 174 be amended by establishing an exemption from the requirement of a

tolerance for residues of Cry1B.868 and Cry1Da_7 proteins derived from *Bacillus thuringiensis* when used as a PIP in or on the following food and feed commodities: corn, field; corn, sweet; and corn, pop. That document referenced a summary of the petition prepared by the petitioner Bayer U.S. – Crop Science, which is available in the docket at <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 Cry1B.868 and Cry1Da_7 proteins 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 “Review of the Application for a FIFRA Section 3 Seed Increase Registration of MON 95379 Corn Expressing Transgenic Insecticidal Plant-Incorporated Protectants *Bacillus thuringiensis* Cry1B.868 and Cry1Da_7 Proteins and associated FFDC Petition to Establish a Permanent Exemption from the Requirement of a Tolerance for Residues of Cry1B.868 and Cry1Da_7 Proteins when used as Plant-Incorporated Protectants in Food and Feed Commodities of 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-2020-0546.

Cry1Da_7 and Cry1B.868 are modified proteins derived from the bacterium *Bacillus thuringiensis* (*Bt*) and are active against lepidopteran pests of corn. Available data demonstrated that, with regard to humans, Cry1B.868 and Cry1Da_7 proteins are not toxic or allergenic via any route of exposure. The most likely route of exposure is dietary, via products produced from corn expressing the Cry1B.868 and Cry1Da_7 proteins. Oral exposure from ingestion of drinking water is unlikely because the Cry1Da_7 and Cry1B.868 proteins are 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. Further, if Cry1Da_7 and Cry1B.868 proteins do enter the water column, they are expected to degrade rapidly through natural processes. Although there may be dietary exposure to residues of Cry1B.868 and Cry1Da_7 proteins, such exposure presents no concern for adverse effects. Submitted data show that the Cry1B.868 and Cry1Da_7 proteins are not toxic via the oral route of exposure. Likewise, the potential for allergenicity is low because: (1) bioinformatic analysis indicates little similarity between

Cry1B.868 and Cry1Da_7 proteins and known allergens; (2) Cry1B.868 and Cry1Da_7 proteins degrade rapidly when digested or exposed to heat; and (3) Cry1B.868 and Cry1Da_7 proteins are not glycosylated, which further reduces their 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. In addition, pesticidal applications of *Bt* and its insecticidal proteins, including PIPs, have been safely used as commercial biological pesticides for over 50 years. The domain structure and the mode-of-action for Cry1B.868 and Cry1Da_7 proteins are similar to other *Bt* Cry insecticidal proteins that have been safely used in agriculture.

Non-dietary occupational or residential exposure via inhalation is not likely since Cry1B.868 and Cry1Da_7 proteins are contained within plant cells, and corn pollen is not respirable nor is it present in commercial corn products. Exposure via the skin may be possible via 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 Cry1B.868 and Cry1Da_7 proteins have little or no potential toxicity or allergenicity. 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.868 and Cry1Da_7 proteins have been identified as no toxicity or allergenicity has been shown for these proteins in the submitted studies. Therefore, EPA has concluded that Cry1B.868 and Cry1Da_7 proteins do 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.868 and Cry1Da_7 proteins. 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.868 and Cry1Da_7 proteins. Therefore, an exemption from the requirement of a tolerance is established for residues of Cry1B.868 and Cry1Da_7 proteins 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, Enzyme-Linked Immunosorbent Assays (ELISA) were submitted for the detection of Cry1B.868 and Cry1Da_7 proteins. These assays have been demonstrated to reliably detect the levels of the Cry1B.868 and Cry1Da_7 proteins in the tissues 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.*, 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 FFDCFA section 408(d), such as the exemption from the requirement of a 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 FFDCFA 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: May 10, 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 § 174.546 to subpart W to read as follows:

§174.546 *Bacillus thuringiensis* Cry1B.868 and Cry1Da_7 proteins; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1B.868 and Cry1Da_7 proteins 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.

