



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 174

[EPA-HQ-OPP-2025-0089; EPA-HQ-OPP-2025-0099; EPA-HQ-OPP-2025-0100; FRL-13294-01-OCSP]

### *Bacillus thuringiensis* Cry1B.34.1, *Bacillus thuringiensis* Cry1B.61.1 and *Adiantum trapeziforme* var. *braziliense* IPD083Cb Proteins; Pesticide Tolerances

**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* Cry1B.34.1, *Bacillus thuringiensis* Cry1B.61.1, and *Adiantum trapeziforme* var. *braziliense* IPD083Cb proteins (hereafter Cry1B.34.1, Cry1B.61, and IPD083Cb proteins) in or on all food and feed commodities when used as plant-incorporated protectants (PIP). Pioneer Hi-Bred International Inc. (Pioneer) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting exemptions from the requirement of a tolerance. This regulation eliminates the need to establish maximum permissible levels for residues of Cry1B.34.1, Cry1B.61, and IPD083Cb proteins when used in accordance with the terms of the exemption.

**DATES:** This regulation 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 dockets for this action, identified by docket identification (ID) numbers EPA-HQ-OPP-2025-0089, EPA-HQ-OPP-2025-0099, and EPA-HQ-OPP-2025-0100 are available at <https://www.regulations.gov>. Additional information about the docket 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 (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](mailto: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, 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 numbers EPA-HQ-OPP-2025-0089, EPA-HQ-OPP-2025-0099, and EPA-HQ-OPP-2025-0100, 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 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 “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](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 Exemptions**

In the *Federal Register* of September 5, 2025 (90 FR 42896) (FRL-12474-06-OCSP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide tolerance petitions (PP 4F9125, 4F9126, and 4F9127) by Pioneer Hi-Bred International Inc., 7300 NW 62<sup>nd</sup> Avenue, P.O. Box Johnston, Iowa 50131. The petition requested that 40 CFR part 174 be amended by establishing exemptions from the requirement of a tolerance for residues of the *Bacillus thuringiensis* Cry1B.34.1, *Bacillus thuringiensis* Cry1B.61.1, and *Adiantum trapeziforme* var. *braziliense* IPD083Cb proteins in or on all food and feed commodities when used as plant incorporated protectants (PIP). That document referenced a summary of the petitions submitted by the petitioner Pioneer, which is available in the dockets.

One comment was received on the notice of filing. EPA's response to the comment is discussed in Unit III.C.

### **III. Final Tolerance Actions**

#### *A. EPA's Safety Determination*

EPA evaluated the available toxicological and exposure data on the Cry1B.34.1, Cry1B.61.1, and IPD083Cb proteins 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 the 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 (PIP) Active Ingredients Cry1B.34.1, Cry1B.61.1, and IPD083Cb, the PIP Inert Ingredient GM-HRA, and the Genetic Material Necessary (PHP90315 T-DNA) for their Production in Event COR23134 Soybean (OECD Unique Identifier: COR-23134-4)" (Human Health Risk Assessment). This document, as well as other relevant information, are available in the docket for this action as described under ADDRESSES.

Cry1B.34.1 and Cry1B.61.1 are both derived from the bacterium *Bacillus thuringiensis* (*Bt*) and IPD083Cb is derived from *Adiantum trapeziforme* var. *braziliense* (maidenhair fern). All three of these PIPs are intended to provide protection from feeding damage caused by certain lepidopteran insect pests. Similar to other insecticidal crystal proteins derived from *Bt*, the pesticidal mode of action effected by both Cry1B.34.1 and Cry1B.61.1 is pore formation in the midgut of the target pest leading to death. The Cry1B.34.1 protein in soybean was determined to be identical to the Cry1B.34 active ingredient in maize, for which an exemption from tolerance was previously established (40 CFR § 174.553). The three-domain core of Cry1B.34.1 is intact and as such is expected to exhibit the mode of action and activity spectrum of Cry1B.34 in maize. Cry1B.61.1 is a modified Cry1B-class protein with changes introduced into the amino acid sequence to improve effectiveness against the target pests. The IPD083Cb protein is a fern-derived insecticidal protein whose mode of action is expected to be similar to that of the *Bt* Cry

proteins. Characterization of fern-derived IPD proteins found that, while they share no significant sequence homology to Cry proteins, they do exhibit high structural and functional similarity to domains I and II of the tryptic core of three-domain Cry proteins, and the insecticidal activity was found to be specific to lepidopteran pests.

The most likely route of exposure to these plant-incorporated protectants are dietary, via consumption of food plants producing the three PIPs. However, Cry1B.34.1, Cry1B.61.1, and IPD083Cb are expected to be of negligible toxicity and are unlikely to be food allergens. The lack of toxicity is due to: (1) the results of the acute oral toxicity studies, which showed no toxicity to mice after exposure to three oral doses totaling 5000 mg/kg/bw (EPA Toxicity Category IV); and (2) bioinformatic analyses of the proteins that showed none of Cry1B.34.1 and Cry1B.61.1 of IPD083Cb were found to exhibit significant homology to any known mammalian toxins. Likewise, the potential for allergenicity is low because: (1) bioinformatic analyses indicate no biologically relevant similarity between the Cry1B.34.1, Cry1B.61.1, and IPD083Cb proteins and any known allergens; (2) Cry1B.34.1, Cry1B.61.1, and IPD083Cb proteins were fully and rapidly digested when exposed to digestive enzymes (gastric proteases); (3) Cry1B.34.1, Cry1B.61.1, and IPD083Cb proteins behave with a predictable tendency toward protein denaturation and loss of functional activity at elevated temperatures, indicating that they are heat labile and will likely denature in the course of normal thermal treatment during food preparation; and (4) Cry1B.34.1, Cry1B.61.1, and IPD083Cb proteins are not glycosylated. Current scientific knowledge suggests that protein glycosylation may contribute to protein stability and enhance its allergenic potential.

Oral exposure to the Cry1B.34.1, Cry1B.61.1, and IPD083Cb proteins via drinking water is considered unlikely. Cry1B.34.1, Cry1B.61.1, and IPD083Cb are proteins and, as such, they are susceptible to degradation by environmental conditions and microbial activity. Therefore, the expectation is that these proteins would be broken down into their amino acid constituents before they could reach drinking water. However, in the unlikely event that Cry1B.34.1, Cry1B.61.1, or

IPD083Cb are present in drinking water, exposure to these proteins would not be expected to result in a human health risk based on the hazard considerations articulated above.

As plant-incorporated protectants, Cry1B.34.1, Cry1B.61.1, and IPD083Cb are contained within the plant cells. Therefore, non-occupational and residential exposure is considered to be negligible except for oral exposure through consumption of the plant expressing those proteins.

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 Cry1B.34.1, Cry1B.61.1, and IPD083Cb proteins. As a result, an additional margin of safety for the protection of infants and children is unnecessary.

Based upon its evaluation in the Human Health Risk Assessment, which concluded that *Bacillus thuringiensis* Cry1B.34.1, *Bacillus thuringiensis* Cry1B.61.1, and *Adiantum trapeziforme* var. *braziliense* IPD083Cb proteins are not toxic or allergenic to mammals, the 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.34.1, Cry1B.61.1, and IPD083Cb proteins. Therefore, exemptions from the requirement of a tolerance are established for residues of *Bacillus thuringiensis* Cry1B.34.1, *Bacillus thuringiensis* Cry1B.61.1, and *Adiantum trapeziforme* var. *braziliense* IPD083Cb proteins in or on all food and feed commodities when used as plant-incorporated protectants and according to the label and good agricultural practices.

#### B. Analytical Enforcement Methodology

EPA has determined that an analytical method is not required for enforcement purposes for Cry1B.34.1, Cry1B.61.1, and IPD083Cb residues since the Agency is establishing exemptions from the requirement of a tolerance without any numerical limitation. Nonetheless, a valid enzyme-linked immunosorbent assay (ELISA) to detect the presence of Cry1B.34.1, Cry1B.61.1, and IPD083Cb proteins in extracts from different plant parts were submitted with

the petitions. The submitted ELISA methodology was determined to be a reliable method of detecting Cry1B.34.1, Cry1B.61.1, and IPD083C proteins in the tissues of soybean.

### *C. Response to Comments*

One comment was received during the public comment period for the notice of filing. The commentor urged the prohibition of PIPs and “manipulated nucleic acids (MNAs)” citing potential health and environmental impacts due to the gene flow (integration) of the modified genetic material from PIPs into other organisms, particularly microbes and marine fauna. EPA’s assessments for PIP active ingredients have concluded that there is no evidence that the transfer of PIP genes and/or toxins to microorganisms or other fauna can occur. Furthermore, experiments published in the scientific literature have been unable to detect PIP gene transfer under typical environmental conditions. Regarding the Cry1B.34.1, Cry1B.61.1, and IPD083C proteins, EPA has performed two in-depth assessments to ascertain the overall risk to human health and the environment. As described in Part III.A above, these PIPs are expected to be of negligible mammalian toxicity and are unlikely to be food allergens. Therefore, no adverse effects to human health are expected when Cry1B.34.1, Cry1B.61.1, and IPD083Cb are expressed as a PIP in food and feed commodities. Further, an ecological risk and environmental fate assessment was conducted to determine the risk to terrestrial and aquatic non-target organisms. The results of this assessment determined that the three PIPs are not expected to pose a hazard to any non-target, non-lepidopteran organisms, including non-lepidopteran marine fauna such as fish and invertebrates, due to the proteins’ lack of activity against non-insect species. Furthermore, exposure to these proteins is anticipated to be limited as off-field dispersal of the PIP pollen and post-harvest residues would result in negligible exposures levels of Cry1B.34.1, Cry1B.61.1, and IPD083Cb to marine environments. Therefore, due to a lack of hazard and/or relevant environmental exposure, there is a reasonable expectation of no discernible effects to occur to marine fish or invertebrate species.

### *D. Conclusion*

Therefore, EPA is finalizing the tolerance exemption that was petitioned for by Pioneer (PP 4F9125 2025-0099) (PP 4F9126 2025-0100) (PP 4F9127 2025-0089).

#### **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 tolerance actions under the FFDCFA, 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....” (FFDCFA 408(b)(2)(C)). The Agency's consideration is documented in Unit III.A.

*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: May 26, 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**

**Subpart W—TOLERANCES AND TOLERANCE EXEMPTIONS**

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 § 174.557 to Subpart W to read as follows:

**§174.557 *Bacillus thuringensis* Cry1B.34.1 protein; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance for residues of *Bacillus thuringensis* Cry1B.34.1 protein in or on all food and feed commodities when used as a Plant-Incorporated Protectant in accordance with label directions and good agricultural practices.

3. Add § 174.558 to Subpart W to read as follows:

**§174.558 *Bacillus thuringensis* Cry1B.61.1 protein; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance for residues of *Bacillus thuringensis* Cry1B.61.1 protein, in or on all food and feed commodities when used as a Plant-Incorporated Protectant in accordance with label directions and good agricultural practices.

4. Add § 174.559 to Subpart W to read as follows:

**§174.559 *Adiantum trapeziforme* var. *braziliense* IPD083Cb protein; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance for residues of *Adiantum trapeziforme* var. *braziliense* IPD083Cb protein in or on all food and feed commodities when used as a Plant-Incorporated Protectant in accordance with label directions and good agricultural practices.