designated by Wisconsin as Limited Forage Fish aquatic life use.

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[FR Doc. 2011–23817 Filed 9–15–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2009–0609; FRL–8889–2]

Bacillus thuringiensis eCry3.1Ab Protein in Corn; Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends the effective date for a temporary exemption from the requirement of a tolerance 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 in accordance with the terms of Experimental Use Permit (EUP) No. 67979–EUP–8. Syngenta Seeds, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting to extend the existing temporary tolerance exemption for *Bacillus thuringiensis* eCry3.1Ab protein in corn that was set to expire on March 1, 2013. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus thuringiensis* eCry3.1Ab protein in corn under the FFDCA. The temporary tolerance exemption now expires on December 31, 2013.

DATES: This regulation is effective September 16, 2011. Objections and requests for hearings must be received on or before November 15, 2011, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0609. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

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; e-mail 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(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–2009–0609 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 November 15, 2011. 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–2009–0609, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of June 8, 2011 (76 FR 33183) (FRL–8874–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 1G7868) by Syngenta Seeds, Inc., P.O. Box 12257, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 174 be amended by extending the effective date of an existing temporary exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis* eCry3.1Ab protein in corn. This notice referenced a summary of the petition prepared by the petitioner, Syngenta Seeds, Inc., which is available in the docket via

http://www.regulations.gov. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit VII.C.

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 section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance exemption 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, section 408(b)(2)(D) of FFDCA requires that EPA 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 section 408(b)(2)(D) of FFDCA, 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 Overview

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.

Syngenta Seeds, Inc. developed Event 5307 maize (*Zea mays*) through *Agrobacterium*-mediated transformation (via plasmid vector PV–ZMIR245) to express eCry3.1Ab protein for use as a plant-incorporated protectant (PIP). This proposed PIP is a chimeric *Bacillus thuringiensis* protein, composed of portions of Cry1Ab and modified Cry3A proteins. The eCry3.1Ab protein was genetically engineered via exchanging the variable regions (V1 to V6) between the mCry3A and the Cry1Ab proteins for enhanced toxicity against western corn rootworm (WCR, *Diabrotica virgifera*). The eCry3.1Ab protein consists of a fusion between the N-terminus (Domain I, Domain II, and a portion of Domain III) of mCry3A and the C-terminus (a portion of Domain III and variable region 6) of Cry1Ab. The eCry3.1Ab protein is 654 amino acid residues in size and is approximately 73.7 kilodaltons.

B. Mammalian Toxicity and Allergenicity Assessment

Syngenta Seeds, Inc. 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 EPA's position regarding toxicity testing and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which this PIP 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 (Master Record Identification Number (MRID No.) 477539–01) indicated that eCry3.1Ab is nontoxic. Two groups of 10 male and 10 female mice were orally dosed (via gavage) with 2,000 milligrams/kilograms bodyweight (mg/kg bwt) (eCry3.1Ab protein mg/kg bwt) of the eCry3.1Ab–0208 test substance, the microbial-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 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 2,000 mg/kg bwt and supports the finding that the eCry3.1Ab protein would be nontoxic 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.

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, see Ref. 7). Current scientific knowledge suggests that common food allergens tend to be resistant to degradation by acid and proteases; may be glycosylated; and 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.* Preliminary expression level analysis shows that the eCry.1Ab protein is present at relatively low levels. Dietary exposure is expected to be correspondingly low. Expression

in Event 5307 leaf is 35 parts per million (ppm); root is 6 ppm; and pollen is 0.15 ppm. Thus, the expression has been shown to be in the parts per million range.

4. *Digestibility.* The eCry3.1Ab protein was rapidly digested in simulated mammalian gastric fluid containing pepsin at a pH of 1.2 at 37 °C. The estimated degradation rate (DT_{50}) is less than 1 minute for eCry3.1Ab protein.

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 Exposure

In examining aggregate exposure, section 408 of FFDCA 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).

EPA 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 have been established for Cry1Ab in food and mCry3A in maize (see 40 CFR 174.511 and 40 CFR 174.505, respectively). Second, and specific to the eCry3.1Ab protein, these considerations include dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for the PIP chemical residue and exposure from non-occupational sources. Exposure via the skin or inhalation is not likely since the PIP is contained within plant cells, which essentially eliminates these exposure routes or reduces these exposure routes to negligible. The amino acid homology 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 *Bacillus thuringiensis* 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, EPA 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 exemption, EPA 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 *Bacillus thuringiensis* eCry3.1Ab protein in corn to share a common mechanism of toxicity with any other substances, and *Bacillus thuringiensis* eCry3.1Ab protein in corn does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that *Bacillus thuringiensis* eCry3.1Ab protein in corn does not have a common mechanism of toxicity with other substances. Following from this, EPA concludes that there are no cumulative effects associated with eCry3.1Ab that need to 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 Web site at *http://www.epa.gov/pesticides/cumulative*.

VI. Determination of Safety for United States (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 protein. 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., 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.

In addition, since eCry3.1Ab is a protein, its potential allergenicity was 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 database 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 in this unit, 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 Cry3.1Ab 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. EPA has also concluded, again for the reasons discussed in more detail in this unit, 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

EPA has determined that an analytical method is not required for enforcement purposes since it is establishing an exemption from the requirement of a tolerance without any numerical limitation. Nonetheless, a method for extraction and two test strip commercial kits to detect eCry3.1Ab protein via enzyme-linked immunosorbent assay analysis in corn have been submitted.

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. In this context, 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 U.N. 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 departing from the Codex level.

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

C. Response to Comments

One comment was received from an anonymous individual who objected to the use or approval of *Bacillus thuringiensis*-based corn. The individual further stated that the subject Bt corn was toxic and harmful and that animals eating it would be poisoned. No basis was given for these comments. While EPA understands that some individuals are opposed to all pesticide use and/or biotechnology based products, relevant data discussed in this unit did serve as the basis for EPA's conclusion in this instance that there is a reasonable certainty of no harm from residues of *Bacillus thuringiensis* eCry3.1Ab protein in corn.

VIII. Conclusion

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 *Bacillus thuringiensis* eCry3.1Ab protein in corn and the genetic material necessary for its production. Therefore, the 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 in accordance with the terms of Experimental Use Permit (EUP) No. 67979–EUP–8 is modified by extending the expiration date to December 31, 2013.

IX. References

1. 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.
2. 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.
3. 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.
4. 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.
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 modifies a tolerance exemption under section 408(d) of FFDCA 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 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 modified on the basis of a petition under section 408(d) of FFDCA, such as the tolerance 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. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. 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 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) (Pub. L. 104–4).

This action does not involve any technical standards that would require EPA 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: September 8, 2011.

Keith Matthews,

Director, Biopesticides and Pollution Prevention Division, 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. Section 174.532 is revised to read as follows:

§ 174.532 Bacillus thuringiensis eCry3.1Ab protein in corn; temporary 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 temporarily from the requirement of a tolerance when *Bacillus thuringiensis* eCry3.1Ab protein in corn is used as a plant-incorporated protectant in accordance with the terms of Experimental Use Permit 67979–EUP–8. This temporary exemption from the requirement of a tolerance expires on December 31, 2013.

[FR Doc. 2011–23813 Filed 9–15–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0360; FRL–8887–5]

Tetrachlorvinphos; Extension of Time-Limited Interim Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an extension of time-limited interim tolerances for the combined residues of the insecticide tetrachlorvinphos [(Z)-2-chloro-1-(2,4,5-trichlorophenyl) vinyl dimethyl phosphate], including its metabolites, 1-(2,4,5-trichlorophenyl)-ethanol (free and conjugated forms), 2,4,5-trichloroacetophenone, and 1-(2,4,5-trichlorophenyl)-ethanediol, in or on multiple commodities which will be identified later in this document, under the Federal Food, Drug, and Cosmetic Act (FFDCA). The time-limited tolerances expire on March 18, 2013.

DATES: This regulation is effective September 16, 2011. Objections and requests for hearings must be received on or before November 15, 2011, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2011–0360. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Carmen Rodia, Registration Division (7504P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0001; *telephone number:* (703) 306–0327; *fax number:* (703) 308–0029; *e-mail address: rodia.carmen@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?

In addition to accessing electronically available documents at *http://www.regulations.gov,* you may access this **Federal Register** document electronically through the EPA Internet under the **Federal Register** listings at *http://www.epa.gov/fedrgstr.* You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr.*

C. How can I file an objection or hearing request?

Under section 408(g) of FFDCA, 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. The EPA procedural