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

Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 605–0515; e-mail address: *reynolds.alan@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 174 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–2007–1204 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–2007–1204, 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 January 30, 2008 (73 FR 5563) (FRL–8348–4), 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 7F7290) by Syngenta Seeds, Inc., P.O. Box 12257, 3054 E. Cornwallis Road, 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* modified Cry1Ab protein containing an additional 26 amino acid sequence (''Geiser Motif'') in all crops and agricultural commodities. A summary of the petition prepared by the petitioner, Syngenta Seeds, Inc., was posted on *www.regulations.gov* in the docket for this action (EPA–HQ–OPP–2007–1204). After review, the Agency determined that the appropriate designation for the protein is *Bacillus thuringiensis* modified Cry1Ab protein as identified under OECD Unique Identifier SYN–IR67B–1 (hereafter referred to as modified Cry1Ab). There was one comment received in response to the notice of filing. The commenter objected to the petition, pesticide residues on food crops, and the widespread use of *Bacillus thuringiensis* (Bt). The Agency understands the commenter's concerns regarding tolerances of pesticide residues on food. Pursuant to its authority under the FFDCA, EPA conducted a comprehensive assessment of modified Cry1Ab protein, including a review of acute oral toxicity data on modified Cry1Ab protein, amino acid sequence comparisons to known toxins and allergens, as well as data demonstrating that modified Cry1Ab protein is rapidly degraded by gastric fluid *in vitro*, is not glycosylated, and is present in low levels in plant tissues. Based on these data, the Agency has concluded that there is a reasonable certainty that no harm will result from dietary exposure to this protein as expressed in plant-incorporated protectants. 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 petitioner Syngenta Seeds, Inc. 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 such residues in those commodities in which it will be used as a plant-incorporated protectant – in this case, 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. 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

Syngenta Seeds, Inc. has submitted acute oral toxicity data demonstrating the lack of mammalian toxicity at high levels of exposure to the pure modified Cry1Ab protein as identified under the Organisation for Economic Co-operation and Development (OECD) Unique Identifier SYN–IR67B–1 (hereafter referred to as modified Cry1Ab). The modified Cry1Ab protein contains a 26 amino acid sequence that is found at the C-terminus of the pro-toxin portion of the modified Cry1Ab protein. This sequence naturally occurs in Cry1Ab protein expressed in microbial *Bacillus thuringiensis* (Bt). The pro-toxin containing the additional 26 amino acid sequence is enzymatically cleaved in the insect gut to produce active Cry1Ab. These toxicity data demonstrate the safety of the product at a level well above maximum possible exposure levels that are reasonably anticipated in the crop. Basing this conclusion on acute oral toxicity data without requiring further toxicity testing and residue data is similar to the Agency position regarding toxicity testing and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which this plant-incorporated protectant was derived (See 40 CFR 158.2140). For microbial products, further toxicity testing (Tiers II and III) and residue data are triggered by significant adverse acute effects in studies such as the acute oral toxicity study, to verify the observed adverse effects and clarify the source of these effects.

An acute oral toxicity study in mice indicated that modified Cry1Ab is non-toxic to humans. Groups of five male and five female mice were given 0 or 1,830 mg/kg bodyweight microbially-produced modified Cry1Ab by oral gavage as a single dose. There were no effects on clinical condition, body weight, food consumption, clinical pathology, organ weight, or macroscopic or microscopic pathology that were attributed to the test substance.

When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Ref. 1). Therefore, since no acute effects were shown to be caused by modified Cry1Ab, even at relatively high dose levels, the modified Cry1Ab protein is not considered toxic.

Since modified Cry1Ab 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 modified Cry1Ab 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 modified Cry1Ab with known allergens showed no significant sequence identity over 80 amino acids or identity at the level of 8 contiguous amino acid residues.

3. *Digestibility.* Modified Cry1Ab was rapidly digested in simulated gastric fluid containing pepsin.

4. *Glycosylation.* Modified Cry1Ab expressed in cotton was shown not to be glycosylated.

5. *Conclusion.* Considering all of the available information, EPA has concluded that the potential for modified Cry1Ab to be a food allergen is minimal.

Although modified Cry1Ab was only shown not to be glycosylated in cotton, it is unlikely to be glycosylated in any other crops because in order for a protein to be glycoslyated, it needs to contain specific recognition sites for the enzymes involved in glycosylation, and the mechanisms of protein glycosylation are similar in different plants (Ref. 2).

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 has considered available information on the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue (i.e., the modified Cry1Ab protein) and to other related substances. These considerations include dietary exposure under the tolerance exemption and all other exposures 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 modified Cry1Ab to be an allergen is low, as discussed above. Although the allergenicity assessment focuses on potential to be a food allergen, the data also indicate a low potential for modified Cry1Ab 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 modified Cry1Ab protein is agricultural. Dietary exposure may occur from ingestion of processed cotton products but is expected to be very low because the already low expression levels in the seed would be reduced further by the heat and pressure used for processing. Also, dietary exposure may theoretically occur

through exposure in drinking water because plant stubble may release modified Cry1Ab protein into ground water upon decay. This protein would not be expected to survive in the soil due to microbial degradation, adherence to soil components and removal upon exposure to drinking water treatment procedures. In addition, oral toxicity testing showed no adverse effects.

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, there is no common mechanism of toxicity for this protein; therefore, section 408(b)(2)(D)(v) does not apply.

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

A. Toxicity and Allergenicity Conclusions

The data submitted and cited regarding potential health effects for the modified Cry1Ab protein includes the characterization of the expressed modified Cry1Ab protein in cotton, as well as the acute oral toxicity study, amino acid sequence comparisons to known allergens, 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 modified Cry1Ab test material derived from microbial culture was biochemically and functionally equivalent to the protein in the plant. Microbially produced protein was used in the safety studies so that sufficient material for testing was available.

The acute oral toxicity data submitted support the prediction that the modified Cry1Ab protein is non-toxic to humans. As mentioned above, when proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Ref. 1). Since no treatment-related adverse effects were shown to be caused by the Cry1Ab protein, even at relatively high dose levels, the modified Cry1Ab protein is not considered toxic. Basing this conclusion on acute oral toxicity data without requiring further toxicity testing and 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 158.2140). 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.

Residue chemistry data were not required for a human health effects assessment of the subject plant-incorporated protectant ingredients because of the lack of mammalian toxicity. However, data submitted demonstrated low levels of the modified Cry1Ab protein in cotton tissues.

Since Cry1Ab is a protein, potential allergenicity is also considered as part of the toxicity assessment. Considering all of the available information (1) modified Cry1Ab originates from a non-allergenic source; (2) modified Cry1Ab has no sequence similarities with known allergens; (3) modified Cry1Ab is not glycosylated; and (4) modified Cry1Ab is rapidly digested in simulated gastric fluid; EPA has concluded that the potential for modified Cry1Ab to be an allergen is minimal.

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 modified Cry1Ab protein, as well as the minimal potential to be an allergen, demonstrate the safety of the product at levels well above possible maximum exposure levels anticipated.

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 modified Cry1Ab 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.

B. Infants and Children Risk Conclusions

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 modified Cry1Ab protein. Thus, there are no threshold effects of concern and, as a result, the provision requiring an additional margin of safety does not apply. Further, the considerations of consumption patterns, special susceptibility, and cumulative effects do not apply.

C. Overall Safety Conclusion

There is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to the modified Cry1Ab protein and the genetic material necessary for its production. 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 above, no toxicity to mammals has been observed, nor any indication of allergenicity potential for the plant-incorporated protectant.

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 this plant-incorporated protectant at this time.

B. Analytical Method(s)

A lateral flow enzyme-linked immunosorbent assay (ELISA) protocol has been provided to the Agency for detecting modified Cry1Ab in cotton.

C. Codex Maximum Residue Level

No Codex maximum residue level exists for the plant-incorporated protectant *Bacillus thuringiensis* modified Cry1Ab protein.

VIII. References

1. Sjoblad, Roy D., *et al.*, ''Toxicological Considerations for

Protein Components of Biological Pesticide Products,'' *Regulatory Toxicology and Pharmacology* 15, 3–9 (1992).

2. Lerouge, P., Cabanes-Macheteau, M., Rayon, C., Fichette-Lainè, A-C., Gomord, V., and Faye, L., ''N-Glycoprotein biosynthesis in plants: recent developments and future trends,'' *Plant Molecular Biology* 38: 31–48 (1998).

IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 26, 2008.

Debra Edwards,

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 174.529 is added to subpart W to read as follows:

§ 174.529 Bacillus thuringiensis modified Cry1Ab protein as identified under OECD Unique Identifier SYN–IR67B–1 in cotton; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* modified Cry1Ab protein as identified under OECD Unique Identifier SYN–IR67B–1 are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in cotton; cotton, undelinted seed; cotton, refined oil; cotton, meal; cotton, hay; cotton, hulls; cotton, forage; and cotton, gin byproducts.

[FR Doc. E8–16277 Filed 7–15–08; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 071106671–8010–02]

RIN 0648–XJ09

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Ocean Perch in the Western Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific ocean perch by catcher processors participating in the limited access or opt-out fisheries that are subject to sideboard limits established under the Central GOA Rockfish Program in the Western Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2008 sideboard limits of Pacific ocean perch established for catcher processors participating in the limited access or opt-out fisheries in the Western Regulatory Area of the GOA.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), July 14, 2008, through 1200 hrs, A.l.t., July 31, 2008.

FOR FURTHER INFORMATION CONTACT: Jennifer Hogan, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2008 Pacific ocean perch sideboard limit established for catcher