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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA-HQ-OPP-2025-0047; FRL-13446-01-OCSPP]

***Bacillus thuringiensis* eCry1Gb.1Ig Protein; Exemption from the Requirement of a Pesticide 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* eCry1Gb.1Ig 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) in corn. Syngenta Seeds, LLC 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 eCry1Gb.1Ig protein under FFDCA when used in accordance with the terms of the exemption.

DATES: This rule is effective on **[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 this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2025-0047, is available online at *https://www.regulations.gov*. Additional information about the docket generally, along with instructions for visiting the docket center in-person, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Shannon Borges, 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. Executive 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:

- 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. *What is EPA's authority for taking this action?*

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(c)(2)(A)(i) 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." FFDCA section 408(c)(2)(A)(ii) 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."

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. 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-2025-0047 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*].**

EPA's Administrative Law Judges Division (ALJD), 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 "Order Urging Electronic Filing and Service," dated December 3, 2025, which can be found at *https://www.epa.gov/system/files/documents/2025-12/2025-12-03-order-urging-electronic-filing-and-service.pdf*. Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, 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*.

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 at *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. If you wish to include CBI in your request, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

II. Petitioned for Exemption

In the ***Federal Register*** of April 7, 2025 (90 FR 14954) (FRL-12474-01-OSCPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a, announcing the filing of a pesticide tolerance petition (PP 4F9142) by Syngenta Seeds, LLC, 9 Davis Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 174 be amended by establishing an exemption from the requirement of a tolerance for residues of the insecticidal PIP *Bacillus thuringiensis* eCry1Gb.1Ig protein and the genetic material (vector pSYN24795) necessary for its production in MZIR260 Corn (SYN-ØØ260Ø-3) in or on corn, field; corn, sweet; and corn, pop. That document referenced a summary of the petition prepared by the petitioner Syngenta Seeds, LLC, which is available in the docket. Two comments were received on the notice of filing. EPA's responses to these comments are discussed in Unit III.C.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is not establishing a new tolerance exemption for residues of the genetic material (vector pSYN24795), because such residues are covered by the existing tolerance exemption at 40 CFR 174.507.

III. Final Tolerance Actions

A. *EPA's safety determination*

EPA evaluated the available toxicological and exposure data for *Bacillus thuringiensis* eCry1Gb.1Ig protein and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. A full explanation 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, eCry1Gb.1Ig, and the Genetic Material Necessary (pSYN24795) for its Production in Event MZIR260 maize (OECD Unique Identifier: SYN-ØØ26Ø-3 and Establishment of a Permanent Tolerance Exemption for Residues of this Protein When Used as a Plant-Incorporated Protectant in Maize." (Human Health Risk Assessment). This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

eCry1Gb.1Ig is a chimeric protein that is composed of three specific domains from insecticidal Cry proteins derived from the soil bacterium *Bacillus thuringiensis* (*Bt*). It is active against fall armyworm, a lepidopteran pest of corn. The mode of action of eCry1Gb.1Ig is equivalent to other Cry proteins, i.e., upon ingestion, insecticidal Cry proteins are proteolytically activated in the insect gut and bound to unique receptors, leading to membrane pore formation in the midgut cells and ultimately insect death. However, eCry1Gb.1Ig is unique, in that it has a different binding receptor on the midgut cell surface than other Cry proteins and therefore confers insecticidal efficacy against traditionally Cry-resistant lepidopterans.

As discussed in the Human Health Risk Assessment, available data demonstrate that, with regard to humans, the eCry1Gb.1Ig protein is unlikely to be toxic to humans and has a low potential for allergenicity. This general conclusion is supported for eCry1Gb.1Ig by acute oral toxicity studies, which showed no toxicity to CD-1 mice after exposure to two oral doses totaling 2,000 mg/kg. Therefore, the protein is unlikely to be toxic to mammals at a level above

maximum possible dietary exposures that are reasonably anticipated from consumption of the crop expressing the PIP. In addition, bioinformatic searches using the amino acid sequence of the protein showed no biologically relevant matches to known toxins. Similarly, data and information provided by the petitioner demonstrated that the likelihood that eCry1Gb.1Ig is a food allergen is minimal. The eCry1Gb.1Ig protein was not found to share amino acid sequence homology with known allergens, was rapidly digested in simulated gastric fluids, did not exhibit resistance to heat treatment, and was not found to be glycosylated. As such, there is no indication that eCry1Gb.1Ig protein would elicit dietary allergic reactions.

Exposure to eCry1Gb.1Ig through the dietary route is expected to occur through ingestion of corn plants expressing the protein. However, exposure to this protein is not expected to result in a human health risk given the lack of oral toxicity and allergenicity as described above. Oral exposure from ingestion of drinking water is unlikely because the eCry1Gb.1Ig protein is expressed within the plant cells, and as such is susceptible to degradation by environmental conditions and microbial activity. In the unlikely event that eCry1Gb.1Ig protein were to enter drinking water, exposure to this protein would not be expected to result in a human health risk given the lack of oral toxicity and allergenicity as described above.

As a PIP, eCry1Gb.1Ig is contained within the plant cells; therefore, non-occupational and residential exposure is considered to be negligible.

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 and allergenicity of eCry1Gb.1Ig protein. As a result, an additional margin of safety for the protection of infants and children is unnecessary.

B. *Analytical enforcement methodology*

An analytical method is not required for eCry1Gb.1Ig protein because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation. However, the petitioner developed an immunoassay method for detection of the eCry1Gb.1Ig

protein in MZIR260 corn tissues.

C. *Response to comments*

EPA received two comments during the public comment period for the notice of filing. Both commenters urged the Agency to assess the long-term effects of *Bt* PIPs and genetically modified plants on human health. In response, EPA notes that pesticides derived from *Bt*, including microbial and PIP applications, have a long history of safe use for over 50 years in agriculture, and no naturally occurring Cry protein from *Bt* has been identified as a known mammalian toxin or allergen to date. Further, the Agency has conducted a comprehensive human health risk assessment for the eCry1Gb.1Ig protein and, as described in this Unit III and in the Human Health Risk Assessment, no adverse effects of concern have been identified.

One commenter also raised concerns about whether approval of eCry1Gb.1Ig would "compromise the precautionary principle that…approvals often move forward before comprehensive, independent studies have fully evaluated the cumulative exposure risks or potential synergistic effects of multiple pesticide residues." EPA follows a well-established risk evaluation process for pesticides (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program). As described in this Unit III and in the Human Health Risk Assessment, EPA does consider cumulative and aggregate exposures, including potential impacts on sensitive subpopulations. Pesticides with dietary exposure must meet the safety standard under section 408 of the FFDCA 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." As described in this Unit III, EPA has determined that the eCry1Gb.1Ig protein meets the FFDCA standard.

The commenter also raised concerns about ecological consequences for pollinators, soil, and water systems. Such considerations are not relevant to the Agency's evaluation of safety under the FFDCA standard, which requires the Agency to evaluate the potential harms to human

health, not effects on the environment. However, ecological risks are evaluated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The ecological risk assessment for the eCry1Gb.1Ig protein is posted in the docket for the FIFRA registration action, docket ID number EPA-HQ-OPP-2025-0048, at https://www.regulations.gov, and it details the Agency's conclusions of a lack of risk of the eCry1Gb.1Ig protein to pollinators and the lack of environmental persistence of the protein in soil and water systems.

D. *Conclusion*

Based upon its evaluation described above and in the Human Health Risk Assessment, which concluded that eCry1Gb.1Ig protein residues in or on corn are not toxic or allergenic to mammals, 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 *Bacillus thuringiensis* eCry1Gb.1Ig protein. Therefore, an exemption from the requirement of a tolerance is established for residues of *Bacillus thuringiensis* eCry1Gb.1Ig 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.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/regulations/and-executive-orders*.

A. *Executive Order 12866: Regulatory Planning and Review*

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 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.

B. *Executive Order 14192: Unleashing Prosperity Through Deregulation*

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions

that establish a tolerance or tolerance exemption under FFDCA section 408 are exempted from review under Executive Order 12866.

C. *Paperwork Reduction Act (PRA)*

This action does not impose an information collection burden under the PRA, 44 U.S.C. 3501 *et seq*., because it does not contain any information collection activities.

D. *Regulatory Flexibility Act (RFA)*

This action is not subject to the RFA, 5 U.S.C. 601 *et seq*. The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule is not subject to the APA but is subject to FFDCA section 408(d), which does not require notice and comment rulemaking to take this action in response to a petition.

E. *Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of $100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local or Tribal governments or the private sector.

F. *Executive Order 13132: Federalism*

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

G. *Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian

Tribes.

H. *Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

However, EPA's 2026 *Policy on Children's Health* applies to this action. This rule finalizes an exemption from the requirement of a tolerance under the FFDCA, which requires 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 . . ." (FFDCA 408(b)(2)(C)). The Agency's consideration is documented in the pesticide-specific review documents, located in the applicable docket at *https://www.regulations.gov*.

I. *Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. *National Technology Transfer Advancement Act (NTTAA)*

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. *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 to 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: August 2, 2026.

Edward Messina

Director, Office of Pesticide Programs.

For the reasons set forth 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.

Subpart W—Tolerances and Tolerance Exemptions

2. Add § 174.560 to Subpart W to read as follows:

§ 174.560 *Bacillus thuringiensis* eCry1Gb.1Ig protein; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* eCry1Gb.1Ig protein in or on the food and 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.

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