



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 174

[EPA-HQ-OPP-2019-0097; FRL-10008-72]

### ***Bacillus thuringiensis* Cry14Ab-1 Protein in Soybean; 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 thuringiensis* Cry14Ab-1 protein (hereafter referred to as Cry14Ab-1) in or on soybean when used as a Plant-Incorporated Protectant (PIP). BASF Corporation 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 Cry14Ab-1.

**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-2019-0097, 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:** Robert McNally, 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](mailto: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](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 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. 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-2019-0097 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-2019-0097, 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>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Background**

In the **Federal Register** of June 28, 2019 (84 FR 30976) (FRL-9995-27), 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 8F8722) by BASF Corporation, 26 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 plant-incorporated protectant Cry14Ab-1 protein in soybean. That document referenced a summary of the petition prepared by the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

A temporary exemption from the requirement of a tolerance (40 CFR 174.538) was previously granted (82 FR 57137) for Cry14Ab-1 protein in soybean as part of an Experimental Use Permit (EPA Registration Number 264-EUP-151). This temporary exemption expired on April 1, 2020.

## **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 Cry14Ab-1 and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. A summary of the data upon which EPA relied and its risk assessment based on those data can be found within the document entitled “Federal Food, Drug, and Cosmetic Act (FFDCa) Safety Determination for Cry14Ab-1 Protein” (Safety Determination). This document, as well as other relevant information, is available in the docket for this action EPA-HQ-OPP-2019-0097.

The available data demonstrated that, with regard to humans, Cry14Ab-1 is not toxic or allergenic via any route of exposure. Although there may be some exposure to residues when Cry14Ab-1 is used in soybeans as a plant-incorporated protectant, exposure to such residues presents no concern for adverse effects. Non-dietary exposure via inhalation is not likely since Cry14Ab-1 is contained within plant cells, which essentially eliminates this exposure route or reduces it to negligible levels. Non-dietary exposure via the skin is somewhat more likely via

contact with soybean products which might have been processed in a way that disrupts cellular structure. However, there are no risks associated with this exposure route to the Cry14Ab-1 protein itself, because it would be present in the plant at low levels, and is not toxic or allergenic. EPA also determined that a Food Quality Protection Act (FQPA) safety factor was not necessary as part of the qualitative assessment conducted for Cry14Ab-1, due to the low risk of this pesticide. These findings are discussed in more detail in the Safety Determination.

Based upon its evaluation in the Safety Determination, 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 Cry14Ab-1. Therefore, an exemption from the requirement of a tolerance is established for residues of Cry14Ab-1 in or on soybeans when used in accordance with label directions and good agricultural practices. In addition, EPA is removing the temporary exemption for Cry14Ab-1 (40 CFR 174.538) that was established for an Experimental Use Permit (EPA Registration Number 264-EUP-151) as that exemption expired on April 1, 2020.

#### *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, an Enzyme-Linked Immunosorbent Assay (ELISA) that detects Cry14Ab-1 protein in soybean seed was submitted by the petitioner as an analytical method. The analytical method is available as a test kit (EnviroLogix QualiPlate™ Cry14Ab ELISA kit number AP 052). An independent laboratory validation of the analytical method showed that the test kit was accurate for the detection of Cry14Ab-1 protein in grain composites containing Cry14Ab-1 soybean grain at 1 in 200 and 1 in 800 levels. Therefore, the limit of

detection for Cry14Ab-1 protein in ground soybean grain was confirmed as one Cry14Ab-1 soybean seed in 800 total seeds.

#### **IV. Statutory and Executive Order Reviews**

This action establishes an exemption from the requirement of a tolerance exemption under FFDCA section 408(d) in response to a petition submitted to EPA. 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, 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 exemption in this action, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (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. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA 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, EPA 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 (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require EPA’s consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (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 14, 2020.

**Richard Keigwin,**

*Director, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 174--[AMENDED]**

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.

**§ 174.538 [Removed]**

2. Remove § 174.538.

3. Add § 174.540 to subpart W to read as follows:

**§174.540 *Bacillus thuringiensis* Cry14Ab-1 protein; exemption from the requirement of a tolerance.**

Residues of *Bacillus thuringiensis* Cry14Ab-1 protein in or on soybean food and feed commodities are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in soybean.

[FR Doc. 2020-11676 Filed: 6/5/2020 8:45 am; Publication Date: 6/8/2020]