EPA-APPROVED GEORGIA NON-REGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date
* * * * * * *			
29. Chattanooga; Fine Particulate Matter 2002 Base Year Emissions Inventory.	Catoosa and Walker Counties	10/27/09	2/8/12 [Insert citation of publication].

Subpart RR—Tennessee

■ 2. Section 52.2220(e) is amended by adding a new entry for ''Chattanooga; Fine Particulate Matter 2002 Base Year Emissions Inventory'' at the end of the table to read as follows:

§ 52.2220 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED TENNESSEE NON-REGULATORY PROVISIONS

Name of non-regulatory SIP provision	Applicable geographic or non-attainment area	State effective date	EPA approval date	Explanation
* * * * * * *				
Chattanooga; Fine Particulate Matter 2002 Base Year Emissions Inventory.	Hamilton County	10/15/09	2/8/12 [Insert citation of publication].	

[FR Doc. 2012–2731 Filed 2–7–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2007–0573; FRL–9333–7]

Bacillus thuringiensis Cry2Ae Protein in Cotton; 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 *Bacillus thuringiensis* Cry2Ae protein in or on the food and feed commodities of cotton; cotton, undelinted seed; cotton, gin byproducts; cotton, forage; cotton, hay; cotton, hulls; cotton, meal; and cotton, refined oil, when used as a plant-incorporated protectant (PIP) in cotton. Bayer CropScience LP 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* Cry2Ae protein in cotton under the FFDCA.

DATES: This regulation is effective February 8, 2012. Objections and requests for hearings must be received on or before April 9, 2012, 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–2007–0573. 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: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8097; email address: *bacchus.shanaz@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–2007–0573 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 April 9, 2012. 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–2007–0573, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online 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 April 8, 2009 (74 FR 15969) (FRL–8407–6), 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 9F7514) by Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Dr., 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 *Bacillus thuringiensis* Cry2Ae insect control protein and the genetic material necessary for its production in or on all food commodities. This notice referenced a summary of the petition prepared by the petitioner, Bayer CropScience LP, which is available in the docket via *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 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

Bayer CropScience LP (Bayer) developed event GHB119 cotton (*Gossypium hirsutum*) to express *Bacillus thuringiensis* (*Bt*) Cry2Ae insecticidal protein (hereinafter referred to as Cry2Ae protein) for use as a PIP. Event GHB119 cotton was created by *Agrobacterium*-mediated transformation using plasmid pTEM12. This PIP provides event GHB119 cotton protection against feeding damage by lepidopteran insect larvae. The Organisation for Economic Cooperation and Development (OECD) Unique Identifier for event GHB119 is BCS–GH005–8. The *cry2Ae* gene was isolated from *Bt* subspecies *dakota* and its sequence modified for optimal expression in plants. The *cry2Ae* gene used in plasmid pTEM12 encodes Cry2Ae insecticidal crystal protein containing 631 amino acids with a molecular weight of 71 kilodaltons.

Bayer's event GHB119 cotton containing the Cry2Ae protein has been in experimental trials since September 1, 2008. The Cry2Ae protein in this cotton is intended to specifically control the larvae of cotton bollworm (CBW, *Helicoverpa zea),* pink bollworm (PBW, *Pectinophora gossypiella),* tobacco budworm (TBW, *Heliothis virescens),* and fall armyworm (FAW, *Spodoptera frugiperda).*

Event GHB119 cotton also expresses the Phosphinothricin Acetyltransferase (PAT) enzyme, which is exempt from the requirement of a tolerance when used as a PIP inert ingredient in all food commodities (40 CFR 174.522; April 25, 2007; 72 FR 20431; FRL–7742–1). This enzyme confers tolerance of the cotton plants to the herbicide, glufosinate.

B. Toxicological Profile of Bacillus thuringiensis Cry2Ae Protein

1. Acute oral toxicity. The toxicological profile of the protein was previously described in the **Federal Register** of September 10, 2008 (73 FR 52591; FRL–8380–1) to establish the temporary tolerance exemption for Cry2Ae protein residues in/on cotton food/feed commodities when used as a PIP in cotton (40 CFR 174.530). The petitioner has now requested that EPA establish a permanent exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis* Cry2Ae protein in or on all food commodities. However, because the

submitted exposure analysis was based upon the expression of *Bacillus thuringiensis* Cry2Ae protein in cotton only and because no other uses of this protein as a PIP exist in connection with any other food or animal feed commodities, the final tolerance exemption for Cry2Ae protein residues that the Agency is granting varies from what the petitioner sought in as much as it is limited to residues of Cry2Ae protein in/on the cotton food/feed commodities specifically listed in the tolerance exemption regulatory text when Cry2Ae protein is used as a PIP in cotton. Further explanation is provided in Unit VII.C.

Consistent with section 408(b)(2)(D) of the FFDCA, EPA reviewed the available scientific data and other relevant information submitted in support of these actions and considered their validity, completeness and reliability, and the relationship of this information to human risk. The health effects data previously reviewed in support of the temporary tolerance exemption (Ref. 1) and additional data on the PIP in question that was previously evaluated in 2011 (Ref. 2) support the establishment of this permanent tolerance exemption for residues of Cry2Ae protein in/on the specifically noted cotton food/feed commodities when Cry2Ae protein is used as a PIP in cotton. When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Ref. 3.) An acute oral toxicity (Tier I) study in mice indicated that Cry2Ae protein is non-toxic to mammals (Master Record Identification (MRID) 47076902; Ref. 1). The acute oral toxicity of Cry2Ae protein was assessed by administering 2000 milligrams/kilogram (mg/kg) body weight of bacterially produced Cry2Ae protein test substance to five female mice by oral gavage. All treated animals gained weight and had no clinical signs or findings at necropsy related to the test material. The acute oral LD_{50} of the Cry2Ae protein is greater than 2,000 mg/kg body weight. (Refs. 1 and 2). These data demonstrate the safety of Cry2Ae protein at a level well above maximum possible parts per million (ppm) exposure levels that are reasonably anticipated in the cotton food/feed commodities covered by this tolerance exemption. Since no acute effects were shown to be caused by Cry2Ae protein, even at such relatively high dose levels, the Cry2Ae protein is not considered toxic. Furthermore, amino acid sequence comparisons showed no similarities between the Cry2Ae protein and known toxic proteins in protein databases that would raise a safety concern.

For microbial products, Tier II and III toxicity testing and residue data are required to verify and clarify any adverse effects observed during Tier I testing. Based on the lack of acute oral toxicity and the absence of adverse effects in the Tier I acute oral toxicity test in mice, EPA did not require Tier II and Tier III testing or residue data for Cry2Ae protein. This conclusion is similar to the Agency 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)).

2. Allergenicity assessment. Since Cry2Ae 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-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 of the protein as recommended by the *Codex Alimentarius Commission,* 2003 (Ref. 4).

Summary level findings of note from the allergenicity assessment for Cry2Ae protein (see Refs. 1, 2, and 5) include:

i. *Source of the trait. Bacillus thuringiensis,* the microorganism from which Cry2Ae protein is derived, is not considered to be a source of allergenic proteins (MRID 47125101 and 47641912, Refs. 6 and 7).

ii. *Amino acid sequence.* A comparison of the amino acid sequence of Cry2Ae protein with known allergens showed no overall sequence similarity meeting the standards for potential allergenicity (i.e., 35% identity over an 80 amino acid segment, and 100% sequence identity at the level of 8 amino acids, the smallest number of amino acids needed to cause an allergic response (MRIDs 47641908 and 47641909)). These results demonstrated that an individual exposed to the Cry2Ae protein in the diet would not be expected to experience an allergic reaction.

iii. *Prevalence in food.* Food allergens may be present at high concentrations (Ref. 4); however, protein expression level analyses showed that Cry2Ae protein in cotton is expressed at relatively low levels, in the ppm range (MRID 47641903). Furthermore, cotton products comprise only a small part of the human diet. Consequently, dietary exposure to Cry2Ae protein expressed in cotton would be extremely limited.

iv. *Digestibility.* Common food allergens tend to be resistant to degradation by acid and proteases (Ref. 4). The Cry2Ae protein was rapidly digested (within 30 seconds) in SGF containing pepsin at a pH of 1.2 (MRID 47125102). Because it is quickly degraded, dietary exposure to the whole protein is low. Consequently, the potential for sensitivity is low.

v. *Glycosylation.* Current scientific knowledge (Ref. 4) suggests that common food allergens may be glycosylated. The Cry2Ae protein expressed in cotton is not glycosylated (MRIDs 48471901 and 48480006), and so does not share this characteristic of some allergens.

All these preceding characteristics are part of the weight-of-evidence approach to determine that a protein is not expected to be an allergen. Considering all of the available information, EPA has concluded that the potential for Cry2Ae protein to be a food allergen is minimal.

IV. Aggregate Exposures

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).

The Agency considered available information on the aggregate exposure levels of consumers (including major identifiable subgroups of consumers) to the PIP residue and to other related substances. These considerations include dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for the PIP residue, and exposure from non-occupational sources.

As previously discussed (Unit III.), the oral toxicity studies conducted at a dose of 2,000 mg/kg testing showed no adverse effects for Cry2Ae protein, which was also shown to be rapidly digested *in vitro.* As previously stated, when Cry2Ae protein is used as a PIP in cotton, it is expressed at very low levels in the cotton. Although cotton is not a directly consumed food commodity, humans may be exposed to extremely low levels in the diet, potentially from ingestion of processed cotton products (e.g., cottonseed flour and oil). There is also a very remote possibility that Cry2Ae protein can get in the water supply the same way that other proteins in crop debris can

migrate into the ground, and, possibly, drinking water. Because such potential dietary exposure from cotton or drinking water is expected to be several orders of magnitude lower than the amounts of these proteins shown to have no toxicity in mammalian tests, EPA concludes that even negligible exposure via food and drinking water would present no harm, based on the lack of mammalian toxicity and allergenicity potential, and the rapid digestibility demonstrated in SGF for the PIP.

Non-occupational dermal and inhalation exposure is not expected, since the PIP is expressed and contained within cotton plant cells. The uses of this PIP are agricultural, so there would be no exposure to infants and children from residential, school or lawn use. The amino acid sequence homology of known aeroallergens was included in the amino acid comparison of Cry2Ae protein with known food allergens, and the results indicated that no respiratory allergencity would be expected if Cry2Ae protein were inhaled. The amino acid sequence results are discussed in more detail in Unit III.B.2.ii., above. 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. 7). This observation is also relevant to the low potential for non-occupational inhalation exposure at levels far below those expected in occupationally exposed populations.

Taking all these data and information into consideration, EPA concludes that even if negligible aggregate exposure should occur it would present no harm to the U.S. human population.

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.''

EPA has not found *Bacillus thuringiensis* Cry2Ae protein to share a common mechanism of toxicity with any other substances, and *Bacillus thuringiensis* Cry2Ae protein 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* Cry2Ae protein does not have a common mechanism of toxicity with other substances. 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 U.S. Population, Infants and Children

To evaluate human risk, EPA considered the validity, completeness, and reliability of the available data from the studies cited in Unit III. regarding potential health effects for Cry2Ae protein. This evaluation included the low levels of expression of Cry2Ae proteins in cotton, as well as the lack of acute oral toxicity at high dose levels, heat stability, and *in vitro* digestibility of this protein. EPA also considered the minimal potential for allergenicity and the non-toxic source of the protein. Because of this lack of demonstrated mammalian toxicity, no protein residue chemistry data for Cry2Ae protein were required for a human health effects assessment.

Finally, and specifically with 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 Units III. and IV. in this document, EPA concluded 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 the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation. Nonetheless, Bayer has submitted an analytical method using enzyme-linked immunosorbent assay (ELISA) analyses for the qualitative detection of Cry2Ae proteins in cotton seed and cotton leaf. Although validation studies showed the test kit can detect Cry2Ae protein in cotton with sufficient accuracy, precision, and sensitivity, a method validation study conducted by an independent third party laboratory to evaluate the ELISA test kit's performance as the designated analytical method for the detection of Cry2Ae protein residues expressed in event GHB119 cotton is still required.

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* Cry2Ae protein in cotton.

C. Revisions to Petitioned-for Tolerance Exemption

The petitioner requested that EPA establish a permanent exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis* Cry2Ae protein in or on all food commodities. A temporary tolerance exemption was previously granted to Bayer for cotton food/feed commodities in association with an Experimental Use Permit, EPA Reg. No. 264–EUP–143 published on September 10, 2008 (73 FR 52591; FRL–8380–1). That exposure analysis and evaluation of additional data to establish this permanent exemption from tolerance are based upon the expression of *Bacillus thuringiensis* Cry2Ae protein in cotton. No other uses of this protein as a PIP in other food or animal feed commodities exist. As a result, there has been no effort to date to ensure that transformation events in plants other than cotton that express Cry2Ae protein have the same safety characteristics as those described in this evaluation.

Consequently, the final tolerance exemption for Cry2Ae protein residues that the Agency is granting varies from what the petitioner sought in as much as it is limited to residues of Cry2Ae protein in/on certain cotton food/feed commodities when Cry2Ae protein is used as a PIP in cotton.

VIII. Conclusions

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* Cry2Ae protein in cotton food/feed commodities. An exemption from the requirement of a tolerance is therefore established for residues of *Bacillus thuringiensis* Cry2Ae protein in or on the food or feed commodities of cotton; cotton, undelinted seed; cotton, gin byproducts; cotton, forage; cotton, hay; cotton, hulls; cotton, meal; and cotton, refined oil, when used as a PIP in these food and feed commodities.

IX. References

1. U.S. EPA BPPD memorandum (R. Edelstein to S. Bacchus), February 12, 2008.
2. U.S. EPA BPPD memorandum (A. Waggoner to S. Bacchus), November 30, 2011. Review of Product Characterization and Human Health Data in support for Sec. 3 Registration of Plant-Incorporated Protectant (PIP) event GHB119 cotton [EPA File Symbol No. 264–RNOL] expressing *Bacillus thuringiensis* Cry2Ae insecticidal protein and Combination PIP TwinLink® cotton [EPA File Symbol No. 264–RNOA], developed by conventional breeding of its constituent parental events GHB119 x T304–40, expressing *Bt* Cry2Ae and Cry1Ab proteins, respectively.
3. Sjoblad, Roy D. *et al.* (1992) Toxicological Considerations for Protein Components of Biological Pesticide Products *Regulatory Toxicology and Pharmacology* 15: pp. 3–9.
4. CAC. 2003. Alinorm 03/34: Joint FAO/WHO Food Standard Programme. Codex Alimentarius Commission, Twenty-Fifth Session, July 30, 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. *CAC,* pp. 47–60.
5. **Federal Register**. September 10, 2008. (73 FR 52591) (FRL–8380–1). *Bacillus thuringiensis* Cry2Ae in Cotton: Temporary Exemption from the Requirement of a Tolerance.
6. Mendelsohn, M., *et al.* 2003. Are *Bt* Crops Safe? *Nat Biotechnol* 21(9): pp. 1003–1009.
7. Bernstein, I.L., *et al.* 1999. Immune responses in farm workers after exposure to *Bacillus thuringiensis* pesticides. *Environ Health Perspect.* 107(7): pp. 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 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, 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) (Pub. L. 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: January 26, 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: 7 U.S.C. 136–136y; 21 U.S.C. 346a and 371.

■ 2. Section 174.530 is revised to read as follows:

§ 174.530 Bacillus thuringiensis Cry2Ae protein in cotton; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry2Ae protein in or on the food and feed commodities of cotton; cotton, undelinted seed; cotton, gin byproducts; cotton, forage; cotton, hay; cotton, hulls; cotton, meal; and cotton, refined oil, are exempt from the requirement of a tolerance when *Bacillus thuringiensis* Cry2Ae protein is used as a plant-incorporated protectant in cotton.

[FR Doc. 2012–2595 Filed 2–7–12; 8:45 am]

BILLING CODE 6560–50–P