



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA-HQ-OPP-2018-0403; FRL-10015-98]

***Bacillus Thuringiensis* Cry1Ab/Cry2Aj Protein and G10-evo Enolpyruvylshikimate-3-Phosphate Synthase (G10evo-EPSPS) Protein; Exemptions from the Requirement of a Tolerance**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of the insecticide *Bacillus thuringiensis* Cry1Ab/Cry2Aj protein in or on the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop, and for residues of the inert ingredient G10-evo Enolpyruvylshikimate-3-phosphate synthase (G10evo-EPSPS) protein in or on the food and feed commodities of all crops when used in a plant-incorporated protectant. Hangzhou Ruifeng Biosciences Co., Ltd. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting exemptions from the requirement of a tolerance for these pesticide chemical residues. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus thuringiensis* Cry1Ab/Cry2Aj and G10evo-EPSPS 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-2018-0403, is available at <http://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 is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; 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 Government Publishing Office's e-CFR site at <http://www.ecfr.gov/cgi-bin/text->

idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCFA 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-2018-0403 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-2018-0403, by one of the following methods:

- *Federal eRulemaking Portal:* <http://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 <http://www.epa.gov/dockets/contacts.html>.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to

provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

II. Background and Statutory Findings

In the *Federal Register* of December 21, 2018 (83 FR 65660) (FRL-9985-67) and March 18, 2019 (84 FR 9735) (FRL-9989-90), EPA issued documents pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide tolerance petitions (PP 8E8669 and IN-11257) by Hangzhou Ruifeng Biosciences Co., Ltd., 1500 Wenyi Rd., Building 1, Room 103, Hangzhou, China (c/o GA Bannon Consulting LLC, 13 Blue Flag Court, Dardenne Prairie, MO 63368). Petition 8E8669 requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis* fusion protein Cry1Ab/Cry2Aj 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; Petition IN-11257 requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Deinococcus radiodurans* 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein in or on all food commodities when used as an inert ingredient in a plant-incorporated protectant. The documents referenced a summary of each petition prepared by the petitioner Hangzhou Ruifeng Biosciences Co., Ltd., which are available in the docket, <http://www.regulations.gov>. One comment was received on the notice of filing that published on December 21, 2018. EPA's response to this comment is discussed in Unit VII.B of the document titled "Federal Food, Drug, and Cosmetic Act (FFDCA) Safety Determination for Cry1Ab/Cry2Aj and G10evo-EPSPS Proteins" available in the docket.

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.”

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of these actions and considered their validity, completeness and reliability, and 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 “Final Human Health Risk Assessment and Review of Product Characterization of the Insecticidal Plant-Incorporated Protectant *Bacillus thuringiensis* Cry1Ab/Cry2Aj, a G10evo-EPSPS Herbicide Tolerance Protein, and the Genetic Material Necessary for their Production in ShuangKang 12-5 Maize and Establishment of a Permanent Tolerance Exemption.” This document, as well as other relevant information, is available in the docket for this action EPA-HQ-OPP-2018-0403.

The *Bacillus thuringiensis* Cry1Ab/Cry2Aj fusion protein is an active ingredient produced within the plant to confer protection against lepidopteran pests. The *Deinococcus*

radiodurans 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein (hereafter referred to by its common name “G10evo-EPSPS”) protein is an inert ingredient used as a selectable marker that is produced in the plant and confers tolerance to the herbicide glyphosate. The available data demonstrated that, with regard to humans, the Cry1Ab/Cry2Aj fusion protein and G10evo-EPSPS are not toxic or allergenic via any anticipated route of exposure. Dietary exposure is the most relevant route of exposure, and the Agency concludes that dietary exposure would present no harm because of the lack of toxicity or allergenicity of either protein. In addition, both proteins are contained within plant cells, which essentially eliminates the dermal and inhalation exposure routes or reduces them to negligible levels. EPA also determined that a Food Quality Protection Act (FQPA) safety factor was not necessary as part of the qualitative assessment conducted for Cry1Ab/Cry2Aj and G10evo-EPSPS, due to the low risk of these ingredients. These findings are discussed in more detail in the document titled “Federal Food, Drug, and Cosmetic Act (FFDCA) Safety Determination for Cry1Ab/Cry2Aj and G10evo-EPSPS Proteins.” Based upon its evaluation in the Federal Food, Drug, and Cosmetic Act (FFDCA) Safety Determination for Cry1Ab/Cry2Aj and G10evo-EPSPS Proteins, 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 Cry1Ab/Cry2Aj and G10evo-EPSPS. Therefore, exemptions from the requirement of a tolerance are established for residues of the *Bacillus thuringiensis* Cry1Ab/Cry2Aj fusion 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, and for residues of G10-evo EPSPS protein in or on the food and feed commodities of all crops when used as an inert ingredient in a plant-incorporated protectant.

B. Analytical Enforcement Methodology

The petitioner submitted Enzyme-Linked Immunosorbent Assays (ELISAs) that detect the G10evo-EPSPS protein and the Cry1Ab/Cry2Aj protein in corn seed, along with a PCR method for use as a Cry1Ab/Cry2Aj screening and confirmation tool. G10evo-EPSPS protein is

detectable via a quantitative, “sandwich” ELISA assay using a commercially available kit (YouLong, Catalog # AA1141). Cry1Ab/Cry2Aj protein is detectable by combining a PCR screening method targeting the junction sequence of the cry1Ab/cry2Aj fusion gene followed by an ELISA assay to detect the Cry1Ab protein. The ELISA assay provided is the commercially available QualiPlate Kit for Cry1Ab/Cry1Ac (Envirologix, Catalog # AP-003-CRBS), which is designed to detect the Cry1Ab protein in corn leaf and seed samples.

C. Revisions to the Requested Tolerance Exemption

The following modifications were made to the original requests for an exemption from a tolerance:

1. EPA replaced “40 CFR part 180” with “40 CFR part 174” because PIP tolerance exemptions are published in part 174.
2. Changed the name from “*Bacillus thuringiensis* fusion protein Cry1Ab/Cry2Aj” to “*Bacillus thuringiensis* Cry1Ab/Cry2Aj protein,” to align with nomenclature for other exemptions published in 40 CFR part 174.
3. Changed the name from “*Deinococcus radiodurans* 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein” to “G10evo Enolpyruvylshikimate-3-phosphate synthase (G10evo-EPSPS) protein,” to align with nomenclature for other exemptions published in 40 CFR part 174.

IV. Statutory and Executive Order Reviews

This action establishes exemptions 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), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). 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: November 5, 2020.

Edward Messina,

Acting 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 § 174.542 to read as follows:

§ 174.542 *Bacillus thuringiensis* Cry1Ab/Cry2Aj protein in corn; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1Ab/Cry2Aj protein in or on the food or feed commodities of corn, field; corn, sweet; and corn, pop, are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in corn.

3. Add § 174.543 to read as follows:

§ 174.543 G10evo-EPSPS protein in all plants; exemption from the requirement of a tolerance.

Residues of G10evo-Enolpyruvylshikimate-3-phosphate synthase (G10evo-EPSPS) protein in or on all food or feed commodities, are exempt from the requirement of a tolerance when used as an inert ingredient in a plant-incorporated protectant.

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