starboard side of any vessel greater than 100 feet in length transiting through the regulated navigation area as described in paragraph (a) of this section.

(2) Federal, State, or local entities operating in official capacity are excepted from paragraph (d).

(3) In an emergency, the master, pilot, or person directing the movement of the vessel may deviate from this section to the extent necessary to avoid endangering persons, property, or the environment, and shall report the deviation to The United States Coast Guard via VHF channel 16 as soon as possible.

(4) Violations of this rule should be reported to the Captain of the Port Sector Lake Michigan, at (414) 747–7182 or on VHF-Channel 16. Vessels or persons in violation of this rule may be subject to the civil and/or criminal penalties set forth in 46 U.S.C. 70036.

Dated: August 1, 2025.

M.I. Kuperman,

Captain, U.S. Coast Guard, Acting Commander, Great Lakes District.

[FR Doc. 2025–14884 Filed 8–5–25; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2024–0293; FRL–12818–01–OCSPP]

Bacillus thuringiensis Cry1A.2 and Cry1B.2 Proteins; 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 Bacillus thuringiensis Cry1A.2 and Cry1B.2 proteins (hereafter Cry1A.2 and Cry1B.2 proteins) in or on the food and feed commodities of soybean when used as plant-incorporated protectants (PIP) in soybean. Bayer CropScience LP submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting these exemptions. This regulation eliminates the need to establish a maximum permissible level for residues of these pesticides when used in accordance with the terms of the exemption.

DATES: This regulation is effective on August 6, 2025. Objections and requests for hearings must be received on or before October 6, 2025, 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–2024–0293, is available at *http://www.regulations.gov.* Additional information about dockets generally, along with instructions for visiting the docket in person, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Shannon Borges, 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) 566–1400; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

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–2024–0293 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 October 6, 2025.

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 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/EABALJupload.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 August 8, 2024 (89 FR 64842) (FRL–11682–06–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 (PP 3F9096) by Bayer CropScience 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 the plant-incorporated protectants (PIPs) *Bacillus thuringienisis* Cry1A.2 and *Bacillus thuringienisis* Cry1B.2 in or on soybean. That document referenced a summary of the petition prepared by the petitioner Bayer Crop Science LP, which is available in the docket. There was one comment received in response to the notice of filing. EPA's response to this comment is discussed in Unit III.C.

III. Final Tolerance Actions

A. EPA's Safety Determination

EPA evaluated the available toxicity and exposure data on Cry1A.2 and Cry1B.2 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 ''Product Characterization Review and Human Health Risk Assessment of the Insecticidal Plant-Incorporated Protectant Active Ingredients, Cry1A.2 and Cry1B.2, and the Genetic Material Necessary (PV–GMIR527237) for their Production in Event MON 94637 Soybean (OECD Unique Identifier: MON 94637–8), and Establishment of a Permanent Tolerance Exemption for Residues of these Proteins When Used as a Plant Incorporated Protectant in Soybean. Data Were Provided in Support of a FIFRA Section 3 Seed Increase Registration'' (Human Health Risk Assessment). This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

Cry1A.2 is a modified protein derived from the bacterium *Bacillus thuringiensis* (*Bt*) and is active against certain lepidopteran pests of soybean. As discussed in the Human Health Risk Assessment, available data demonstrated that, with regard to humans, the Cry1A.2 protein does not pose a toxic risk to humans and has a low risk of allergenicity.

Cry proteins, such as Cry1A.2, have specific activity limited to certain insect orders due to the alkaline environment found in the insect midgut and the presence of specific receptors in the insect gut to which activated Cry proteins bind. Upon ingestion of the protein by the insect, the Cry protein is proteolytically activated by the alkaline environment, where it binds to membrane receptors in the midgut epithelium and then oligomerizes to form pores in the membrane, resulting in ion imbalance and ultimately death of the insect. Unlike insects, the human gut environment is highly acidic and contains proteases which facilitate protein degradation rather than protein activation. In addition, there are no known equivalent insecticidal Cry protein receptor sites in mammalian species which could be affected. This general expectation is supported for Cry1A.2 by the results of an acute oral toxicity study in which the oral LD_{50} of Cry1A.2 in mice was determined to be greater than 5,000 mg/kg body weight, indicating a lack of toxicity at a level well above maximum possible dietary exposure levels that are reasonably anticipated from consumption of the crop. In addition, a bioinformatics analysis of the primary protein sequence did not identify any significant homologies of the Cry1A.2 protein to known mammalian toxins. Likewise, the potential for allergenicity is low because: (1) the bacterial source of the Cry1A.2 protein, *Bt,* is ubiquitous in the environment, has a long history of safe use in agriculture, and no Cry protein produced by *Bt* is known to be an allergen; (2) bioinformatic analyses indicate no biologically relevant similarity between the Cry1A.2 protein and any known allergens; (3) the Cry1A.2 protein degrades rapidly when exposed to digestive enzymes (gastric proteases) present in the human gastrointestinal tract; (4) the Cry1A.2 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) the Cry1A.2 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 route of exposure to this plant-incorporated protectant is dietary, via consumption of products produced from soybean expressing the Cry1A.2 protein. Oral exposure from ingestion of drinking water is unlikely because the Cry1A.2 protein is present within the plant cells, and as such they are susceptible to degradation by environmental conditions and microbial activity. In the unlikely event that Cry1A.2 protein were to enter drinking water, exposure to this protein would not expect to result in a human health risk given the lack of toxicity and allergenicity as described above.

The Cry1A.2 protein is not proposed for use in any residential settings and as a plant-incorporated protectant, Cry1A.2 is contained within the plant cells and as such, non-occupational and residential exposure is considered to be negligible. The human health safety findings summarized above are discussed in more detail in the Human Health Risk Assessment. Cry1B.2 is also derived from the bacterium *Bt* and is active against certain lepidopteran pests of soybean. Available data demonstrated that, with regard to humans, the Cry1B.2 protein does not pose a toxic risk to humans and has a low risk of allergenicity. Like Cry1A.2, Cry1B.2 is a Cry protein with activity specific to certain insect orders through a midgut receptor-mediated mode of action. As described above, effects to humans are not expected since humans lack *Bt* receptors and the gut conditions necessary to activate Cry proteins. This general expectation is supported for Cry1B.2 by the results of an acute oral toxicity study in which the oral LD_{50} of Cry1B.2 in mice was determined to be greater than 5,000 mg/kg body weight, indicating a lack of toxicity at a level well above maximum possible exposure levels that are reasonably anticipated for the crop. In addition, a bioinformatics

analysis of the primary protein sequence did not identify any significant homologies of the Cry1B.2 protein to known mammalian toxins. Likewise, the potential for allergenicity is low because: (1) the bacterial source of the Cry1B.2 protein, *Bt,* is ubiquitous in the environment has a long history of safe use, including use as a pesticide, and no Cry protein produced by *Bt* is known to be an allergen; (2) bioinformatic analyses indicate no biologically relevant similarity between the Cry1B.2 protein and any known allergens; (3) the Cry1B.2 protein degrades rapidly when exposed to digestive enzymes (gastric proteases) present in the human gastrointestinal tract; (4) the Cry1B.2 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) the Cry1B.2 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 route of exposure to this plant-incorporated protectant is dietary, via products produced from soybean expressing the protein. Oral exposure from ingestion of drinking water is unlikely because the Cry1B.2 protein is present within the plant cells, and as such they are susceptible to degradation by environmental conditions and microbial activity. In the unlikely event that Cry1B.2 protein were to enter drinking water, exposure to this protein would not expect to result in a human health risk given the lack of toxicity and allergenicity as described above.

The Cry1A.2 protein is not proposed for use in any residential settings and as a plant-incorporated protectant, Cry1B.2 is contained within the plant cells and as such, non-occupational and residential exposure is considered to be negligible. The human health safety findings summarized above 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 the Cry1A.2 protein has been identified as no toxicity or allergenicity has been shown for this protein in the submitted studies. Therefore, EPA has concluded that the Cry1A.2 protein does not have a common mechanism of toxicity with other substances. Similarly, no risk of cumulative toxicity or effects from the Cry1B.2 protein has been identified as no toxicity or allergenicity has been shown for this protein in the submitted studies. Therefore, EPA has concluded that the Cry1B.2 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 the Cry1A.2 protein. Because there are no threshold levels of concern to infants, children, and adults, EPA concludes that no additional margin of safety is necessary to protect infants and children. Similarly, EPA has determined that there are no such effects due to the lack of toxicity of the Cry1B.2 protein. Because there are no threshold levels of concern to infants, children, and adults, EPA concludes that no additional margin of safety is necessary to protect infants and children.

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 Cry1A.2 protein derived from the bacterium *Bacillus thuringiensis* (*Bt*). Therefore, an exemption from the requirement of a tolerance is established for residues of the Cry1A.2 protein in or on the food and feed commodities of soybean when used as a plant-incorporated protectant in soybean. Similarly, 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 Cry1B.2 protein derived from the bacterium *Bacillus thuringiensis* (*Bt*). Therefore, an exemption from the requirement of a tolerance is established for residues of the Cry1B.2 protein in or on the food and feed commodities of soybean when used as a plant-incorporated protectant in soybean.

B. Analytical Enforcement Methodology

EPA has determined that analytical methods are not required for enforcement purposes since the there is no need to monitor residues due to a lack of safety concerns. Nonetheless, a method was submitted for an enzyme-linked immunosorbent assay (ELISA) to detect the presence of Cry1A.2 and Cry1B.2 proteins in flower, forage, and grain tissues and could serve as the analytical method for these PIPs.

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 tolerances for pesticides but did not provide any specific or substantive objections to the petition for tolerance exemptions of the Cry1A.2 and Cry1B.2 proteins. 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 Cry1A.2 and Cry1B.2 proteins, when used as plant-incorporated protectants, is safe under the FFDCA. Therefore, EPA is establishing an exemption from the requirement of a tolerance for residues of Cry1A.2 and Cry1B.2 proteins in or on the food and feed commodities of soybean.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-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 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 2021 *Policy on Children's Health* applies to this action. This rule finalizes tolerance actions 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 the 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: July 29, 2025.

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. 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 §§ 174.554 and 174.555 to subpart W to read as follows:

§ 174.554 *Bacillus thuringiensis* Cry1A.2 protein; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1A.2 protein in or on the food and feed commodities of soybean are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in soybean.

§ 174.555 *Bacillus thuringiensis* Cry1B.2 protein; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1B.2 protein in or on the food and feed commodities of soybean are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in soybean.

[FR Doc. 2025–14887 Filed 8–5–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2024–0426; FRL–12782–01–OCSPP]

Ethyl Formate; 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 ethyl formate in or on citrus (10–10), kiwifruit (fuzzy and hardy), and table grapes when used as a fumigant in accordance with label directions and good agricultural practices. VPTox LLC, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) on behalf of Draslovka Services Pty Ltd, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ethyl formate in or on citrus, crop group 10–10; kiwifruit, fuzzy; kiwifruit, hardy, and grape, table in accordance with the terms of the exemption.

DATES: This regulation is effective August 6, 2025. Objections and requests for hearings must be received on or before October 6, 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–2024–0426, is available at *https://www.regulations.gov.* Additional information about dockets generally, along with instructions for visiting the docket in person, is available at *https://www.epa.gov/dockets.*