272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 15, 2008. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: June 3, 2008.

Wayne Nastri,

Regional Administrator, Region IX.

■ Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(347)(i)(D) and (c)(350)(i)(B)(*2*) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(347) * * *

(i) * * *

(D) Ventura County Air Pollution Control District.

(*1*) Rule 74.30, Wood Products Coatings, adopted May 17, 1994 and revised on June 27, 2006.

* * * * *

(350) * * *

(i) * * *

(B) * * *

(*2*) Rule 1106, Marine Coating Operations, adopted on August 28, 2006 and amended on October 23, 2006.

* * * * *

[FR Doc. E8–16020 Filed 7–15–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2007–0346; FRL–8369–3]

Bacillus thuringiensis Cry 1A.105 protein; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the *Bacillus thuringiensis* Cry 1A.105 protein in or on corn when used as a plant–incorporated protectant in the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop. Monsanto Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting to amend the existing temporary tolerance in 40 CFR 174.502 for the *Bacillus thuringiensis* Cry 1A.105 protein to establish a permanent exemption from the requirement of a tolerance for residues of the *Bacillus thuringiensis* Cry 1A.105 protein in or on all food commodities when used as a plant-incorporated protectant in all food commodities. This regulation eliminates the need to establish a maximum permissible level for residues of the *Bacillus thuringiensis* Cry 1A.105 insecticidal protein in or on the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop.

DATES: This regulation is effective July 16, 2008. Objections and requests for hearings must be received on or before September 15, 2008, 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–2007–0346. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Susanne Cerrelli, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8077; e-mail address: *cerrelli.susanne@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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket 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 pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2007–0346 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 15, 2008.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2007–0346, by one of the following methods.

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (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'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 August 1, 2007 (72 FR 42075) (FRL–8129–8), 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 6F7142) by Monsanto Company, 800 North Lindbergh Blvd. St. Louis, MO 63167. The petition requested that 40 CFR part 174 be amended by establishing an exemption from the requirement of a tolerance for residues of the *Bacillus thuringiensis* Cry 1A.105 protein in or on all food commodities when used as plant–incorporated protectant in all food commodities. This notice included a summary of the petition prepared by the petitioner Monsanto Company. One commenter objected to the petition, expressing concerns about Monsanto obtaining an exemption from tolerance and potential harmful effects. The Agency understands the commenter's concerns about potential effects of this particular plant-incorporated protectant to humans and the environment. Pursuant to its authority under the FFDCA, EPA conducted a comprehensive assessment of Cry 1A.105 protein, including a review of acute oral toxicity data on Cry 1A.105 protein, amino acid sequence comparisons to known toxins and allergens, as well as data demonstrating that Cry 1A.105 protein is rapidly degraded by gastric fluid *in vitro*, is not glycosylated, and is present at low levels in the tissues expressing the plant-incorporated protectant. Based on these data, the Agency has concluded that there is a reasonable certainty that no harm will result from dietary exposure to residues of Cry1A.105 protein in the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop, when used as a plant-incorporated protectant. Thus, under the standard in FFDCA section 408(b)(2), a tolerance exemption is appropriate. In taking this action, EPA, pursuant to its authority under section 408(d)(4)(A)(i) of the FFDCA, is issuing a final regulation that varies from the regulation sought by Monsanto in its petition. Specifically, instead of issuing a tolerance exemption that covers residues of the subject plant-incorporated protectant in all food commodities, EPA is issuing a tolerance exemption that covers residues of the subject plant-incorporated protectant in those commodities in which it will be used as a plant-incorporated protectant— in this case, the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop. In this way, the tolerance exemption is coextensive with the registered uses for this particular plant-incorporated protectant.

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 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 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 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.

Mammalian Toxicity and Allergenicity Assessment. Monsanto has submitted acute oral toxicity data demonstrating the lack of mammalian toxicity at high levels of exposure to the pure Cry1A.105 protein. These data demonstrate the safety of the product at a level well above maximum possible exposure levels that are reasonably anticipated in corn using submitted Cry1A.105 expression values. 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). 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 the observed adverse effects and clarify the source of these effects (Tiers II & III).

An acute oral toxicity study in mice (MRID 46694603) indicated that Cry1A.105 is non-toxic to humans. The oral LD_{50} for mice was greater than 2,072 milligrams/kiligrams (mg/kg) bodyweight. This dose level is above 2,000 mg/kg, which is above the limit dose (i.e., the highest dose used in acute toxicity testing).

When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Sjoblad, Roy D., *et al.*, ''Toxicological Considerations for Protein Components of Biological Pesticide Products,'' Regulatory Toxicology and Pharmacology 15, 3-9 (1992)). Therefore, since no acute effects were shown to be caused by Cry1A.105, even at relatively high dose levels, the Cry1A.105 protein is not considered toxic. Further, amino acid sequence comparisons between the Cry1A.105 and known toxic proteins in protein databases showed no similarities that would raise a safety concern. In addition, the Cry1A.105 protein was shown to be substantially degraded by heat when examined by immunoassay. This instability to heat would also lessen the potential dietary exposure to intact Cry1A.105 protein in cooked or processed foods. These biochemical features along with the lack of adverse results in the acute oral toxicity test support the conclusion that there is a reasonable certainty no harm from toxicity will result from dietary exposure to residues of Cry1A.105 in or on the identified corn commodities.

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

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

2. *Amino acid sequence.* A comparison of the amino acid sequence of Cry1A.105 with known allergens showed no overall sequence similarity (35% identity over 80 amino acids) or identity at the level of eight contiguous amino acid residues, indicating a lack of potential linear epitopes found in known food allergens.

3. *Digestibility.* The Cry1A.105 protein was digested within 30 seconds in simulated gastric fluid containing pepsin. The rapid degradation of Cry1A.105 in the gastric environment suggests little possible exposure to intact protein in the intestinal lumen where sensitization to food allergens occurs.

4. *Glycosylation.* Cry1A.105 expressed in corn was shown not to be glycosylated.

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

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

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.)

A. Dietary Exposure

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. These considerations include dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for the plant-incorporated protectants 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. In addition, even if exposure can occur through inhalation, the potential for Cry1A.105 to be an allergen is low, as discussed in unit III. Although the allergenicity assessment focuses on potential to be a food allergen, the data (comparing amino acid sequence similarity to allergens, including aeroallergens) also indicate a low potential for Cry1A.105 to be an inhalation allergen. Exposure via residential or lawn use to infants and children is also not expected because the use sites for the Cry1A.105 protein are agricultural. Oral exposure, at very low levels, may occur from ingestion of processed corn products and, theoretically, drinking water. However oral toxicity testing showed no adverse effects.

Food. The data submitted and cited regarding potential health effects for the Cry1A.105 protein includes the characterization of the expressed Cry1A.105 protein in corn, as well as the acute oral toxicity study, amino acid sequence comparisons to known allergens and toxins, 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.

Adequate information was submitted to show that the Cry1A.105 test material derived from microbial culture was biochemically and functionally equivalent to the protein produced by the plant-incorporated protectant ingredient in the plant. Microbially produced protein was used in the studies so that sufficient material for testing was available.

The acute oral toxicity data submitted support the prediction that the Cry1A.105 protein would be non-toxic

to humans. As mentioned in this unit, when proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Sjoblad, Roy D., *et al.*, ''Toxicological Considerations for Protein Components of Biological Pesticide Products,'' Regulatory Toxicology and Pharmacology 15, 3-9 (1992)). Since no treatment-related adverse effects were shown to be caused by the Cry1A.105 protein, even at relatively high dose levels (e.g., 2072 mg/kg body weight), the Cry1A.105 protein is not considered toxic. Basing this conclusion on acute oral toxicity data without requiring further toxicity testing or residue data is similar to the Agency position regarding toxicity and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which this plant-incorporated protectant was derived (See 40 CFR 158.740(b)(2)(i)). For microbial products, further toxicity testing and residue data are triggered when significant adverse effects are seen in studies such as the acute oral toxicity study. Further studies verify the observed adverse effects and clarify the source of these effects (Tiers II and III).

Residue chemistry data were not required for a human health effects assessment of the subject plant-incorporated protectant because of the lack of mammalian toxicity. Nonetheless, data submitted demonstrated low levels of the Cry1A.105 protein in corn tissues (5-7 ppm in grain, 20-570 ppm in forage or leaf tissue), indicating a low potential for dietary exposure.

Since Cry1A.105 is a protein, potential allergenicity is also considered as part of the toxicity assessment. Considering all of the available information:

1. Cry1A.105 originates from a non-allergenic source;

2. Cry1A.105 has no sequence similarities with known allergens;

3. Cry1A.105 is not glycosylated; and

4. Cry1A.105 is rapidly digested in simulated gastric fluid; EPA has concluded that the potential for Cry1A.105 to be a food allergen is minimal.

The genetic material necessary for the production of the plant-incorporated protectant active ingredient include the nucleic acids (DNA, RNA) that encode these proteins and regulatory regions. The genetic material (DNA, RNA) necessary for the production of the Cry1A.105 protein has been exempted from the requirement of a tolerance under 40 CFR 174.507 (Nucleic acids that are part of a plant-incorporated protectant; exemption from the requirement of a tolerance).

B. Other Non-Occupational Exposure

Dermal and Inhalation exposure. 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. In addition, even if exposure can occur through inhalation, the potential for Cry1A.105 to be an allergen is minimal, as discussed in this unit. Although the allergenicity assessment focuses on potential to be a food allergen, the data also indicate a low potential for Cry1A.105 to be an inhalation allergen.

V. Cumulative Effects

Pursuant to FFDCA section 408(b)(2)(D)(v), EPA has considered available information on the cumulative effects of such residues and other substances that have a common mechanism of toxicity. These considerations included the cumulative effects on infants and children of such residues and other substances with a common mechanism of toxicity. Because there is no indication of mammalian toxicity from the plant-incorporated protectant, we conclude that there are no cumulative effects for the Cry1A.105 protein.

VI. Determination of Safety for U.S. Population, 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) also 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. In this instance, based on all the available information, the Agency concludes that there is a finding of no toxicity for the Cry1A.105 protein. Thus, there are no threshold effects of concern and, as a result, the provision requiring an additional tenfold margin of safety does not apply. Further, the considerations of consumption patterns, special susceptibility, and cumulative effects do not apply.

Neither available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers including infants and children) nor safety factors that are generally recognized as appropriate for the use of animal experimentation data were evaluated. The lack of mammalian toxicity at high levels of exposure to the Cry1A.105 protein, as well as the minimal potential to be a food allergen, demonstrate the safety of the product at levels well above possible maximum exposure levels anticipated.

VII. Other Considerations

A. Endocrine Disruptors

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

B. Analytical Method

A standard operating procedure for an enzyme-linked immunosorbent assay for the detection and quantification of Cry1A.105 in corn tissue has been submitted.

C. Codex Maximum Residue Level

No Codex maximum residue level exists for the plant-incorporated protectant *Bacillus thuringiensis* Cry1A.105 protein.

VIII. Conclusions

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

IX. 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,

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 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 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) (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).

X. 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: June 10, 2008.

Janet L. Andersen,

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

■ 2. Section 174.502 to subpart D is revised to read as follows:

§ 174.502 Bacillus thuringiensis Cry 1A.105 protein in corn; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry 1A.105 protein 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 the *Bacillus thuringiensis Cry* 1A.105 protein is used as a plant–incorporated protectant in those food and feed corn commodities.

[FR Doc. E8–15836 Filed 7–15–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2007–1204; FRL–8371–6]

Bacillus thuringiensis Modified Cry1Ab Protein; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the *Bacillus thuringiensis* modified Cry1Ab protein as identified under OECD Unique Identifier SYN–IR67B–1 when used as a plant-incorporated protectant in the food and feed commodities of cotton; cotton, undelinted seed; cotton, refined oil; cotton, meal; cotton, hay; cotton, hulls; cotton, forage; and cotton, gin byproducts. Syngenta Seeds, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), 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* modified Cry1Ab protein as identified under OECD Unique Identifier SYN–IR67B–1 when used as a plant-incorporated protectant in cotton.

DATES: This regulation is effective July 16, 2008. Objections and requests for hearings must be received on or before September 15, 2008, 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–2007–1204. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Alan Reynolds, Biopesticides and