Port at telephone number 617–223–3008 or via on-scene patrol personnel on VHF channel 16 to seek permission to do so. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port or his or her designated representative.

Dated: July 24, 2008.

Claudia C. Gelzer,

Commander, U.S. Coast Guard, Acting Captain of the Port Boston, Massachusetts.

[FR Doc. E8–18076 Filed 8–5–08; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2007–0830; FRL–8374–2]

Bacillus thuringiensis Vip3Aa Proteins in Corn and Cotton; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the *Bacillus thuringiensis* Vip3Aa proteins in or on the food and feed commodities of corn; corn, field; corn, sweet; corn, pop; and cotton; cotton, undelinted seed; cotton, refined oil; cotton, meal; cotton, hay; cotton, hulls; cotton, forage; and cotton, gin byproducts, when used as plant-incorporated protectants in those food and feed commodities. 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* Vip3Aa proteins in or on corn; corn, field; corn, sweet; corn, pop; and cotton, undelinted seed; cotton, refined oil; cotton, meal; cotton, hay; cotton, hulls; cotton, forage; and cotton, gin byproducts, when applied or used as plant-incorporated protectants.

DATES: This regulation is effective August 6, 2008. Objections and requests for hearings must be received on or before October 6, 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–2007–0830. 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 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–0830 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 October 6, 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–2007–0830, 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 November 2, 2007 (72 FR 62237) (FRL–8153–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 7F7254) by Syngenta Seeds, Inc., P.O. Box 12257, 3054 E. Cornwallis Road, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis* Vip3Aa proteins in or on all food commodities when applied or used as plant-incorporated protectants. This notice included a summary of the petition prepared by the petitioner Syngenta Seeds, Inc. One comment was received in response to the notice of filing. The commenter objected to the petition and expressed concerns about EPA's regulation of human exposure to toxic chemicals. The Agency understands the commenter's concerns regarding toxic substances and the potential effects to humans. Pursuant to its authority under the FFDCA, and as discussed further in this Unit, EPA conducted a comprehensive assessment of representative Vip3Aa proteins, including a review of acute oral toxicity data on several Vip3Aa proteins, amino acid sequence comparisons to known toxins and allergens, as well as data demonstrating that the representative Vip3Aa proteins are rapidly degraded by gastric fluid *in vitro*, are not glycosylated, and are present in low levels in the tissues of the corn and cotton plants containing these plant-incorporated protectants. Based on these data, the Agency has concluded that there is a reasonable certainty that no harm will result from dietary exposure to residues of these proteins in or on the food and feed commodities corn; corn, field; corn, sweet; corn, pop; and cotton, undelinted seed; cotton, refined oil; cotton, meal; cotton, hay; cotton, hulls; cotton, forage; and cotton, gin byproducts, when used as plant-incorporated protectants in those food and feed commodities. 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 corn; corn, field; corn, sweet; corn, pop; and 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 Vip3Aa19 and Vip3Aa20 proteins. These data demonstrate the safety of these particular Vip3Aa proteins at levels well above the maximum possible exposure levels that are reasonably anticipated in cotton (Vip3Aa19) and corn (Vip3Aa20). 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 these plant-incorporated protectants were derived (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 mouse oral toxicity study, to verify the observed adverse effects and clarify the source of these effects.

Syngenta submitted four acute oral toxicity studies conducted on mice. Three of the studies were conducted with microbially-produced Vip3Aa proteins (Vip3Aa1, Vip3Aa19, and Vip3Aa20) with slight variations in amino acid sequence (1-2 amino acid differences), and one study was conducted with transgenic corn leaf tissue expressing Vip3Aa19 as the test material. No treatment-related adverse effects were observed in any of the studies. The results of these studies showed that the oral LD_{50} for mice (males, females, and combined) was greater than 3,675 milligrams/kilogram/body weight (mg/kg/bwt) (the highest dose tested) for the tested Vip3Aa proteins.

When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Sjoblad, Roy D., *et al.*, ''Toxicological Considerations for Protein Components of Biological Pesticide Products,'' Regulatory Toxicology and Pharmacology 15, pages 3–9 (1992)). Therefore, since no acute effects were shown to be caused by the Vip3Aa19 and Vip3Aa20 proteins, even at relatively high dose levels, they are not considered toxic. (This is also true

of the Vip3Aa1 protein that was tested.) Further, amino acid sequence comparisons showed no similarities between Vip3Aa19 and Vip3Aa20, on the one hand, and known toxic proteins in protein databases, on the other hand, that would raise a safety concern.

Since Vip3Aa 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 Vip3Aa follows:

- *Source of the trait. Bacillus thuringiensis*, the microorganism from which Vip3Aa proteins are derived, is not considered to be a source of allergenic proteins.
- *Amino acid sequence.* A comparison of the amino acid sequence of Vip3Aa19 and Vip3Aa20 with known allergens showed no significant sequence identity over 80 amino acids or identity at the level of eight contiguous amino acid residues.
- *Digestibility.* Both Vip3Aa19 and Vip3Aa20 proteins are digested rapidly in simulated gastric fluid containing pepsin.
- *Glycosylation.* Both Vip3Aa19 and Vip3Aa20 were shown not to be glycosylated.

Considering all of the available information on Vip3Aa19 and Vip3Aa20, EPA concludes that the potential for these specific proteins to be food allergens is minimal. Moreover, as further explained below (and in section VI.a. of this final rule), EPA believes these data and the other submitted data demonstrating a lack of mammalian toxicity at high levels of exposure to Vip3Aa19 and Vip3Aa20 can be extrapolated to cover Vip3Aa more generally.

Vip3Aa is the designation assigned to a closely-related group of similar insecticidal proteins isolated from *Bacillus thuringiensis*. The specific variants referred to throughout this document (i.e., Vip3Aa19 and Vip3Aa20) are isolates of Vip3Aa protein. All Vip3Aa proteins (there are 25 known Vip3Aa proteins and there are sequences available for 19 of these) are highly related. Indeed, the amino acid sequence of all the Vip3Aa proteins can only vary up to 5% to be considered a part of the Vip3Aa group. With respect to the 19 Vip3Aa proteins for which sequences are available, they vary by less than 28 amino acids out of the 789 amino acids that make up the protein. This level of sequence similarity makes that group of 19 Vip3Aa protein variants 96% identical overall. The sequence identity between any two individual sequences is even higher. For example, the sequences of the protein variants tested by Syngenta (i.e., Vip3Aa19 and Vip3Aa20) are over 99.7% identical. Finally, as to the few amino acid differences that do exist between the Vip3Aa variants, these differences do not alter the surrounding sequence, rarely occur as contiguous amino acids, and are often substitutions with similar chemical side groups indicating similar chemical functionality. Therefore, EPA finds that none of the Vip3Aa variants would be expected to have significant amino acid sequence identity — which is defined as either 35% identity over an 80 amino acid stretch and, for allergens, at the level of eight contiguous amino acids — with a toxin, an anti-nutrient or an allergen.

This conclusion is further supported by EPA's overall safety assessment that includes other considerations such as the source of the trait, digestibility and glycosylation. As noted in this Unit, *Bacillus thuringiensis* (from which the Vip3Aa proteins are derived) is not considered to be a source of allergenic proteins. Furthermore, since all the Vip3Aa proteins have extremely homogenous structural similarities (as explained in this Unit), they are highly likely to show similar biochemical characteristics in terms of digestibility and glycosylation. So, as is the case for both Vip3Aa19 and Vip3Aa20, EPA expects that all Vip3Aa proteins will be rapidly digested under simulated gastric conditions and will not be glycosylated. Finally, it is also highly relevant here that microbial pesticide products, which are distinct from plant-incorporated protectant pesticide products, containing *Bacillus thuringiensis* and its components (which could include microbially-expressed Vip3Aa proteins) are already exempt from the requirement for a tolerance under 40 CFR 180.1011.

Accordingly, EPA believes that the foregoing supports EPA's reasonable certainty of no harm finding not only for the Vip3Aa19 and Vip3Aa20 protein variants, but also for all other closely-related members of the Vip3Aa designation as described using the Crickmore classification system (Crickmore, N., Zeigler, D.R., Schnepf, E., Van Rie, J., Lereclus, D., Baum, J, Bravo, A. and Dean, D.H. ''*Bacillus thuringiensis* toxin Nomenclature'' (2007) *http://www.lifesci.sussex.ac.uk/Home/Neil_Crickmore/Bt/)*.

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 Vip3Aa proteins) and to other related substances. These considerations include dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for the plant-incorporated protectant's chemical residue, and exposure from non-occupational sources. Exposure via the skin or inhalation is not likely since the plant-incorporated protectant is contained within plant cells, which essentially eliminates these exposure routes or reduces these exposure routes to negligible. In addition, even if exposure can occur through inhalation, the potential for Vip3Aa to be an allergen is low, as discussed in this Unit. Although the allergenicity assessment focuses on potential to be a food allergen, the data also indicate a low potential for Vip3Aa to be an inhalation allergen. Exposure via residential or lawn use to infants and children is also not expected because the use sites for Vip3Aa proteins are agricultural. Oral exposure, at very low levels, may occur from ingestion of food commodities containing Vip3Aa protein residues and, theoretically, drinking water. However oral toxicity testing (as discussed above) 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 residues of representative Vip3Aa proteins 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 resulting from exposure to Vip3Aa proteins, we conclude that there are no cumulative effects for the Vip3Aa proteins.

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

1. *Toxicity and allergenicity conclusions*. The data submitted and cited regarding potential health effects for Vip3Aa proteins includes the characterization of representative Vip3Aa proteins, as well as the acute oral toxicity studies, amino acid sequence comparisons to known allergens and toxins, and *in vitro* digestibility of the representative Vip3Aa proteins. The results of these studies were used to evaluate humansk, and the validity, completeness, and reliability of the available data from the studies were also considered.

Adequate information was submitted to show that the Vip3Aa test materials derived from microbial cultures were biochemically and functionally equivalent to the proteins produced by the plant-incorporated protectant ingredient in the plants. Microbially produced proteins were used in the studies so that sufficient material for testing was available.

The acute oral toxicity data submitted for the representative Vip3Aa proteins support the prediction that Vip3Aa proteins will be 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 (Sjoblad, Roy D., *et al.*, ''Toxicological Considerations for Protein Components of Biological Pesticide Products,'' Regulatory Toxicology and Pharmacology 15, pages 3–9 (1992)). Since no treatment-related adverse effects were shown to be caused by the representative Vip3Aa proteins, even at relatively high dose levels, Vip3Aa proteins are not considered toxic. Basing this conclusion on acute oral toxicity data without requiring further toxicity testing or residue data is similar to the Agency position regarding toxicity and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which this plant-incorporated protectant was derived (see 40 CFR 158.2140). For microbial products, further toxicity testing (Tiers II and III) 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 representative Vip3Aa proteins in corn and cotton tissues.

Since Vip3Aa are proteins, potential allergenicity is also considered as part of the toxicity assessment. Considering all of the available information, including that:

- Vip3Aa originates from a non-allergenic source.
- Vip3Aa19 and Vip3Aa20 have no sequence similarities with known allergens.
- Vip3Aa19 and Vip3Aa20 are not glycosylated.
- Vip3Aa19 and Vip3Aa20 are rapidly digested in simulated gastric fluid.
- The data developed for Vip3Aa19 and Vip3Aa20 can be extrapolated to all Vip3Aa proteins due to the extremely high level of structural similarity that exists between and among Vip3Aa proteins, EPA has concluded that the potential for Vip3Aa 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 representative Vip3Aa proteins, as well as the minimal potential to be a food allergen, demonstrate the safety of Vip3Aa 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 deoxyribo nucleic acids/ribonucleic acid (DNA/RNA) that encode these proteins and regulatory regions. The genetic material DNA/RNA necessary for the production of Vip3Aa proteins has been exempted from the requirement of a tolerance under 40 CFR 174.507 (Nucleic acids that are part of a plant-incorporated protectant; exemption from the requirement of a tolerance).

2. *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 Vip3Aa proteins. Thus, there are no threshold effects of concern and, as a result, the provision requiring an additional tenfold margin of safety does not apply. Further, the considerations of consumption patterns, special susceptibility, and cumulative effects do not apply.

3. *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 Vip3Aa proteins. 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 Vip3Aa proteins.

VII. Other Considerations

A. Endocrine Disruptors

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

B. Analytical Method(s)

A lateral flow enzyme-linked immunosorbent assay (ELISA) protocol has been provided to the Agency for detecting Vip3Aa in cotton as well as a qualitative ELISA method for detecting Vip3Aa in corn.

C. Codex Maximum Residue Level

No Codex maximum residue level exists for the plant-incorporated protectant *Bacillus thuringiensis* Vip3Aa proteins and the genetic material necessary for their production in corn and 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 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).

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

■ 2. Section 174.501 in subpart D is revised to read as follows:

§ 174.501 Bacillus thuringiensis Vip3Aa protein in corn and cotton; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Vip3Aa proteins in or on corn or cotton are exempt from the requirement of a tolerance when used as plant–incorporated protectants in or on the food and feed commodities of corn; corn, field; corn, sweet; corn, pop; and cotton; cotton, undelinted seed; cotton, refined oil; cotton, meal; cotton, hay; cotton, hulls; cotton, forage; and cotton, gin byproducts.

§ 174.528 [Removed]

■ 3. Section 174.528 is removed from Subpart D.

[FR Doc. E8–17931 Filed 8–5–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0484; FRL–8375–5]

Difenoconazole; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of difenoconazole, 1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole in or on almond, almond hulls, cantaloupe, cucumber, and watermelon. This action is in response to EPA's granting crisis exemptions to the California Environmental Protection Agency and the Georgia Department of Agriculture under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on almond, almond hulls, cantaloupe, cucumber, and watermelon. This regulation establishes a maximum permissible level for residues of difenoconazole in these food commodities. The time-limited tolerances expire and are revoked on December 31, 2011.

DATES: This regulation is effective August 6, 2008. Objections and requests for hearings must be received on or before October 6, 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–2008–0484. 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 either in the electronic docket