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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA-HQ-OPP-2014-0454; FRL-9926-23]

***Bacillus thuringiensis* Cry1A.105 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* (*B.t.*) Cry1A.105 protein in or on soybean when the protein is used as a plant-incorporated protectant (PIP) in soybean. Monsanto Company 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 *B.t.* Cry1A.105 protein in or on soybean.

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-2014-0454, 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.

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 174 through the Government Printing 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 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. 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-2014-0454 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-2014-0454, 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 and Statutory Findings

In the **Federal Register** initially on October 24, 2014 (79 FR 63596) (FRL-9916-03) and then again on December 17, 2014 (79 FR 75111) (FRL-9918-90), 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 4F8275) by Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 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 *B.t.* Cry1A.105 protein in or on all food commodities. That document referenced a summary of the petition prepared by the petitioner Monsanto Company, which is available in the docket, <http://www.regulations.gov>. A comment was received on the October 24, 2014, notice of filing. EPA's response to this comment is discussed in Unit VII.C.

Based on available data, EPA is amending the existing exemption for residues of *B.t.* Cry1A.105 protein to include residues in soybean rather than all food commodities as requested. The reasons for this change are discussed in Unit VII.D.

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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its 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.

The acute oral toxicity data demonstrates the lack of mammalian toxicity at high levels of exposure to the pure *B.t.* Cry1A.105 protein. Further, amino acid sequence comparisons showed no similarities between the *B.t.* Cry1A.105 protein and known toxic proteins in protein databases. In addition, the *B.t.* Cry1A.105 protein was shown to be substantially degraded by heat when examined by immunoassay. This instability to heat would also lessen the potential dietary exposure to intact *B.t.* Cry1A.105 protein in cooked or processed foods. These biochemical features along with the lack of adverse results in the acute oral toxicity test support the conclusion that there is a reasonable certainty no harm from toxicity will result from dietary exposure to residues of the *B.t.* Cry1A.105 protein in the identified soybean commodities.

Since the PIP is a protein, allergenic potential was also considered. Currently, no definitive tests for determining the allergenic potential of novel proteins exist. Therefore, EPA uses a weight-of-evidence approach where the following factors are considered: Source of the trait; amino acid sequence comparison with known allergens; and biochemical properties of the protein, including *in-vitro* digestibility in simulated gastric fluid (SGF) and glycosylation. This approach is consistent with the approach outlined in the Annex to the Codex Alimentarius, “Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants.” The allergenicity assessment for the *B.t.* Cry1A.105 protein follows:

1. *Source of the trait.* *Bacillus thuringiensis* is not considered to be a source of allergenic proteins.

2. *Amino acid sequence.* A comparison of the amino acid sequence of the *B.t.* Cry1A.105 protein with known allergens showed no significant overall sequence similarity or identity at the level of eight contiguous amino acid residues.

3. *Digestibility.* The *B.t.* Cry1A.105 protein was rapidly digested in less than 30 seconds in simulated mammalian gastric fluid containing pepsin.

4. *Glycosylation.* The *B.t.* Cry1A.105 protein expressed in soybean was shown not to be glycosylated.

5. *Conclusion.* Considering all of the available information, EPA has concluded that the potential for the *B.t.* Cry1A.105 protein to be a food allergen is minimal.

The information on the safety of the pure *B.t.* Cry1A.105 protein provides adequate justification to address possible exposures in all soybean crops.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

The Agency considered available information on the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances. These considerations include dietary exposure under the tolerance exemption and all other exemptions in effect for the *B.t.* Cry1A.105 protein residue, and exposure from non-occupational sources. Oral exposure may occur at very low levels from ingestion of corn and soybean products. With respect to drinking water, since the PIP is integrated into the plant genome and based upon EPA's human health and environmental assessments for *B.t.* Cry1A.105 protein (Refs. 1 and 2), the Agency expects residues in drinking water to be extremely low or non-existent.

Exposure via the skin or inhalation is not likely since the plant-incorporated protectant is contained within plant cells, which essentially eliminates these exposure routes or reduces exposure by these routes to negligible. Exposure to infants and children via residential or lawn use is also not expected because the use sites for the *B.t.* Cry1A.105 protein is agricultural.

V. Cumulative Effects from Substances with a Common Mechanism of Toxicity

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."

Since the *B.t.* Cry1A.105 protein does not act through a toxic mode of action, nor does the *B.t.* Cry1A.105 protein appear to produce a toxic metabolite produced by other substances, the protein does not have a common mechanism of toxicity with other substances; therefore, the requirements of section 408(b)(2)(D)(v) do not apply.

VI. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. This additional margin of exposure (safety) is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Based on the information discussed in Unit III., EPA concludes that there are no threshold effects of concern to infants, children, or adults from exposure to the *B.t.* Cry1A.105 protein. As a result, EPA concludes that no additional margin of exposure (safety) is necessary to protect infants and children and that not adding any additional margin of exposure (safety) will be safe for infants and children.

Therefore, based on the discussion in Unit III. and the supporting documentation, 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 the residues of the *B.t.* Cry1A.105 protein in soybean, when it is used as a plant-incorporated protectant. Such exposure includes all anticipated dietary exposures and all other exposures for which there is reliable information.

VII. Other Considerations

A. Endocrine Disruptors

The pesticidal active ingredient is a protein, derived from a source that is not known to exert an influence on the endocrine system. Therefore, the Agency is not requiring information on the endocrine effects of the plant-incorporated protectant at this time.

B. Analytical Enforcement Methodology

A standard operating procedure for an enzyme-linked Immunosorbent assay for the detection and quantification of the *B.t.* Cry1A.105 protein in soybean tissue has been submitted.

C. Response to Comments

EPA received one comment that is potentially relevant to this petition. The commenter generally opposed approval of the use of a Monsanto “*B.t. pip*,” but did not specify any particular PIP or any particular safety concern. As no specific basis for denying the petition was provided, the comment is not being further considered.

D. Revisions to Petition for Tolerance

Monsanto’s petition requested an exemption for residues of the *B.t. Cry1A.105* protein in or on all food and feed commodities. However, based on the data provided, the Agency can only support a safety finding for residues in or on soybean at this time. Currently, the Agency does not have adequate information for a full range of crops for an exemption for the *B.t. Cry1A.105* protein in or on all food and feed commodities.

VIII. Conclusions

There is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to residues of the *B.t. Cry1A.105* protein in all food and feed commodities of soybean. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed in this unit, no toxicity to mammals has been observed, nor is there any indication of allergenicity potential for the plant-incorporated protectant.

Therefore, an exemption is established for residues of the *B.t. Cry1A.105* protein in or on soybean when the protein is used as a PIP in soybean. In addition, the Agency is removing the existing paragraph (b) contained in section 174.502 because that tolerance has expired.

IX. References

1. U.S. EPA. 2014a. Review of Product Characterization and Human Health Data for Plant-Incorporated Protectant *Bacillus thuringiensis* (*Bt*) Cry2Ab2 and Cry1A.105 Insect Control Protein and the Genetic Material Necessary for Its Production in MON 87751 and the Combined-Trait Insect Protected Soybeans in Support for an Experimental Use Permit, Sec. 3 Registration and Exemptions from the Requirement of a Tolerance. Memorandum from J. Facey, Ph.D. through J. Kough, Ph.D. to K. Haymes, Ph.D., dated December 23, 2014.

2. U.S. EPA. 2014b. Environmental Risk Assessment for the FIFRA Section 3 Seed Increase Registration of the Plant-Incorporated Protectant (PIP), *Bacillus thuringiensis* (*Bt*) Cry1A.105 and Cry2Ab2 Insect Control Proteins and the Genetic Material (PV-GMIR13196) Necessary for Their Production in Event MON 87751 Soybean. Memorandum from I. You, Ph.D. through S. Borges to K. Haymes, Ph.D., dated December 16, 2014.

X. Statutory and Executive Order Reviews

This action establishes an exemption 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). 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 exemption 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).

XI. 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: April 22, 2015.

Jack Housenger,

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. 346a and 371.

2. In § 174.502, revise paragraph (b) to read as follows:

§ 174.502 *Bacillus thuringiensis* Cry1A.105 protein; exemption from the requirement of a tolerance.

* * * * *

(b) Residues of *Bacillus thuringiensis* Cry1A.105 protein in or on soybean are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in the food and feed commodities of soybean.

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