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## PART 93—[AMENDED]

■ 4. The authority citation for part 93 continues to read as follows:

**Authority:** 21 U.S.C. 101; 42 U.S.C. 7401–7671q.

## Subpart B—[Amended]

■ 5. Section 93.152 is amended by removing the ''; and'' at the end of paragraph (1) and adding a period in its place and adding paragraph (3) to definition of ''Precursors of criteria pollutant'' to read as follows:

**§ 93.152 Definitions.**

* * * * *

*Precursors of a criteria pollutant* are:

* * * * *

(3) For $PM_{2.5}$:

(i) Sulfur dioxide ($SO_2$) in all $PM_{2.5}$ nonattainment and maintenance areas,

(ii) Nitrogen oxides in all $PM_{2.5}$ nonattainment and maintenance areas unless both the State and EPA determine that it is not a significant precursor, and

(iii) Volatile organic compounds (VOC) and ammonia ($NH_3$) only in $PM_{2.5}$ nonattainment or maintenance areas where either the State or EPA determines that they are significant precursors.

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■ 6. Section 93.153 is amended by revising paragraph (b) to read as follows:

**§ 93.153 Applicability.**

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(b) For Federal actions not covered by paragraph (a) of this section, a conformity determination is required for each criteria pollutant or precursor where the total of direct and indirect emissions of the criteria pollutant or precursor in a nonattainment or maintenance area caused by a Federal action would equal or exceed any of the rates in paragraphs (b)(1) or (2) of this section.

(1) For purposes of paragraph (b) of this section, the following rates apply in nonattainment areas (NAA's):

| | Tons/year |
|---|---|
| Ozone (VOC's or $NO_X$): | |
| Serious NAA's | 50 |
| Severe NAA's | 25 |
| Extreme NAA's | 10 |
| Other ozone NAA's outside an ozone transport region | 100 |
| Other ozone NAA's inside an ozone transport region: | |
| VOC | 50 |
| $NO_X$ | 100 |
| Carbon monoxide: All NAA's | 100 |
| $SO_2$ or $NO_2$: All NAA's | 100 |
| PM–10: | |
| Moderate NAA's | 100 |
| Serious NAA's | 70 |
| $PM_{2.5}$: | |
| Direct emissions | 100 |
| $SO_2$ | 100 |
| $NO_X$ (unless determined not to be a significant precursor) | 100 |
| VOC or ammonia (if determined to be significant precursors) | 100 |
| Pb: All NAA's | 25 |

(2) For purposes of paragraph (b) of this section, the following rates apply in maintenance areas:

| | Tons/year |
|---|---|
| Ozone ($NO_X$, $SO_2$ or $NO_2$): | |
| All Maintenance Areas | 100 |
| Ozone (VOC's): | |
| Maintenance areas inside an ozone transport region | 50 |
| Maintenance areas outside an ozone transport region | 100 |
| Carbon monoxide: All Maintenance Areas | 100 |
| PM–10: All Maintenance Areas | 100 |
| $PM_{2.5}$: | |
| Direct emissions | 100 |
| $SO_2$ | 100 |
| $NO_X$ (unless determined not to be a significant precursor) | 100 |
| VOC or ammonia (if determined to be significant precursors) | 100 |
| Pb: All Maintenance Areas | 25 |

* * * * *

[FR Doc. E6–11241 Filed 7–14–06; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 174

**[EPA–HQ–OPP–2006–0554; FRL–8076–5]**

## Bacillus Thuringiensis Cry1A.105 Protein and the Genetic Material Necessary for Its Production in Corn in or on All Corn Commodities; 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* Cry1A.105 protein and the genetic material necessary for its production in corn on field corn, sweet corn, and popcorn when applied/used as a plant-incorporated protectant. Monsanto Company 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* Cry1A.105 protein and the genetic material necessary for its production in corn. The temporary tolerance exemption will expire on June 30, 2009.

**DATES:** This regulation is effective July 17, 2006. Objections and requests for hearings must be received on or before September 15, 2006, 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–2006–0554. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, 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:** Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8715; e-mail address: *mendelsohn.mike@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–2006–0554 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 15, 2006.

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–2006–0554, 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 Building), 2777 S. Crystal Drive, 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 May 26, 2006 (71 FR 30401) (FRL–8066–5), 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 5G6940) by Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167. The petition requested that 40 CFR part 174 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis* Cry1A.105 protein and the genetic material necessary for its production in corn. This notice included a summary of the petition prepared by the petitioner Monsanto Company. One comment was received in response to the notice of filing. The commenter objected to an exemption from the requirement of a tolerance, stated that she does not favor genetically engineered corn, and stated that such corn should be labeled. The commentor also expressed concern about the mechanics of submitting comments via the www.regulations.gov site for the notice of filing. The Agency understands the commenter's concerns and recognizes that some individuals believe that genetically modified crops and food should be banned completely. Pursuant to its authority under the FFDCA, EPA conducted a comprehensive assessment of the Cry1A.105 protein and the genetic material necessary for its production in corn, including a review of acute oral toxicity data on the Cry1A.105 protein, amino acid sequence comparisons to known toxins and allergens, as well as data demonstrating that the Cry1A.105 protein is rapidly degraded by gastric fluid *in vitro*, is not glycosylated, and is present in low levels in corn tissue, and as 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(b)(2), a tolerance exemption is appropriate. The labeling of food is under the jurisdiction of the Food and Drug Administration (FDA). When commenting on notices of filing, commentors should either choose ''Notices'' or ''All Document Types'' in the Document Type box.

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 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 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.

Monsanto has submitted acute oral toxicity data demonstrating the lack of mammalian toxicity at high levels of exposure to the pure Cry1A.105 protein. These data demonstrate the safety of the product at a level well above maximum possible exposure levels that are reasonably anticipated in the crop. Basing this conclusion on acute oral toxicity data without requiring further toxicity testing and residue data is similar to the Agency position regarding toxicity testing and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which this plant-incorporated protectant was derived (See 40 CFR Sec. 158.740(b)(2)(i)). For microbial products, further toxicity testing 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 (Tiers II and III).

An acute oral toxicity study in mice (MRID 46694603) indicated that Cry1A.105 is non-toxic to humans. Cry1A.105 produced from microbial culture was dosed by gavage as two doses separated by 4 hours (±20 minutes) to 10 females and 10 males (2,072 milligrams/kilogram (mg/kg) body weight). Two control groups were also included in the study: A bovine serum albumin protein control, and a vehicle control. One male in the test protein group was moribund and sacrificed on day 1 due to a mechanical dosing error; this death was not attributed to the test material. All other mice survived the study. There were no significant differences in body weight or body weight change among the three groups during the study, and no treatment-related gross pathological findings were observed. The oral LD50 for males, females, and combined mice was greater than 2,072 mg/kg.

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, 3–9 (1992)). Therefore, since no acute effects were shown to be caused by Cry1A.105, even at relatively high dose levels, the Cry1A.105 protein is not considered toxic. Further, amino acid sequence comparisons showed no similarities between the Cry1A.105 and known toxic proteins in protein databases that would raise a safety concern.

Since Cry1A.105 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 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 by heat, acid, and proteases, may be glycosylated, and can be present at high concentrations in the food.

1. *Source of the trait. Bacillus thuringiensis* is not considered to be a source of allergenic proteins.

2. *Amino acid sequence.* A comparison of the amino acid sequence of Cry1A.105 with known allergens showed no overall sequence similarity or identity at the level of eight contiguous amino acid residues.

3. *Prevalence in food.* Expression level analysis indicated that the protein is present at relatively low levels in corn: Approximately 3 µg/g in grain on a dry weight basis. Thus, the expression has been shown to be in the parts per million range is much lower than the amounts of allergen protein found in commonly allergenic foods. In those foods, allergens are major protein components such as seed storage globulin proteins in nuts and legumes, meat associated proteins like tropomyosin in fish and shellfish, ovalbumin and ovomucoid in egg white and lactalbumin and casein in milk. In these cases, the allergens can be from 10% to 50% of the total protein found whereas the plant-incorporated protectant (PIP) that is the subject of this tolerance determination is found in the parts per million range.

4. *Digestibility.* The Cry1A.105 protein was digested within 30 seconds in simulated gastric fluid containing pepsin.

5. *Glycosylation.* Cry1A.105 expressed in corn was shown to have not to be glycosylated

6. *Conclusion.* Considering all of the available information, EPA has concluded that the potential for Cry1A.105 to be a food allergen is minimal.

## IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the 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 plant-incorporated protectants 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 Cry1A.105 to be an allergen is low, as discussed above. Although the allergenicity assessment focuses on potential to be a food allergen, the data also indicate a low potential for Cry1A.105 to be an inhalation allergen. Exposure via residential or lawn use to infants and children is also not expected because the use sites for the Cry1A.105 protein is agricultural. Oral exposure, at very low levels, may occur from ingestion of processed corn products and, theoretically, drinking water. However oral toxicity testing showed no adverse effects. Furthermore, the expression of the Cry1A.105 protein in corn kernels has been shown to be in the parts per million range, which makes the expected dietary exposure several orders of magnitude lower than the amount of Cry1A.105 shown to have no toxicity. Therefore, even if negligible aggregate exposure should occur, the Agency concludes that such exposure would result in no harm due to the lack of mammalian toxicity and low potential for allergenicity demonstrated for the Cry1A.105 protein.

## V. Cumulative Effects

Pursuant to FFDCA section 408(b)(2)(D)(v), EPA has considered available information on the cumulative effects of such residues and other substances that have a common mechanism of toxicity. These considerations included the cumulative effects on infants and children of such residues and other substances with a common mechanism of toxicity. Because there is no indication of

mammalian toxicity from the plant-incorporated protectant, we conclude that there are no cumulative effects for the Cry1A.105 protein.

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

### *A. Toxicity and Allergenicity Conclusions*

The data submitted and cited regarding potential health effects for the Cry1A.105 protein includes the characterization of the expressed Cry1A.105 protein in corn, as well as the acute oral toxicity study, amino acid sequence comparisons to known allergens and toxins, and *in vitro* digestibility of the protein. The results of these studies were used to evaluate human risk, and the validity, completeness, and reliability of the available data from the studies were also considered.

Adequate information was submitted to show that the Cry1A.105 test material derived from microbial culture was biochemically and functionally equivalent to the protein produced by the plant-incorporated protectant ingredient in corn. Microbially produced protein was used in the safety studies so that sufficient material for testing was available.

The acute oral toxicity data submitted support the prediction that the Cry1A.105 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.*, ''Toxicological Considerations for Protein Components of Biological Pesticide Products,'' Regulatory Toxicology and Pharmacology 15, 3–9 (1992)). Since no treatment-related adverse effects were shown to be caused by the Cry1A.105 protein, even at relatively high dose levels, the Cry1A.105 protein is not considered toxic. Basing this conclusion on acute oral toxicity data without requiring further toxicity testing and residue data is similar to the Agency position regarding toxicity and the requirement of residue data for the microbial Bacillus thuringiensis products from which this plant-incorporated protectant was derived (See 40 CFR 158.740(b)(2)(i)). For microbial products, further toxicity testing and residue data are triggered when significant adverse effects are seen in studies such as the mouse oral toxicity study. Further studies verify the observed adverse effects and clarify the source of these effects (Tiers II and III).

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 Cry1A.105 in corn tissues.

Since Cry1A.105 is a protein, potential allergenicity is also considered as part of the toxicity assessment. Considering all of the available information (1) Cry1A.105 originates from a non-allergenic source; (2) Cry1A.105 has no sequence similarities with known allergens; (3) Cry1A.105 is not glycosylated; (4) Cry1A.105 will only be present at low levels in food; and (5) Cry1A.105 is rapidly digested in simulated gastric fluid; EPA has concluded that the potential for Cry1A.105 to be a food allergen is minimal.

Neither available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers including infants and children) nor safety factors that are generally recognized as appropriate for the use of animal experimentation data were evaluated. The lack of mammalian toxicity at high levels of exposure to the Cry1A.105 protein, as well as the minimal potential to be a food allergen, demonstrate the safety of the product at levels well above possible maximum exposure levels anticipated in the crop.

The genetic material necessary for the production of the plant-incorporated protectant active ingredient include the nucleic acids (DNA, RNA) that encode these proteins and regulatory regions. The genetic material (DNA, RNA), necessary for the production of the Cry1A.105 protein has been exempted under the 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 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 finds that there is no toxicity for the Cry1A.105 protein and the genetic material necessary for its production. Thus, there are no threshold effects of concern and, as a result, the provision requiring an additional margin of safety does not apply. Further, the considerations of consumption patterns, special susceptibility, and cumulative effects do not apply.

### *C. Overall Safety Conclusion*

There is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to the Cry1A.105 protein and the genetic material necessary for its production. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, no toxicity to mammals has been observed, nor any indication of allergenicity potential for the plant-incorporated protectant.

## VII. Other Considerations

### *A. Endocrine Disruptors*

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

### *B. Analytical Method(s)*

A short description of an enzyme-linked immunosorbent assay for the detection and quantification of Cry1A.105 in corn tissue has been submitted.

### *C. Codex Maximum Residue Level*

No Codex maximum residue level exists for the plant-incorporated protectant *Bacillus thuringiensis* Cry1A.105 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 tolerance requirement under section 408(d) of the 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 due to its lack of significance,

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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

### IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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 29, 2006.

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

■ 2. Section 174.453 is added to subpart W to read as follows:

**§ 174.453 Bacillus Thuringiensis Cry1A.105 Protein and the Genetic Material Necessary for Its Production in Corn.**

*Bacillus thuringiensis* Cry1A.105 protein and the genetic material necessary for its production in corn is exempt from the requirement of a tolerance when used as plant-incorporated protectant in the food and feed commodities of field corn, sweet corn and popcorn. Genetic material necessary for its production means the genetic material which comprise genetic material encoding the Cry1A.105 protein and its regulatory regions. Regulatory regions are the genetic material, such as promoters, terminators, and enhancers, that control the expression of the genetic material encoding the Cry1A.105 protein. This temporary exemption from the requirement of a tolerance will permit the use of the food commodities in this paragraph when treated in accordance with the provisions of the experimental use permit 524–EUP–97 which is being issued under 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 June 30, 2009; however, if the experimental use permit is revoked, or if any experience with or scientific data on this pesticide indicate that the tolerance is not safe, this temporary exemption from the requirement of a tolerance may be revoked at any time.

[FR Doc. E6–11245 Filed 7–14–06; 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 174

**[EPA–HQ–OPP–2006–0553; FRL–8076–6]**

### Bacillus Thuringiensis Cry2Ab2 Protein and the Genetic Material Necessary for Its Production in Corn in or on All Corn Commodities; 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