Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD, and Department of Homeland Security Management Directive 5100.1 which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. This rule fits the category selected from paragraph (34)(g), as it establishes a safety zone. A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' will be available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.T05–040 to read as follows:

§ 165.T05–040 Safety Zone; Pamlico River, Washington, North Carolina.

(a) *Regulated area.* The safety zone includes all waters of Pamlico River south of the intersection of the Highway 17 Swing Bridge south along the west river bank to latitude 35°32′19″ N, longitude 077°03′40″ W, thence across the river on a line 045 degrees due northeast across the river to the intersection of the east river bank at position 35°32′30″ N, longitude 077°03′25″ W, thence north along the shoreline to the Highway 17 Swing Bridge thence west to the point of origin. All coordinates reference Datum NAD 1983.

(b) *Definitions.* The following definitions apply to this section: (1) *Coast Guard Patrol Commander* means a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the Commander, Coast Guard Sector North Carolina.

(2) *Official Patrol* means any vessel assigned or approved by the Sector Commander, Coast Guard Sector North Carolina with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

(c) *Regulations.* The general regulations governing safety zones, found in 33 CFR 165.23, apply to the safety zone described in paragraph (a) of this section.

(1) Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area.

(2) The operator of any vessel in the regulated area must:

(i) Stop the vessel immediately when directed to do so by any Official Patrol.

(ii) Proceed as directed by any official patrol.

(d) *Enforcement period.* This section will be enforced from 8:30 p.m. to 10 p.m. on June 8 & 9 and July 4, 2007.

Dated: April 24, 2007.

Gregory D. Case,

Commander, U.S. Coast Guard, Captain of the Port, Atlantic Beach, North Carolina.

[FR Doc. E7–8814 Filed 5–8–07; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2006–0913; FRL–8124–6]

Bacillus thuringiensis Vip3Aa19 Protein in Cotton; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an extension of the temporary exemption from the requirement of a tolerance for residues of the *Bacillus thuringiensis* Vip3Aa19 protein in cotton when applied/used as a plant-incorporated protectant (PIP). 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 the temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of the *Bacillus thuringiensis* Vip3Aa19 protein in cotton when applied/used as a PIP on cotton. The temporary tolerance exemption expires on May 1, 2008.

DATES: This regulation is effective May 9, 2007. Objections and requests for hearings must be received on or before July 9, 2007, 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–2006–0913. 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), Office of Pesticide Programs, 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–2006–0913 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 July 9, 2007.

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–2006–0913, 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 12, 2007 (72 FR 1513) (FRL–8105–3), 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 3G6547) by Syngenta Seeds, Inc., P.O. Box 12257, Research Triangle Park, NC 27709. The petition requested that 40 CFR 174.452 be amended by establishing an extension of the temporary exemption from the requirement of a tolerance for residues of the *Bacillus thuringiensis* Vip3A protein when applied/used as a PIP on cotton. This notice included a summary of the petition prepared by the petitioner Syngenta Seeds, Inc. No public comments were received.

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.

Data have been submitted demonstrating a lack of mammalian toxicity at high levels of exposure to the pure (microbially expressed) Vip3Aa19 protein. These data demonstrate the safety of Vip3Aa19 at levels well above maximum possible exposure levels that are reasonably anticipated in the crops. This is similar to the Agency position regarding toxicity and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which this PIP was derived (see 40 CFR 158.740(b)(2)(i)). For microbial products, the need for Tier II and III toxicity testing and residue data to verify the observed effects and clarify the source of these effects is triggered only by significant acute effects in studies such as the mouse oral toxicity study.

In previously submitted Vip3A studies and applications, the designation VIP3A or Vip3A was used to describe the Vip PIP protein and/or test material. In the final rule, it is necessary to distinguish the various Vip3A designations based on the Crickmore *Bacillus thuringiensis* Vip3A nomenclature (see *http://www.lifesci.sussex.ac.uk/Home/Neil_Crickmore/Bt/*). The original Vip3A toxin as expressed in COT102 is now known as Vip3Aa19 toxin according to the Crickmore nomenclature designation. A temporary exemption from the requirement of a tolerance already has been established for the *Bacillus thuringiensis* Vip3A protein and the genetic material necessary for its production in cotton published in the **Federal Register** on April 26, 2006 (71 FR 24582) (FRL–7772–7); (40 CFR 174.452). This temporary exemption from the requirement of a tolerance will be modified to reflect the new Crickmore designation, Vip3Aa19.

An acute oral toxicity study was submitted for the Vip3Aa19 protein. Male and female mice (16 of each) were dosed with 3,675 milligrams/kilograms bodyweight (mg/kg bwt) of Vip3Aa19 protein. All mice survived the study, gained weight, had no test material related clinical signs, and had no test material related findings at necropsy. This acute oral toxicity data supports the prediction that the Vip3Aa19 protein would be non-toxic to humans.

When proteins are toxic, they are known to act via acute mechanisms and at very low-dose levels (Sjoblad, Roy D., et al. 1992). Therefore, since no effects were shown to be caused by the PIPs, even at relatively high-dose levels, the Vip3Aa19 protein is not considered toxic. Amino acid sequence comparisons showed no similarity between the Vip3Aa19 protein and known toxic proteins available in public protein data bases. According to the Codex Alimintarius Commission (Codex) guidelines, the assessment of potential toxicity also includes stability to heat (Joint FAO/WHO Food Standard Programme, Codex Alimentarius Commission, 2003[1]). A heat liability study demonstrated that Vip3Aa19 is inactivated against fall armyworm when heated to 55 °C for 30 minutes.

Since Vip3Aa19 is a protein, allergenic sensitivities were considered. Currently, no definitive tests exist for determining the allergenic potential of novel proteins. Therefore, EPA uses a weight of the evidence approach where the following factors are considered: Source of the trait; amino acid sequence similarity with known allergens; prevalence in food; and biochemical properties of the protein, including *in vitro* digestibility in simulated gastric fluid (SGF), and glycosylation. This approach was described by the Codex guidelines for the conduct of food safety assessment of food derived from recombinant-DNA plants including the assessment of possible allergenicity in 2003 (Joint FAO/WHO Food Standard Programme, Codex Alimentarius Commission, 2003).

Data have been submitted that demonstrate that the Vip3A from recombinant maize (LPPACHA-0199) and *E. coli* (VIP3A-0100) proteins are rapidly degraded by gastric fluid *in vitro*. (VIP3A-0100 refers to a microbially expressed Vip3A that has been shown to be the equivalent of the plant-expressed Vip3A protein.) In a solution of simulated gastric fluid (containing pepsin) and either 80 µL of LPPACHA-0199 or 320 µL of VIP3A-0100 test protein, both were shown to be susceptible to pepsin degradation. These data support the conclusion that Vip3A proteins expressed in transgenic plants will be readily digested as a conventional dietary protein under typical mammalian gastric conditions. Further data demonstrate that Vip3Aa19 is not glycoslylated and a comparison of amino acid sequences of known allergens uncovered no evidence of any homology with Vip3Aa19, even at the level of eight contiguous amino acid residues. These data demonstrated that the mean Vip3Aa19 concentration in cotton seed ranged from ca. 2.51 to 3.23 µg Vip3A/g dry weight. Vip3Aa19 was not detected in cotton fiber or nectar. Analysis of the refined oil and de-fatted meal by Enzyme-Linked Immunosorbent Assay (ELISA) detected Vip3Aa19 protein in COT102 meal, but not in oil. Therefore, based on the data provided for the specific Vip3Aa19 protein, one can conclude that the Vip3Aa19 protein is present in low levels in cotton seed and not detected in cotton fiber.

Therefore, the potential for the Vip3Aa19 protein to be a food allergen is minimal. As noted in Unit III., toxic proteins typically act as acute toxins at low-dose levels. Therefore, since no effects were shown to be caused by this PIP, even at relatively high-dose levels, the Vip3Aa19 protein is not considered toxic.

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 and to other related substances. These considerations include dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for the PIP chemical residue, and exposure from non-occupational sources. Exposure via the skin or inhalation is not likely since the PIP is contained within plant cells, which essentially eliminates these exposure routes or reduces these exposure routes to negligible. The amino acid homology assessment revealed no similarities to known aeroallergens, indicating that Vip3Aa19 has a low potential to be an inhalation allergen. It has been demonstrated that there is no evidence of occupationally related respiratory symptoms, based on a health survey on migrant workers after exposure to *Bacillus thuringiensis* pesticides (Berstein, et al. 1999), which provides further evidence of the negligible respiratory risks of *Bacillus thuringiensis* PIPs. Exposure via residential or lawn use to infants and children is also not expected because the use sites for the Vip3Aa19 protein are all the agricultural for control of insects. Oral exposure, at very low levels, may occur from ingestion of

[1] Alinorm 03/34: Joint FAO/WHO Food Standard Programme, Codex Alimentarius Commission, Twenty-Fifth Session, Rome, Italy 30 June–5 July, 2003. Appendix III, Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants and Appendix IV, Annex on the assessment of possible allergenicity. Rome, Codex Alimentarius Commission, 2003. pp. 47–60.

processed corn products and, theoretically, drinking water.

However, oral toxicity testing done in rats at a dose in excess of 3 gram(g)/kg showed no adverse effects. Furthermore, the expected dietary exposure from cotton is several orders of magnitude lower than the amounts of Vip3Aa19 protein shown to have no toxicity. Therefore, even if negligible aggregate exposure should occur, the Agency concludes that such exposure would present no harm due to the lack of mammalian toxicity and the rapid digestibility demonstrated for the Vip3Aa19 proteins.

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 include 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, the Agency concludes that there are no cumulative effects arising from Vip3Aa19 protein residues in cotton.

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 Vip3Aa19 protein include the characterization of the expressed Vip3Aa19 protein in cotton, as well as the acute oral toxicity, heat stability, and *in vitro* digestibility of the proteins. The results of these studies were determined applicable to evaluate human risk, and the validity, completeness, and reliability of the available data from the studies were considered.

Adequate information was submitted to show that the Vip3A protein test material derived from microbial cultures (designated VIP3A-0100) was biochemically and functionally similar to the Vip3Aa19 protein expressed in cotton. Microbially produced protein was chosen in order to obtain sufficient material for testing.

The acute oral toxicity data submitted supports the prediction that the Vip3Aa19 protein would be non-toxic to humans. As mentioned Unit III., when proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Sjoblad, Roy D., et al. 1992). Since no effects were shown to be caused by Vip3Aa19 protein, even at relatively high dose levels (3,675 mg Vip3Aa19/kg bwt), the Vip3Aa19 protein is not considered toxic. This is similar to the Agency position regarding toxicity and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which this PIP was derived. (See 40 CFR 158.740(b)(2)(i)). Moreover, Vip3Aa19 showed no sequence similarity to any known toxin.

Protein residue chemistry data for Vip3Aa19 were not required for a human health effects assessment of the subject PIP ingredients because of the lack of mammalian toxicity. Expression data demonstrated that mean Vip3Aa19 concentrations in cotton seed ranged from approximately 2.51 to 3.23 µg Vip3Aa19/g dry weight. Vip3Aa19 was not detected in cotton fiber or nectar. Analysis of the refined oil and de-fatted meal by ELISA detected Vip3Aa19 protein in COT102 meal, but not in oil. Therefore, Vip3Aa19 is present in low levels in cotton seed and not detect in cotton fiber.

Since Vip3Aa19 is a protein, its potential allergenicity is also considered as part of the toxicity assessment. Information considered as part of the allergenicity assessment included data demonstrating that the Vip3Aa19 protein came from a *Bacillus thuringiensis* which is not a known allergenic source, showed no sequence similarity to known allergens, was readily degraded by pepsin, and was not glycosylated when expressed in the plant. Therefore, there is a reasonable certainty that the Vip3Aa19 protein will not be an allergen.

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 Vip3Aa19 protein, as well as the minimal potential to be a food allergen, demonstrate the safety of Vip3Aa19 at levels well above possible maximum exposure levels anticipated in the crop.

The genetic material necessary for the production of the PIP active ingredients are the nucleic acids (DNA, RNA) which comprise genetic material encoding these proteins and their regulatory regions. The genetic material (DNA, RNA) necessary for the production of Vip3Aa19 protein already are exempted from the requirement of a tolerance under a blanket exemption for all nucleic acids (40 CFR 174.475).

B. Infants and Children Risk Conclusions

Section 408(b)(2)(C) of FFDCA 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 data base, 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 Vip3Aa19 protein and the genetic material necessary for its production in cotton. Because there are no threshold effects of concern, the Agency has determined that the additional tenfold margin of safety is not necessary to protect infants and children. Further, the provisions 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 to the U.S. population, including infants and children, from aggregate exposure to residues of the Vip3Aa19 protein and the genetic material necessary for its production in cotton, when it is applied/used in accordance with good agricultural practices. 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 previously discussed, no toxicity to mammals has been observed, nor has there been any indication of allergenicity potential for this PIP.

VII. Other Considerations

A. Endocrine Disruptors

The pesticidal active ingredient is a protein, derived from sources that are not known to exert an influence on the endocrine system. Therefore, the Agency is not requiring information on the endocrine effects of the PIP at this time.

B. Analytical Method(s)

A method for extraction and ELISA analysis of the Vip3Aa19 protein in cotton has been submitted and is under review by the Agency. For the temporary tolerance exemption, the ELISA method described with the expression data is sufficient.

C. Codex Maximum Residue Level

No Codex maximum residue levels exist for the PIP *Bacillus thuringiensis* Vip3Aa19 protein and the genetic material necessary for its production in cotton.

VIII. 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 rule has been exempted from review under Executive Order 12866, this 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 6, 2000) do not apply to this rule. In addition, this 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).

IX. 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: April 26, 2007.

W. Michael McDavit,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

[PART 174—AMENDED]

■ 1. The authority citation for part 174 continues to read as follows:

Authority: 7 U.S.C. 136-136y; 21 U.S.C. 346a and 371.

■ 2. Section 174.452 is revised to read as follows:

§ 174.452 Bacillus thuringiensis Vip3Aa19 protein in cotton; temporary exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Vip3Aa19 protein in cotton are temporarily exempt from the requirement of a tolerance when used as a plant-incorporated protectant (PIP) in the food and feed commodities of cotton; vegetative-insecticidal protein in cotton seed, cotton oil, cotton meal, cotton hay, cotton hulls, cotton forage, and cotton gin byproducts. This temporary exemption from the requirement of tolerance will permit the use of the food commodities in this section when treated in accordance with the provisions of the experimental use permit (EUP) 67979–EUP–7, which is being issued in accordance with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136). This temporary exemption from the requirement of a tolerance expires and is revoked May 1, 2008. However, if the EUP is revoked, or if any experience with or scientific data on this pesticide indicate that the temporary tolerance exemption is not safe, this temporary exemption from the requirement of a tolerance may be revoked at any time.

[FR Doc. E7–8951 Filed 5–8–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0965; FRL–8124–2]

Flufenacet; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes pesticide tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA) for combined residues of flufenacet and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety in or on grass (forage, hay), sweet corn (forage, kernel plus cob with husk removed, stover), wheat (bran, forage, grain, hay, straw), cattle kidney, goat kidney, hog kidney, horse kidney, and sheep kidney. Bayer Cropscience petitioned EPA to establish these tolerances.

DATES: This regulation is effective May 9, 2007. Objections and requests for hearings must be received on or before July 9, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also