which equal 100 percent of total State NPDES program costs.

(2) The maximum share to any State under this subsection shall not exceed 50 percent of the State's previous year's total Section 106 allotment determined under paragraph (b) of this section.

(3) Any funds left remaining after all shares have been allotted under this subsection will be re-allotted to the States under paragraph (b) of this section.

(4) In order for a State to be eligible for this incentive, a State must: be authorized by EPA to implement the NPDES program by the first day of the Federal fiscal year, October 1, for which the funds have been appropriated; and submit to EPA a certification meeting the requirements of paragraph (e)(5) of this section.

(5) The certification required under paragraph (e)(4) of this section must meet the following requirements:

(i) The certification must be submitted annually to EPA (to the attention of the Regional Administrator). For FY 2009, the certification must be postmarked by November, 14, 2008. For every year thereafter the certification must be postmarked by October 1; and

(ii) The certification must include the total NPDES State program costs and the percentage of NPDES program costs, as defined in paragraph (e)(6) of this section, recovered by the State through permit fee collections during the most recently completed State fiscal year, and a statement that the amount of permit fees collected is used by the State to defray NPDES program costs; and

(iii) The certification must include a statement that State recurrent expenditures for water quality programs have not decreased from the previous State fiscal year or indicate that a decrease in such expenditures is attributable to a non-selective reduction of the programs of all executive branch agencies of the State government.

(6) NPDES program costs are defined as all permitting, enforcement, and compliance costs.

[FR Doc. E8–21046 Filed 9–9–08; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2007–0573; FRL–8380–1]

Bacillus thuringiensis Cry2Ae in Cotton; Temporary Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the *Bacillus thuringiensis* Cry2Ae in or on cotton and its food and feed commodities when used as a Plant-Incorporated Protectant (PIP) in accordance with the terms of Experimental Use Permit 264–EUP–143. Bayer CropScience LP submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus thuringiensis* Cry2Ae. The temporary tolerance exemption expires on December 31, 2012.

DATES: This regulation is effective September 10, 2008. Objections and requests for hearings must be received on or before November 10, 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–2007–0573. 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 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; e-mail 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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 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, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural 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–2007–0573 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 November 10, 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–2007–0573, 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 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 August 8, 2007 (72 FR 44521–44523) (FRL–8139–7), 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 7F7192) by Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR be amended by establishing a temporary exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis* Cry2Ae in or on cotton when used as a Plant-Incorporated Protectant (PIP). Bayer has requested an Experimental Use Permit (EUP), EPA File Symbol 264–EUP–143, under which it seeks to use Cry2Ae as a PIP on 1,919 acres of cotton. A summary of the petition prepared by the petitioner was included in the docket. 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 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.

The following toxicological profile is based on summaries of the Agency's reviews of the petitioner's data submissions (Ref. 1).

A. Acute Oral Toxicity

Bayer CropScience has submitted acute oral toxicity data demonstrating the lack of mammalian toxicity at high levels of exposure to the pure Cry2Ae protein. An acute oral toxicity study in mice indicated that Cry2Ae is non-toxic to humans. The acute oral toxicity of Cry2Ae was assessed by administering *Bacillus thuringiensis*-produced Cry2Ae protein by oral gavage at a dose of 2,000 milligrams/kilogram of body weight (mg/kg b.w.) to groups of five female mice. There were no mortalities, and no treatment-related adverse effects observed. Therefore, the acute oral LD_{50} of the Cry2Ae protein is greater than 2,000 mg/kg body weight (Ref. 2).

For microbial products, further toxicity tests and residue data (Tiers II and III) are only required to verify and clarify adverse effects observed during Tier I testing. In the submitted studies for this PIP, no adverse acute effects were observed in the Tier I acute oral or acute injection studies. Therefore, Tier II and Tier III studies were not required. Thus, EPA concluded that these data demonstrate the safety of the product at a level well above maximum possible exposure levels that are reasonably anticipated in the crop. Basing this conclusion on acute oral toxicity data without requiring further toxicity testing and residue data is similar to the Agency position regarding toxicity testing and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which this PIP was derived (See 40 CFR 158.2140).

When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Ref. 3). Therefore, since no acute effects were shown to be caused by Cry2Ae, even at relatively high dose levels, the Cry2Ae protein is not considered toxic. Further, amino acid sequence comparisons showed no similarities between the Cry2Ae and known toxic proteins in protein databases that would raise a safety concern.

B. Cry2Ae Allergenicity Assessment

Since Cry2Ae 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 Cry2Ae is based on the potential of the source of the protein, the similarity of its amino acid sequence to known allergens, its glycosylation and its digestibility. The applicant submitted data to demonstrate that Cry2Ae: (1) Originates from a non-allergenic source (Ref. 4); (2) has no sequence similarities with known

allergens (Ref. 5); (3) is not glycosylated (Ref. 6); and (4) is rapidly digested in simulated gastric fluid (Ref. 7). Thus EPA has concluded that the potential for Cry2Ae to be an allergen is minimal (Ref. 1).

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—Food and Drinking Water

As discussed in Unit III, laboratory tests show that Cry2Ae demonstrates a very low to minimal acute oral toxicity and allergenicity potential. Thus, EPA does not expect any harm to human adults, infants and children exposed to Cry 2Ae via consumption of food commodities related to cotton.

Oral exposure, at very low levels, may occur from ingestion of processed cotton products and, theoretically, drinking water. Based on the lack of adverse effects during the acute oral toxicity study conducted in mice (LD_{50} greater than 2,000 mg/kg), the Agency does not expect any harm via dietary exposure, including exposure to drinking water.

B. Other Non-Occupational Exposure—Dermal and Inhalation

Non-occupational dermal and inhalation exposure is expected to be negligible or non-existent.

Exposure via the skin or inhalation is not likely since the Plant-Incorporated Protectant is contained within plant cells. Thus, exposure and risk via dermal and inhalation routes are essentially negligible or eliminated. In addition, even if exposure can occur through inhalation, the potential for Cry2Ae to be an allergen is low, as discussed above in Unit III. Although the allergenicity assessment focuses on potential to be a food allergen, the data also indicate a low potential for Cry2Ae to be an inhalation allergen. Furthermore, non-occupational dermal and inhalation exposure via residential or lawn use to human adults, infants and children is also not expected because the use sites for the Cry2Ae protein are agricultural.

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 Cry2Ae protein.

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 Cry2Ae protein include the characterization of the expressed Cry2Ae protein in cotton, 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.

The acute oral toxicity data submitted support the prediction that the Cry2Ae protein would be non-toxic to humans. As mentioned above in Unit III no treatment-related adverse effects were shown to be caused by the Cry2Ae protein, even at relatively high dose levels and Tier I studies showed no adverse effects. Thus, Tiers II and III studies were not required and the Cry2Ae protein is not considered toxic.

Since Cry2Ae is a protein, potential allergenicity is also considered as part of the toxicity assessment. Considering all of the available information: (1) Cry2Ae originates from a non-allergenic source; (2) Cry2Ae has no sequence similarities with known allergens; (3) Cry2Ae is not glycosylated; and (4) Cry2Ae is rapidly digested in simulated gastric fluid; EPA has concluded that the potential for Cry2Ae to be an allergen is minimal.

The lack of mammalian toxicity at high levels of exposure to the Cry2Ae 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.

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 Cry2Ae 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 Cry2Ae protein. 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 the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry2Ae protein at this time.

B. Analytical Method(s)

Because this is only a temporary exemption from the requirement of a tolerance, EPA is not requiring an analytical detection method at this time.

C. Codex Maximum Residue Level

No Codex Maximum Residue Level (MRL) exists at this time for the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry2Ae protein.

VIII. References

1. USEPA BPPD memorandum dated February 12, 2008 from Rebecca Edlestein to Shanaz Bacchus.
2. Master Record Identification Number (MRID No.) 47076902, USEPA, BPPD memo 2/12/2008).
3. Sjoblad, Roy D., et al., ''Toxicological Considerations for Protein Components of Biological Pesticide Products,'' *Regulatory Toxicology and Pharmacology* 15, 3–9 (1992).
4. MRID 47125101.
5. MRID 46708903.
6. MRIDs 46708903 and 46708907.
7. MRIDs 46708905 and 47125102.

IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of 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, 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 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: August 25, 2008.

Marty Monell,

Acting 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 added to subpart W to read as follows:

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

Residues of *Bacillus thuringiensis* Cry2Ae protein in or on the food commodities of cotton, cotton; cotton, undelinted seed; cotton, refined oil; cotton, meal; cotton, hay; cotton, hulls; cotton, forage; and cotton, gin byproducts are exempt temporarily from the requirement of a tolerance when *Bacillus thuringiensis* Cry2Ae protein in cotton plants is used as a Plant-Incorporated Protectant in accordance with the terms of Experimental Use Permit 264–EUP–143. This temporary exemption from the requirement of a tolerance will expire on December 31, 2012.

[FR Doc. E8–20728 Filed 9–9–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0507; FRL–8378–8]

Hexythiazox; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the established tolerances for combined residues of hexythiazox in or on citrus dried pulp; citrus oil; pome fruit, crop group 11; wet apple pomace; and meat byproducts of cattle, goat, horse, and sheep. Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 10, 2008. Objections and requests for hearings must be received on or before November 10, 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–2007–0507. 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