Dated: March 21, 2007.

Patrick G. Gerrity,

Captain, U.S. Coast Guard, Captain of the Port.

[FR Doc. E7–6145 Filed 4–3–07; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2006–0783; FRL–8120–5]

Bacillus thuringiensis Vip3Aa20 Protein and the Genetic Material Necessary for its Production in Corn; 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* Vip3Aa20 protein and the genetic material necessary for its production in corn when applied or/used as a plant-incorporated protectant. 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 *Bacillus thuringiensis* Vip3Aa20 protein and the genetic material necessary for its production in corn when applied or/used as a plant-incorporated protectant on field corn, sweet corn, and popcorn. The temporary tolerance exemption expires on March 31, 2008.

DATES: This regulation is effective April 4, 2007. Objections and requests for hearings must be received on or before June 4, 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–2006–0783. 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 web site 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 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 the FFDCA, as amended by the 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–2006–0783 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 June 4, 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–2006–0783, 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 telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of November 1, 2006 (71 FR 64269) (FRL–8095–4), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 6G7091) by Syngenta Seeds, Inc., P.O. Box 12257, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 174 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of the *Bacillus thuringiensis* Vip3Aa20 protein and the genetic material necessary for its production in corn when applied or used as a plant-incorporated protectant on field corn, sweet corn, and popcorn. 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 an exemption from the requirement of tolerance and expressed opposition to genetic alterations. The Agency understands the commenter's concerns and recognizes that some individuals believe that genetically modified crops and food should be completely banned. However, pursuant to its authority under the FFDCA, EPA conducted a comprehensive assessment of the Vip3Aa20 protein and the genetic material necessary for its production in corn, including a review of acute oral toxicity data and amino acid sequence comparisons to known toxins and allergens. In addition, data were reviewed that demonstrate that the Vip3Aa20 protein is rapidly degraded by gastric fluid *in vitro*, is not glycosylated, and is present in low levels in corn tissue. Based on these data, EPA concluded that there is a reasonable certainty that no harm will result from dietary exposure to this protein as expressed in genetically modified corn. Thus, under the standard in FFDCA section 408(c)(2), a tolerance exemption is appropriate.

Section 408(c)(2)(A)(i) of the 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 the 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), 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), which requires 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 the 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 the 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) Vip3Aa20 protein. These data demonstrate the safety of Vip3Aa20 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 plant-incorporated protectant 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 order to clarify the discussion that follows in the remainder of this Final Rule, it is necessary to distinguish the various Vip3A designations that are used. Vip3Aa20 is the designation applicable to Vip3A protein expressed in corn. Vip3Aa19 is the designation applicable to Vip3A protein expressed in cotton. Because the Agency has determined that both Vip3Aa19 and Vip3Aa20 are functionally equivalent, the Agency in establishing this temporary tolerance exemption for Vip3Aa20 expressed in corn has relied on data and analysis specifically developed for Vip3Aa20, as well as on data and analysis specifically developed for Vip3Aa19. A separate temporary exemption from the requirement of tolerance already has been established for Vip3Aa19 as expressed in cotton (71 FR 24582; 40 CFR 174.452).)

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 also supports the prediction that the Vip3Aa20 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 plant-incorporated protectants, even at relatively high dose levels, the Vip3Aa20 protein is not considered toxic. Amino acid sequence comparisons showed no similarity between the Vip3Aa20 protein and known toxic proteins available in public protein data bases. According to the Codex Alimintarius guidelines, the assessment of potential toxicity also includes stability to heat (FAO/WHO Standards Programme, 2001). A heat lability study demonstrated that Vip3Aa19 is inactivated against Fall Armyworms (FAW), when heated to 55 °C for 30 minutes.

Since Vip3Aa20 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. Current scientific knowledge suggests that common food allergens tend to be resistant to degradation acids and

proteases; may be glycosylated; and present at high concentrations in the food.

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 microliters (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 Vip3Aa20 is not glycoslylated and a comparison of amino acid sequences of known allergens uncovered no evidence of any homology with Vip3Aa20, even at the level of 8 contiguous amino acid residues. Preliminary data of the quantification of Vip3Aa20 protein in various maize tissues were also submitted. This data demonstrated that mean Vip3Aa20 concentrations in corn kernels ranged from approximately 24.6 - 40.3 micrograms (µg) Vip3Aa20/dry weight, representing approximately 0.003% of the total protein in grain (assuming that corn grain contains 10% total protein by weight). Therefore, Vip3Aa20 is present in low levels in corn tissue and the protein expression is much lower than the amounts of allergen protein found in commonly allergenic foods. In those foods, the allergens can be 10 to 50% of the total protein found.

Therefore, the potential for the Vip3Aa20 protein to be a food allergen is minimal. As noted above, toxic proteins typically act as acute toxins with low dose levels. Therefore, since no effects were shown to be caused by this plant-incorporated protectant, even at relatively high dose levels, the Vip3Aa20 protein is not considered toxic.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residues 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 plant-incorporated protectant 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. The amino acid homology assessment revealed no similarities to known aeroallergens, indicating that Vip3A 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 *Bt* pesticides (Berstein *et al.* 1999), which provides further evidence of the negligible respiratory risks of Bt plant-incorporated protectants. Exposure via residential or lawn use to infants and children is also not expected because the use sites for the Vip3Aa20 protein are all agricultural for control of insects. Oral exposure, at very low levels, may occur from ingestion of processed corn products and, theoretically, drinking water.

However, oral toxicity testing done at a dose in excess of 3 gm/kg showed no adverse effects. Furthermore, the expected dietary exposure from both cotton and corn are several orders of magnitude lower than the amounts of Vip3Aa20 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 Vip3Aa20 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 Vip3Aa20 protein residues in corn.

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 Vip3Aa20 protein include the characterization of the expressed Vip3Aa20 protein in corn, 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 Vip3Aa20 protein expressed in corn. Microbially produced protein was chosen in order to obtain sufficient material for testing.

The acute oral toxicity data submitted supports the prediction that the Vip3Aa20 protein would 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.* 1992). Since no effects were shown to be caused by Vip3Aa20 protein, even at relatively high dose levels (3,675 mg Vip3Aa19/kg bwt), the Vip3Aa20 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 plant-incorporated protectant was derived. (See 40 CFR 158.740(b)(2)(i)). Moreover, Vip3Aa20 showed no sequence similarity to any known toxin.

Protein residue chemistry data for Vip3Aa20 were not required for a human health effects assessment of the subject plant-incorporated protectant ingredients because of the lack of mammalian toxicity. However, preliminary data (that were submitted with administrative materials for an Experimental Use Permit application for corn expressing the Vip3Aa20 protein) demonstrated low levels of Vip3Aa20 in corn tissues with less than 40 µg Vip3Aa20 protein/gram dry weight in kernels and less than 75 µg Vip3Aa20 protein/gram dry weight of whole corn plant.

Since Vip3Aa20 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 Vip3Aa20 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 Vip3Aa20 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 Vip3Aa20 protein, as well as the minimal potential to be a food allergen, demonstrate the safety of Vip3Aa20 at levels well above possible maximum exposure levels anticipated in the crop.

The genetic material necessary for the production of the plant-incorporated protectant 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 Vip3Aa20 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

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 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 Vip3Aa20 protein and the genetic material necessary for its production in corn. 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 Vip3Aa20 protein and the genetic material necessary for its production in corn, when it is applied or/used in accordance with good agricultural practices on field corn, sweet corn, and popcorn. 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 plant-incorporated protectant.

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 plant-incorporated protectant at this time.

B. Analytical Method

A method for extraction and enzyme linked immunosorbent assay (ELISA) analysis of Vip3Aa20 protein in corn has been submitted and is under review by the Agency.

C. Codex Maximum Residue Level

No Codex maximum residue levels exist for the plant-incorporated protectant *Bacillus thuringiensis* Vip3Aa20 protein and the genetic material necessary for its production in corn.

VIII. 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 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 exemption 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: March 23, 2007.

James Jones,

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 174.458 is added to subpart W to read as follows:

§ 174.458 Bacillus thuringiensis Vip3Aa20 protein and the genetic material necessary for its production in corn; temporary exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Vip3Aa20 protein in corn are temporarily exempt from the requirement of a tolerance when used as a plant-incorporated protectant in the food and feed commodities of corn; corn, field; corn, sweet; corn, pop. This temporary exemption from the requirement of tolerance will permit the use of the food commodities in this paragraph when treated in accordance with the provisions of the experimental use permit 67979–EUP–6, 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 March 31, 2008; however, if the experimental use permit 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. E7–6256 Filed 4–3–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0731; FRL–8120–4]

Diphenylamine; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of diphenylamine in or on pear. Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 4, 2007. Objections and requests for hearings must be received on or before June 4, 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-2006-0731. 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 web site 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 telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-3194; e-mail address: *brothers.shaja@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 those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide 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**.

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C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in