tribes, 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.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

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

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

Environment

We have analyzed this rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g.), of the Instruction, from further environmental documentation. This rule establishes a safety zone.

A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add temporary § 165.T08–999 to read as follows:

§ 165.T08–999 Safety zones; Sector New Orleans.

(a) Location. The following areas are safety zones:

(1) A 25-yard radius surrounding all damaged barges located in navigable waters within Sector New Orleans.

(b) Definitions.

(1) The *Captain of the Port New Orleans* means the Commander, Coast Guard Sector New Orleans.

(2) *Damaged barge* means a barge requiring salvage operations.

(c) Regulations.

(1) Salvage operations may not begin on any Coast Guard inspected barge located within a safety zone established by paragraph (a) of this section until the Captain of the Port New Orleans, or his designee, has approved a salvage plan for that barge.

(2) Salvage operations may not begin on any uninspected barge located within a safety zone established by paragraph (a) of this section that is affecting waterway traffic until the Captain of the Port New Orleans, or his designee, has approved a salvage plan for that barge.

(3) The Captain of the Port New Orleans, or his designee, must approve a salvage plan for any barge located within a safety zone established by paragraph (a) of this section when salvage operations on that barge will affect waterway traffic.

(4) The salvage plan shall provide the information contained in the Brownwater Salvage Checklist. To receive the checklist, contact the Coast Guard Incident Command Post (ICP) in Alexandria, Virginia:

(i) Via phone at: (318) 443–2084, (318) 448–5351, or (318) 443–0651;

(ii) Via fax at: (318) 443–2573; or

(iii) Via e-mail at: *secnolasalvage@yahoo.com.*

(5) The Captain of the Port New Orleans, or his designee, must be notified when salvage operations commence and are completed on uninspected barges located within a safety zone established by paragraph (a) of this section but not affecting the navigation channel or vessel traffic.

(d) The salvage plan required in paragraph (c) above should be faxed to Coast Guard Incident Command Post (ICP) in Alexandria, LA at (318) 443–2573, Attention: Salvage Group. You may contact the Salvage Operations Department at the ICP at (318) 443–2084, (318) 448–5351, or (318) 443–0651 for more information.

(e) Enforcement. The U.S. Coast Guard may be assisted in the patrol and enforcement of the zone by Federal, State and local agencies.

(f) Effective period. This section is effective from September 19, 2005 through December 31, 2005.

Dated: September 19, 2005.

Steve Venckus,

Chief, Office of Regulations & Administrative Law, Office of the Judge Advocate General, United States Coast Guard.

[FR Doc. 05–18966 Filed 9–19–05; 1:18 pm]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[OPP–2005–0211; FRL–7735–4]

Bacillus Thuringiensis Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Material Necessary for Their Production in Corn; 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* Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production in corn on corn, field; corn, sweet; and corn, pop when applied/used as a plant–incorporated protectant. Mycogen Seeds c/o Dow AgroSciences LLC 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* Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production in corn.

DATES: This regulation is effective September 21, 2005. Objections and requests for hearings must be received on or before November 21, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0211. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This 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 (7511C), 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit I. 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 and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.* A frequently updated electronic version of 40 CFR part 174 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of August 31, 2004 (69 FR 53060) (FRL–7369–7), 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 3F6785) by Mycogen Seeds c/o Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that a temporary exemption from the requirement of a tolerance be established for residues of *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production in corn. This notice included a summary of the petition prepared by the petitioner Mycogen Seeds c/o Dow AgroSciences LLC. One comment was received from a private citizen who opposed issuance of a final rule. She expressed concern regarding Dow's record, genetically modified corn, the impact that killing rootworm would have on the environment, and that the notice of filing mentioned ''studies'' without giving a specific number. The Agency understands and recognizes that some individuals believe that genetically modified crops and food should be banned completely. Corn rootworms are a significant agricultural pest and are extensively treated in the United States. Pursuant to its authority under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA has conducted a comprehensive assessment of the Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production in corn. EPA has concluded that there is a reasonable certainty that no harm will result from dietary exposure to these proteins as expressed in genetically modified corn. Specific studies were listed in the administrative material provided in the docket.

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.

Acute oral toxicity data have been submitted demonstrating the lack of mammalian toxicity at high levels of exposure to the pure Cry34Ab1 and Cry35Ab1 proteins separately and combined. These data demonstrate the safety of the products at levels well above maximum possible exposure levels that are reasonably anticipated in the crops. 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 these plant-incorporated protectants were derived (See 40 CFR 158.740(b)(2)(i)). For microbial products, further toxicity testing and residue data are triggered by significant acute effects in studies such as the mouse oral toxicity study, to verify the observed effects and clarify the source of these effects (Tiers II and III).

Three acute oral toxicity studies on Cry34Ab1 and Cry35Ab1 in mice were submitted, which indicated that these proteins are non-toxic to humans.

In an oral toxicity study of Cry34Ab1 alone, Cry34Ab1 produced from microbial culture was administered to five male mice (5,000 milligrams/kilogram (mg/kg) body weight) by oral gavage as a 20% mixture in a 0.5% aqueous methylcellulose vehicle. All animals survived the 2–week study. No clinical signs were noted for any animals during the study. An initial weight loss was observed in three mice at test days 1 and 2, but they gained weight for the remainder of the study. The two other animals gained weight throughout the study. No treatment-related gross pathologic changes were observed during the study. Under the conditions of this study, the acute oral LD_{50} for the test substance in male CD-1 mice is greater than 5,000 mg/kg. Since the test substance contained Cry34Ab1 at 54% purity, the acute oral LD_{50} for the pure Cry34Ab1 protein is greater than 2,700 mg/kg.

In an oral toxicity study of Cry35Ab1 alone, Cry35Ab1 produced from microbial culture was administered to five male mice (5,000 mg/kg body weight) by oral gavage as a 20% mixture in a 0.5% aqueous methylcellulose vehicle. All animals survived the 2–week study. No clinical signs were noted for any animal during the study. An initial weight loss was observed in two mice at test days 1 and 2, but they gained weight for the remainder of the study. One animal had fluctuating body weight. The other two animals gained weight throughout the study. No treatment-related gross pathologic changes were observed during the study. Under the conditions of this study, the acute oral LD_{50} for the test substance in male CD-1 mice is greater than 5,000 mg/kg. Since the test substance contained Cry35Ab1 at 37% purity, the acute oral LD_{50} for the pure Cry35Ab1 protein is greater than 1,850 mg/kg.

Finally, in an oral toxicity of Cry34Ab1 and Cry35Ab1 combined, a mixture of the microbially produced Cry34Ab1 and Cry35Ab1 proteins (5,000 mg test material, containing 482 mg pure Cry34Ab1 and 1,520 mg pure Cry35Ab1 (corresponding to an equimolar ratio), per kg body weight) was administered by oral gavage to five female and five male mice as a 20% mixture in 0.5% aqueous methylcellulose. All animals survived the 2–week study. One female mouse exhibited protruding or bulging eyes on days 6 and 7, but this resolved thereafter. This observation was not attributed to the treatment as it was an isolated observation (i.e., no other animals exhibited this). No other clinical signs were noted for any animals during the study. An initial weight loss was observed in two mice at test days 1 and 2, but both gained weight for the remainder of the study. All other animals gained weight throughout the study. No treatment related gross pathologic changes were noted. Under the conditions of the study, the acute oral LD_{50} of the test material in male and female CD-1 mice is greater than 5,000 mg/kg body weight, corresponding to 2,000 mg/kg of an equimolar ratio of the pure 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, 3–9 (1992)). Therefore, since no effects were shown to be caused by the plant-incorporated protectants, even at relatively high dose levels, the Cry34Ab1 and Cry35Ab1 proteins are not considered toxic. Further, amino acid sequence comparisons showed no similarity between the Cry34Ab1 and Cry35Ab1 proteins to known toxic proteins available in public protein data bases.

Since Cry34Ab1 and Cry35Ab1 are proteins, allergenic potential was also considered. Currently, no definitive tests for determining the allergenic potential of novel proteins exist. 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 by acid and proteases; may be glycosylated, and can be present at high concentrations in the food. In the past, EPA has also considered heat stability in assessing allergenicity potential; however, the FIFRA Scientific Advisory Panel at a March 1–2, 2005 meeting stated that heat stability based on a bioactivity assay is of minimal to no value in predicting the allergenicity potential of novel proteins, and EPA agrees. Therefore, EPA did not consider heat stability of these proteins in its weight-of-evidence approach.

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

2. *Amino acid sequence*. A comparison of amino acid sequences of Cry34Ab1 and Cry35Ab1 with known allergens showed no overall sequence similarities or homology at the level of eight contiguous amino acid residues.

3. *Prevalence in food*. Expression level analysis indicated that the proteins are present at relatively low levels in corn; on a dry weight basis, Cry34Ab1 is present at a concentration of approximately 50 nanograms/milligram (ng/mg) in grain from Event 59122–7, and Cry35Ab1 is present at a concentration of approximately 1 ng/mg in grain from Event 59122–7. Thus, expression of the Cry34Ab1 and Cry35Ab1 proteins in corn kernels has been shown to be in the parts per million range.

4. *Digestibility*. Two *in vitro* digestibility studies were conducted to determine the stability of the Cry34Ab1 and Cry35Ab1 proteins in simulated gastric fluid (i.e., an acid environment containing pepsin; SGF). In the first *in vitro* digestibility study, the proteins were incubated in SGF (pepsin concentration: 3.2 milligrams/milliliter (mg/mL); pH 1.2; 37° C) with a pepsin to protein substrate ratio of approximately 20:1, molecule/molecule (mol/mol) (equivalent to 60:1, w/w for Cry34Ab1 and 17:1, w/w for Cry35Ab1). Samples taken at 1, 5, 7, 15, 20, 30, and 60 minutes were analyzed by sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE) and western blot. Cry35Ab1 was no longer visible at the 5–minute time-point using both SDS-PAGE stained with Coomassie Brilliant Blue and western blot detection. Cry34Ab1 was visible on the stained gel for the 15–minute sample,

but not in later sample time points. In the western blot analysis, Cry34Ab1 was visible in the 20–minute sample, but not in later sample time points. In conclusion, this first study showed that Cry34Ab1 was digested within 30 minutes and Cry35Ab1 was digested within 5 minutes in SGF under the conditions of the study.

Because Cry34Ab1 appeared to be somewhat resistant to SGF in the study described above that used the time-to-disappearance endpoint, Dow submitted a second study on the *in vitro* digestibility of Cry34Ab1 in SGF using a kinetic approach. The digestion was performed under the same conditions as the previous study except that reaction mixtures were shaken during incubation, and samples were analyzed at 1, 2, 3, 5, 7.5, 10, 15, and 20 minutes. The previous study on pepsin digestibility of Cry34Ab1 and Cry35Ab1, as well as other pepsin digestibility studies used in allergenicity assessments, focused on the time required for the protein to become undetectable, and therefore, the results are dependent on the detection limit of the analytical method used. In this second study, Dow determined the rate of pepsin digestion of Cry34Ab1 by measuring the relative amounts of Cry34Ab1 at each of the time points based on SDS-PAGE densitometry estimates. Under the conditions of the study, the rate of decay fit a first-order model (with respect to Cry34Ab1 concentration), and Dow estimated the DT_{50} (half-life) and DT_{90} (time until 90% decay) to be 1.9 minutes and 6.2 minutes, respectively. In this experiment, Cry34Ab1 was visible on gels and blots in 15–minute time point samples but not in 20–minute time point samples.

Because the digestibility of Cry34Ab1 was assessed using a different method (i.e., the kinetic approach) rather than the typical end-point method that has been used previously, comparison studies using the kinetic approach to assess the digestibility of known allergens and non-allergens were submitted to validate the method and allow comparison of the digestibility of Cry34Ab1 with known allergens and non-allergens. In the comparison study where the conditions used were the same as those used in the kinetic study on the digestibility of Cry34Ab1, two allergens and two non-allergens were shown to digest similarly to Cry34Ab1. From these studies and published studies, EPA concludes that Cry35Ab1 is rapidly digested and Cry34Ab1 is digested at a moderate rate in SGF; Cry34Ab1 appears to digest slower than previously registered proteins and many other proteins that are not considered allergens but faster than most previously tested allergens.

On March 1–2, 2005, EPA held a FIFRA Scientific Advisory Panel (SAP) meeting, *http://www.epa.gov/oscpmont/sap/#march*, to address the scientific issues that arose during the human health safety assessment of Cry34Ab1 and Cry35Ab1. EPA asked the SAP to comment on EPA's allergenicity assessment of Cry34Ab1. The SAP agreed with EPA's preliminary assessment that the allergenicity potential of Cry34Ab1 is low. However, the Panel based its conclusion in part on statements made by Dow that Cry34Ab1 and Cry35Ab1 do not aggregate in solution. The Panel was concerned that if the proteins were to aggregate, protease binding sites could be masked, and the rate of digestion could be slower than was observed for the individual proteins. Therefore, EPA asked Dow to submit data supporting the claim that Cry34Ab1 and Cry35Ab1 do not associate with one another in solution.

To support the digestibility studies on the individual proteins, Dow submitted a study using size exclusion chromatography, which demonstrated that Cry34Ab1 and Cry35Ab1 do not associate with one another in solution under acidic conditions.

5. *Glycosylation*. Cry34Ab1 and Cry35Ab1 expressed in corn were shown not to be glycosylated.

6. *Conclusion*. Considering all of the available information: (1) Cry34Ab1 and Cry35Ab1 originate from a non-allergenic source;(2) Cry34Ab1 and Cry35Ab1 have no overall sequence similarities or homology at the level of eight contiguous amino acid residues with known allergens; (3) Cry34Ab1 and Cry35Ab1 will only be present at low levels in food; (4) Cry35Ab1 is rapidly digested in SGF, and Cry34Ab1 is digested at a moderate rate in SGF; and (5) Cry34Ab1 and Cry35Ab1 are not glycoslyated when expressed in maize. EPA has concluded that the potential for the Cry34Ab1 and Cry35Ab1 proteins to be food allergens is minimal. The FIFRA SAP that met on March 1–2, 2005, agreed with this conclusion regarding the allergenicity potential of Cry34Ab1. There were no triggers to raise concern about the allergenicity of Cry35Ab1, so the SAP was not asked to comment specifically on Cry35Ab1. As noted above, toxic proteins typically act as acute toxins with low dose levels. Therefore, since no effects were shown to be caused by the plant-incorporated protectants, even at relatively high dose levels, the Cry34Ab1 and Cry35Ab1 proteins are 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 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 protectants are contained within plant cells, which essentially eliminates these exposure routes or reduces these exposure routes to negligible. Exposure via residential or lawn use to infants and children is also not expected because the use sites for the Cry34Ab1 and Cry35Ab1 proteins are all agricultural for control of insects. Oral exposure, at very low levels, may occur from ingestion of processed corn products and, potentially, drinking water. However, oral toxicity testing showed no adverse effects. Furthermore, the expression of the Cry34Ab1 and Cry35Ab1 proteins 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 amounts of Cry34Ab1 and Cry35Ab1 proteins 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 Cry34Ab1 and Cry35Ab1 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 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, resulting from the

plant-incorporated protectants, we conclude that there are no cumulative effects for the Cry34Ab1 and Cry35Ab1 proteins.

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 Cry34Ab1 and Cry35Ab1 proteins include the characterization of the expressed Cry34Ab1 and Cry35Ab1 proteins in corn, as well as the acute oral toxicity, 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 Cry34Ab1 and Cry35Ab1 proteins test material derived from microbial cultures was biochemically and, functionally similar to the protein produced by the plant-incorporated protectant ingredients in corn. Production of microbially produced protein was chosen in order to obtain sufficient material for testing.

The acute oral toxicity data submitted support the prediction that the Cry34Ab1 and Cry35Ab1 proteins 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 effects were shown to be caused by the Cry34Ab1 and Cry35Ab1 proteins, even at relatively high dose levels, the Cry34Ab1 and Cry35Ab1 proteins are 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 these plant-incorporated protectants were derived. (See 40 CFR 158.740(b)(2)(i)). For microbial products, further toxicity testing and residue data are triggered by significant acute effects in studies such as the mouse oral toxicity study to verify the observed effects and clarify the source of these effects (Tiers II and III).

Cry34Ab1 and Cry35Ab1 proteins 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 Cry34Ab1 and Cry35Ab1 proteins in corn tissues.

Since Cry34Ab1 and Cry35Ab1 are proteins, their potential allergenicity is also considered as part of the toxicity assessment. Considering all of the available information (1) Cry34Ab1 and Cry35Ab1 originate from a non-allergenic source; (2) Cry34Ab1 and Cry35Ab1 have no overall sequence similarities or homology at the level of eight contiguous amino acid residues with known allergens; (3) Cry34Ab1 and Cry35Ab1 are not glycoslyated when expressed in maize; (4) Cry34Ab1 and Cry35Ab1 will only be present at low levels in food; and (5) Cry35Ab1 is rapidly digested in SGF, and Cry34Ab1 is digested at a moderate rate in SGF; EPA has concluded that the potential for the Cry34Ab1 and Cry35Ab1 proteins to be food allergens is minimal. The FIFRA Scientific Advisory Panel (SAP) that met on March 1–2, 2005 agreed with this conclusion regarding the allergenicity potential of Cry34Ab1. There were no triggers to raise concern about the allergenicity of Cry35Ab1, so the SAP was not asked to comment specifically on Cry35Ab1.

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 Cry34Ab1 and Cry35Ab1 proteins, 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 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 the Cry34Ab1 and Cry35Ab1 proteins have 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 concludes that there is a finding of no toxicity for the Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their 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 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 from aggregate exposure to the U.S. population, including infants and children, to the Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their 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 protectants.

VII. Other Considerations

A. Endocrine Disruptors

The pesticidal active ingredients are proteins, 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 protectants at this time.

B. Analytical Method(s)

Validated enzyme-linked immunosorbent assays for the detection and quantification of Cry34Ab1 and Cry35Ab1 in corn tissue have been submitted and found acceptable by the Agency.

C. Codex Maximum Residue Level

No Codex maximum residue levels exist for the plant-incorporated protectants *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for its production in corn.

VIII. Objections and Hearing Requests

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. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0211 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 21, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0211 , to: Public Information and Records Integrity Branch, Information Technology and Resource Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IX. 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.

X. 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: August 29, 2005.

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 174.457 is added to subpart W to read as follows:

§ 174.457 Bacillus thuringiensis Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production in corn; exemption from the requirement of a tolerance.

Bacillus thuringiensis Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production in corn are exempted from the requirement of a tolerance when used as plant-incorporated protectants in the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop.

[FR Doc. 05–18582 Filed 9–20–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0248; FRL–7736–1]

Myclobutanil; Re-Establishment of a Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation re-establishes a time-limited tolerance for combined residues of the fungicide myclobutanil and its metabolite in or on artichoke, globe at 1.0 parts per million (ppm) for an additional 2½ year period. This tolerance will expire and is revoked on December 31, 2007. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on artichoke, globe. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18.

DATES: This regulation is effective September 21, 2005. Objections and requests for hearings must be received on or before November 21, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit III. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0248.

All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This 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: Stacey Milan Groce, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–2505; e-mail address:*milan.stacey@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