This document is scheduled to be published in the
Federal Register on 08/08/2012 and available online at
http://federalregister.gov/a/2012-19319, and on FDsys.gov

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA-HQ-OPP-2012-0109; FRL-9357-4]

Bacillus thuringiensis eCry3.1Ab Protein in Corn; 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 plant-incorporated protectant (PIP), Bacillus thuringiensis eCry3.1Ab protein in corn, in or on the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop. Syngenta Seeds, Inc., Field Crops NAFTA 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 Bacillus thuringiensis eCry3.1Ab protein in corn.

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-2012-0109, is available either electronically through *http://www.regulations.gov* or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, 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: Mike Mendelsohn**,** Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8715; email address: *mendelsohn.mike@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. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. 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. 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://ecfr.gpoaccess.gov/cgi/t/text/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-2012-0109 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0109, 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

● *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 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.htm*.

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** of April 4, 2012 (77 FR 20337) (FRL-9340-4), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 1F7857) by Syngenta Seeds, Inc., Field Crops NAFTA, P.O. Box 12257, 3054 E. Cornwallis Road, Research Triangle

Park, NC 27709-2257. The petition requested that 40 CFR 174.532 be amended by establishing a permanent exemption from the requirement of a tolerance for residues of Bacillus thuringiensis eCry3.1Ab protein in corn, in or on the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop. This notice referenced a summary of the petition prepared by the petitioner Syngenta Seeds, Inc., Field Crops NAFTA, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

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.

A. Product Characterization

Based on amino acid sequence homology and crystal structures, known Cry proteins have a similar three-dimensional structure comprised of three domains, Domain I, II, and III (Refs. 1, 2, 3, and 4). The toxin portions of Cry proteins are characterized by having five conserved blocks (CB) across their amino acid sequence. These are numbered CB1 to CB5 from the N-terminus to the C-terminus (Ref. 5). The sequences preceding and following these conserved blocks are highly variable and are designated as variable regions V1 to V6. Because Cry proteins share structural similarities, chimeric cry genes can be engineered via the exchange of domains that are homologous between different cry genes.

eCry3.1Ab is an engineered chimera protein, composed of portions of modified Cry3A (mCry3A) protein, a protein derived from the native Cry3A protein from *Bt* subsp. *tenebrionis,* and of the Cry1Ab protein from *Bt thuringiensis* subsp. *kurstaki* HD-

1. The ecry3.1Ab gene (Entrez Accession Number GU327680 NCBI, 2011) (Walters *et al.* 2010) consists of a fusion between the N-terminus (Domain I, Domain II, and a portion of Domain III) of a mcry3A gene and the C-terminus (a portion of Domain III and Variable Region 6) of a cry1Ab gene (Ref. 5). The eCry3.1Ab protein is 654 amino acid residues in size and is approximately 74.8 kilodaltons.

B. Mammalian Toxicity Assessment

Syngenta has submitted acute oral toxicity data demonstrating the lack of mammalian toxicity at high levels of exposure to the pure eCry3.1Ab protein. These data demonstrate the safety of the product at a level well above maximum possible exposure levels that are reasonably anticipated in the crop. Basing this conclusion on acute oral toxicity data without requiring further toxicity testing and residue data is similar to the Agency position regarding toxicity testing and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which this plant-incorporated protectant was derived (see 40 CFR 158.2130(d)(1)(i) and 158.2140(d)(7)). For microbial products, further toxicity testing and residue data are triggered by significant adverse acute effects in studies, such as the mouse oral toxicity study, to verify and quantify the observed adverse effects and clarify the source of these effects (Tiers II & III).

An acute oral toxicity study in mice (MRID No. 477539-01) indicated that eCry3.1Ab is non-toxic. Two groups of 10 male and 10 female mice were orally dosed (via gavage) with 2,000 milligrams/kilograms bodyweight (eCry3.1Ab protein mg/kg bwt) of the eCry3.1AB-0208 test substance, a biochemically and functionally equivalent microbially-produced eCry3.1Ab protein. All treated animals gained weight and had no test material-related clinical signs and no test material-related findings at necropsy. Since

there were no significant differences between the test and control groups related to the oral administration of the eCry3.1AB-0208 test material, the eCry3.1Ab protein does not appear to cause any significant adverse effects at an exposure level of up to 2000 mg/kg bwt, which supports the finding that the eCry3.1Ab protein would be non-toxic to mammals.

When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Ref. 6). Therefore, since no acute effects were shown to be caused by eCry3.1Ab, even at relatively high dose levels, the eCry3.1Ab protein is not considered toxic. Further, amino acid sequence comparisons showed no similarities between the eCry3.1Ab protein and known toxic proteins in protein databases that would raise a safety concern.

C. Allergenicity Assessment

Since eCry3.1Ab is a protein, allergenic sensitivities were considered. Currently, no definitive tests exist for determining the allergenic potential of novel proteins. Therefore, EPA uses a "weight-of-the evidence" approach where the following factors are considered: source of the trait; amino acid sequence similarity with known allergens; prevalence in food; and biochemical properties of the protein, including *in vitro* digestibility in simulated gastric fluid (SGF), and glycosylation (as recommended by CAC, 2003) (Ref. 7). Current scientific knowledge suggests that common food allergens tend to be resistant to degradation by acid and proteases; may be glycosylated; and may be present at high concentrations in the food.

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 eCry3.1Ab with known allergens showed no significant overall sequence similarity or identity at the level of eight contiguous amino acid residues. This is the appropriate level of sensitivity to detect possible IgE epitopes without high false positive rates.

3. *Prevalence in food.* Expression level analysis of eCry.1Ab protein demonstrates that it is present at relatively low levels. The expression has been shown to be in the parts per million range. Thus, dietary exposure is expected to be correspondingly low.

4. *Digestibility.* The eCry3.1Ab protein was rapidly digested in less than 30 seconds in simulated mammalian gastric fluid containing pepsin (pH 1.2) after incubation at 37°C.

5. *Glycosylation.* The eCry3.1Ab protein expressed in corn was shown not to be glycosylated.

6. *Conclusion.* Considering all of the available information, EPA has concluded that the potential for eCry3.1Ab to be a food allergen is minimal.

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 has 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. First, with respect to other related substances, the eCry3.1Ab protein is a chimeric *Bacillus thuringiensis* protein, composed of portions of Cry1Ab and mCry3A proteins, both of which are registered PIPs that were previously assessed as having a lack of mammalian toxicity at high levels of exposure. Exemptions from the requirement of a tolerance already have been established for Cry1Ab in food and mCry3A in maize, see 40 CFR 174.505 and 40 CFR 174.511, respectively. Second, and specific to the eCry3.1Ab protein, EPA has considered dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for the plant-incorporated protectant chemical residue and exposure from non-occupational sources. 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 these exposure routes to negligible. The amino acid similarity assessment included similarity to known aeroallergens. It has been demonstrated that there is no evidence of occupationally related respiratory symptoms, based on a health survey on migrant workers after exposure to *Bt* pesticides (Ref. 8). Exposure via residential or lawn use to infants and children is also not expected because the use sites for the eCry3.1Ab protein are all agricultural for control of insects. Oral exposure, at very low levels, may occur from ingestion of processed corn products and, potentially, drinking water.

However, oral toxicity testing done at a dose of 2 gm/kg showed no adverse effects. Furthermore, the expected dietary exposure from corn is several orders of magnitude lower than the amounts of eCry3.1Ab protein shown to have no toxicity. Therefore, even if negligible aggregate exposure should occur, the Agency concludes that

such exposure would present no harm due to the lack of mammalian toxicity and the rapid digestibility demonstrated for the eCry3.1Ab protein.

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 eCry3.1Ab is not considered toxic, EPA has not found eCry3.1Ab to share a common mechanism of toxicity with any other substances, and eCry3.1Ab does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that eCry3.1Ab does not have a common mechanism of toxicity with other substances. Following from this, therefore, EPA concludes that there are no cumulative effects associated with eCry3.1Ab that need be considered. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

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

The data submitted and cited regarding potential health effects for the eCry3.1Ab protein include the characterization of the expressed eCry3.1Ab protein in corn, as well as the acute oral toxicity, heat stability, and *in vitro* digestibility of the proteins. The results of these studies were used to evaluate human risk, and the validity, completeness, and reliability of the available data from the studies were also considered.

As discussed more fully in Unit III. B. above, the acute oral toxicity data submitted supports the prediction that the eCry3.1Ab protein would be nontoxic to humans. Moreover, eCry3.1Ab showed no sequence similarity to any known toxin. Because of this lack of demonstrated mammalian toxicity, no protein residue chemistry data for eCry3.1Ab were required for a human health effects assessment. Even so, preliminary expression level analysis showed eCry3.1Ab protein is present at relatively low levels. Dietary exposure is expected to be correspondingly low.

Since eCry3.1Ab is a protein, its potential allergenicity is also considered as part of the toxicity assessment. Data considered as part of the allergenicity assessment include that the eCry3.1Ab protein came from *Bacillus thuringiensis* which is not a known allergenic source, showed no sequence similarity to known allergens, was readily degraded by pepsin, and was not glycosylated when expressed in the plant. Therefore, there is a reasonable certainty that eCry3.1Ab protein will not be an allergen.

Considered together, the lack of mammalian toxicity at high levels of exposure to the eCry3.1Ab protein and the minimal potential for that protein to be a food allergen demonstrate the safety of the product at levels well above possible maximum exposure levels anticipated in the crop.

Finally, and specifically in regards to infants and children, FFDCA section 408(b)(2)(C) provides that 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 margin

of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base, unless EPA determines that a different margin of safety will be safe for infants and children.

Based on its review and consideration of all the available information, as discussed in more detail above, the Agency 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 eCry3.1Ab protein and the genetic material necessary for its production in corn. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has also concluded, again for the reasons discussed in more detail above, that there are no threshold effects of concern and, as a result, that an additional margin of safety for infants and children is unnecessary in this instance.

VII. Other Considerations

A. Analytical Enforcement Methodology

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, Syngenta has submitted validation method studies on two qualitative lateral flow strip kits for the analytical detection of eCry3.1Ab protein in corn grain, leaf and seed corn matrices. Results showed the test kits are able to detect eCry3.1Ab protein residues in corn with sufficient accuracy, precision, and sensitivity.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and

agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for establishing a difference tolerance.

The Codex has not established a MRL for *Bacillus thuringiensis* eCry3.1Ab protein in corn.

VIII. Conclusions.

For all the reasons summarized above, 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 plant incorporated protectant (PIP) *Bacillus thuringiensis* eCry3.1Ab protein in corn and the genetic material necessary for its production. Therefore, the current temporary exemption for residues of *Bacillus thuringiensis* eCry3.1Ab protein in corn, in or on the food or feed commodities of corn; corn, field; corn, sweet; and corn, pop, when used as a plant-incorporated protectant is amended in order to remove its expiration date and make it a permanent exemption.

IX. References

1. Nakamura K, Oshie K, Shimizu M, Takada Y, Oeda K, Ohkawa H. 1990. Construction of Chimeric Insecticidal Proteins Between the 130-kDa and 135-kDa Proteins of *Bacillus thuringiensis* subsp. *aizawai* for Analysis of Structure-

Function Relationship. *Agricultural Biological Chemistry.* 54: 715–724.

2. Li J, Carroll J, Ellar DJ. 1991. Crystal Structure of Insecticidal delta-Endotoxin from *Bacillus thuringiensis* at 2.5 A resolution. *Nature.* 353: 815–821.

3. Ge A, Rivers D, Milne R, Dean DH. 1991. Functional Domains of *Bacillus thuringiensis* Insecticidal Crystal Proteins. Refinement of *Heliothis virescens* and *Trichoplusiani* Specificity Domains on Cry1A(c). *Journal of Biological Chemistry.* 266: 17954–17958.

4. Honee G, Convents D, Van Rie J, Jansens S, Peferoen M, Visser B. 1991. The C–Terminal Domain of the Toxic Fragment of a *Bacillus thuringiensis* Crystal Protein Determines Receptor Binding.*Molecular Microbiology.* 5: 2799–2806.

5. Hofte H, Whitley HR. 1989. Insecticidal Crystal Proteins of *Bacillus thuringiensis. Microbiology Review.* 53: 242–255.

6. Sjoblad RD, McClintock JT, Engler R. 1992. Toxicological Considerations for Protein Components of Biological Pesticide Products. *Regulatory Toxicology and Pharmacology.* 15(1): 3–9.

7. CAC. 2003. Alinorm 03/34: Joint FAO/ WHO Food Standard Programme. Codex Alimentarius Commission, Twenty-Fifth Session, 30 July 2003. Rome, Italy. Appendix III: Guideline for Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA Plants; Appendix IV: Annex on Assessment of Possible Allergenicity. Codex Alimentarius Commission, 47–60.

8. Bernstein IL, Bernstein JA, Miller M, Tierzieva S, Bernstein DI., Lummus Z, Selgrade MK, Doerfler DL, Seligy VL. 1999. Immune responses in farm workers

after exposure to *Bacillus thuringiensis* pesticides. *Environmental Health Perspectives.* 107(7):575–82.

X. Statutory and Executive Order Reviews

This final rule establishes a tolerance exemption under section 408(d) of FFDCA 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

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 of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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 30, 2012.

Steven Bradbury,

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: 21 U.S.C. 321(q), 346a and 371.

2. Section 174.532 is revised to read as follows:

§174.532 Bacillus thuringiensis eCry3.1Ab protein in corn; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* eCry3.1Ab protein in corn, in or on the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop are exempt from the requirement of a tolerance when *Bacillus thuringiensis* eCry3.1Ab protein in corn is used as a plant-incorporated protectant.

[FR Doc. 2012-19319 Filed 08/07/2012 at 8:45 am; Publication Date: 08/08/2012]