N, 079°55.25′ W; 32°48.2′ N, 079°54.35′ W.

(2) Another temporary fixed security zone is established for the waters around the Interstate 526 Bridge spans (Don Holt Bridge) in Charleston Harbor and on the Cooper River and will encompass all waters within a line connecting the following points: 32°53.49′ N, 079°58.05′ W; 32°53.42′ N, 079°57.48′ W; 32°53.53′ N, 079°58.05′ W; 32°53.47′ N, 079°57.47′ W.

(b) *Regulations.* In accordance with the general regulations in § 165.33 of this part, vessels are allowed to transit through these zones but are prohibited from mooring, anchoring, or loitering within these zones unless specifically authorized by the Captain of the Port.

(c) *Authority.* In addition to 33 U.S.C. 1321, the authority for this section includes 33 U.S.C. 1226.

(d) *Effective period.* This section is effective from 12 midnight on July 15, 2003, until 11:59 p.m. January 15, 2004.

Dated: June 16, 2003.

Gary W. Merrick,

Commander, Coast Guard, Captain of the Port.

[FR Doc. 03–16969 Filed 7–3–03; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0154; FRL–7310–1]

Bacillus thuringiensis Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Material Necessary for their 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* Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production in corn on corn 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 the temporary tolerance exemption. 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. The temporary tolerance exemption will expire on April 30, 2006.

DATES: This regulation is effective July 7, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0154, must be received by EPA on or before September 5, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**.

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 categories and entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 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 Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0154. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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.

2. *Electronic access.* 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 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of March 7, 2003 (68 FR 11100) (FRL–7285–8), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide tolerance petition (PP 0G6112) by Mycogen Seeds c/o Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268–1054. This notice included a summary of the petition prepared by the petitioner Mycogen Seeds c/o Dow AgroSciences LLC. The docket, OPP–2002–0350, cited in the notice contained the petition. However, the administrative pesticide petition number cited in the notice (PP 0G6112) was incorrect. The correct number is PP 1G6279. There was one comment received in response to the notice of filing by the Center for Science in the Public Interest (CSPI).

Summary of Comment

The major focus of the comments from CSPI is on the results of tests done to establish the sensitivity of the

Cry34Ab1 protein to pepsin degradation. CSPI contests the interpretation of the results provided by Dow AgroSciences that indicate the Cry34Ab1 degrades under the influence of pepsin. CSPI asserts that EPA cannot make a safety determination in light of these results and international consensus on how to address allergenicity as stated in the Food and Agricultural Organization/World Health Organization (FAO/WHO) expert consultation. Specifically, CSPI claims use of a less sensitive protein detection method, a pH of 1.2 instead of 2.0 for the pepsin buffer solution and a low concentration of the Cry34Ab1 protein in the assays were all utilized to achieve the results. CSPI suggests that all these features combine to artificially skew the results of the pepsin assay to show that Cry 34Ab1 is readily broken down by pepsin. CSPI suggests that the Cry34Ab1 protein is stable to gastric fluid breakdown since it is visible on Coomassie blue stained gels at 7 to 10 minutes of pepsin incubation. CSPI also claims that the initial Dow AgroScience data using a more sensitive Western blot assay clearly show the protein present at the 20 to 30 minute sample and that this endpoint is scientifically agreed upon to indicate resistance to pepsin degradation. CSPI recognizes that the total dietary exposure to the Cry34Ab1 protein likely to occur during an experimental use permit would not be expected to induce an allergic reaction and that there is still considerable scientific controversy around the determination of potential allergenicity of a protein new to the food supply. Finally, CSPI states that a test to determine potential allergenicity is still needed and, in the interim, acceptable standards for performing the currently available tests are provided by the FAO/WHO report on Evaluation of Allergenicity of Genetically Modified Foods (Rome, 2001).

EPA Response

EPA agrees that there is still the need to develop definitive tests to assess potential allergenicity and that the currently employed tests need to follow standardized procedures. EPA also agrees that no single criterion of those currently utilized can alone be an indication of potential allergenicity. However, EPA would suggest that, while the guidance given by the 2001 FAO/WHO report is invaluable, there is still no consensus on how to implement several of the tests suggested in the FAO/WHO guidance nor any direction given as to critical endpoints for the tests suggested. This lack of consensus was confirmed by a CODEX ad hoc working group on allergenicity which met in Vancouver, Canada in September 2001, to consider the advice of the FAO/WHO expert consultation report from Rome 2001. This CODEX group found that, without development and implementation of the new tests suggested by FAO/WHO expert consultation, the current weight of evidence approach provides essentially the same information for judging allergenicity as that suggested by the 2001 FAO/WHO report. This advice has been incorporated into the latest version of the CODEX food safety assessment for genetically engineered foods. (CODEX, ftp://ftp.fao.org/codex/alinorm03/Al03__34e.pdf)

The current criteria used by EPA to judge allergenicity include amino acid sequence similarity analyses, stability to heat, and enzymatic degradation. The Cry34Ab1 protein does not share significant amino acid similarity with known allergens either on a whole sequence level or on the eight amino acid stepwise comparisons, nor does the Cry34Ab1 protein appear to be stable to temperatures above 90 °C. The initial data reported from the company indicated that one of the two proteins, Cry34Ab1, was moderately resistant to the action of pepsin by still being detectable on an SDS-PAGE western blot at 20–30 minutes. EPA questioned the results found in the initial submission on pepsin degradation and requested more information.

In the absence of a definitive endpoint for determining the pepsin resistance of a given protein, the initial results reported by Dow were not conclusive. The 2001 Rome FAO/WHO expert consultation report specifically does not mention a time endpoint for pepsin degradation of a protein other than the protein or a significant sized fragment being present at the final endpoint of 60 minutes. The literature references CSPI itself provided cite a range of values for pepsin stability ranging from 8 minutes to 2 hours and demonstrate a lack of consensus on pepsin resistance. EPA would therefore disagree with CSPI that there is a scientific consensus on visible protein bands in an SDS PAGE assay at 20 to 30 minutes indicating pepsin stability.

Dow AgroScience's second submission presents results that indicate more rapid breakdown than the initial data. Dow AgroScience's approach where enzymatic degradation is expressed as a kinetic rate instead of a definitive substrate disappearance endpoint makes the results less variable since the sensitivity of the detection system does not affect the final result. This is because the pepsin activity can be expressed as a rate constant, an endpoint that is not dependent on the sensitivity of the detection system, is substrate concentration independent and is the classical method used by protein chemists to determine enzyme activity or in this case substrate disappearance. While this method may not be the final iteration of the pepsin degradation assay, EPA believes that an analysis that lessens assay variability and makes the results independent of the sensitivity of the detection method is an improvement.

EPA finds that the literature references CPSI cited are diametrically opposed in their view of the usefulness of the pepsin degradation assay for prediction of allergenicity (Ref. 1). The Astwood et al. paper shows that, while lowering the pepsin concentration can lead to the appearance of fragments in an otherwise rapidly degraded protein, the pepsin assay is a good predictor of allergenicity (Ref. 1). The Fu et al. paper indicates that both allergens and non-allergens can be stable to pepsin activity so the assay is not predictive (Ref. 2). Both papers emphasize that protein doses, pepsin concentrations, and assay conditions should be equivalent when comparing proteins. Neither paper suggests a definitive timepoint that could be interpreted as indicating protein stability to pepsin. The Fu et al. paper in fact suggests that allergens and non-allergens can both be either resistant to or degraded by pepsin. The final conclusion in the Fu paper is that the pepsin sensitivity assay alone has no predictive value for allergenicity. EPA does not agree with this position but does agree that pepsin stability alone is not a sole criterion to be used for an allergenicity assessment.

EPA agrees with CSPI that the tests used to determine potential allergenicity need standardization and supports efforts in that area. EPA believes that there is sufficient data available, considering all information on the Cry34Ab1 protein, to make a finding that there is a reasonable certainty that no harm will result from the aggregate exposure to the Cry34Ab1 and Cry35 Ab1 proteins as expressed in corn.

The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of the plant-incorporated protectants *Bacillus thuringiensis* Cry34Ab1/Cry35Ab1 proteins and the genetic material necessary for their production in corn in or on corn. The Mycogen/Dow AgroSciences and Pioneer Hi-Bred experimental use permits associated with the petition are 68467–EUP–3, 68467–EUP–5, 68467–EUP–T(7), 68467–

EUP–I(8), 29964–EUP–1, 29964–EUP–3, 29964–EUP–U(4), and 29964–EUP–L(5)

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. Section 408(b)(2)(C) of the FFDCA 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 the lack of mammalian toxicity at high levels of exposure to pure Cry34Ab1/Cry35Ab1 proteins. These data demonstrate the safety of the products 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 microbial pesticides. 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).

The acute oral toxicity data submitted support the prediction that the Cry34Ab1 and Cry35Ab1 proteins would be non-toxic to humans. The test substance was administered to five female and five male mice (5,000 milligrams/kilogram (mg/kg) body weight)) in a 1:4.6 mixture of the two proteins, 14 kDa and 44 kDa. A single dose gavage (25 milliliter/kilogram (mL/kg)) delivered as a 20% mixture in 0.5% methycellulose. 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 gross treatment related observations were recorded during the study as represented by gross pathologic observations. An acute oral LD_{50} was calculated for this study based upon a dosage of a 1:4.6 ratio mixture of Cry34Ab1 (54% pure) and Cry35Ab1 (37% pure) proteins at greater than 5,000 mg/kg, and greater than 2,000 mg/kg for an equimolar mixture (1:3) of the pure proteins.

When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Ref. 3). Therefore, since no acute 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.

Since Cry34Ab1 and Cry35Ab1 are proteins, allergenic sensitivities were considered. Current scientific knowledge suggests that common food allergens tend to be resistant to degradation by heat, acid, and proteases, may be glycosylated and present at high concentrations in the food. Data have been submitted that demonstrate that the Cry34Ab1 and Cry35Ab1 proteins are rapidly degraded by gastric fluid *in vitro* and are non-glycosylated. Two *in vitro* digestibility studies were conducted to determine the lability of the Cry34Ab1 and Cry35Ab1 proteins in an acid environment containing pepsin. In the first *in vitro* digestibility study, 1 microgram (µg) of the 14 kDa protein (Cry34Ab1) were loaded and was visible on the SDS-PAGE gel up to the 15 minute sample point and on the Western blot, which has greater sensitivity, up to the 20 minute time point. Two micrograms of the 44 kDa protein (Cry35Ab1) was loaded on the SDS gel. A single band was observed on the 44 kDa SDS-PAGE at approximately 15 to 16 kDa. Western blot bands were observed at approximately 42 kDa and 14 kDa. These bands were only observed at the one minute time point, but not afterwards. It was concluded that both proteins are susceptible to degradation in the simulated gastric environment, but that the Cry35Ab1 was more rapidly degraded. In the second *in vitro* digestibility study, the digestibility of Cry34Ab1 was further investigated and enzyme kinetics were used in evaluating the data. In this study, 0.36 µg of the protein was loaded in the SDS gel. The protein appears to have approached full degradation by 7.5 minutes. Volumes remaining at the 10 and 15 minute time points were excluded from the calculations since they were below background levels. Using this first order decay model, the DT50 and DT90 for this protein in the simulated gastric fluid GF were estimated to be 1.9 and 6.2 minutes, respectively. The Cry34Ab1 protein is rapidly degraded in the simulated gastric fluid using this assay and detection methodology. The conditions of the assay are biologically appropriate in temperature, pH, and chemical makeup of the digestive solution. The first order decay rate kinetics accurately portray the digestion of Cry34Ab1.

Submitted studies regarding heat stability of the Cry34Ab1 and Cry35Ab1 proteins demonstrate that these proteins are inactivated at ≤90 °C and ≤60 °C, respectively. A comparison of amino acid sequences of known allergens uncovered no evidence of any homology with Cry34Ab1 or Cry35Ab1, even at the level of 8 contiguous amino acids residues. The potential for the Cry34Ab1 and Cry35Ab1 proteins to be food allergens is minimal.

Regarding toxicity to the immune system, the acute oral toxicity data submitted support the prediction that the Cry34Ab1 and Cry35Ab1 proteins would be non-toxic to humans. When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Ref. 3). 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).

Dietary Exposure

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. Oral exposure, at very low levels, may occur from ingestion of processed corn products and, potentially, drinking water. However a lack of mammalian toxicity and the digestibility of the plant-incorporated protectants have been demonstrated. The use sites for the Cry34Ab1 and Cry35Ab1 proteins are all agricultural for control of insects. Therefore, exposure via residential or lawn use to infants and children is not expected. Even if negligible exposure should occur, the Agency concludes that such exposure would present no risk due to the lack of toxicity 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 to these 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, 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 Cry34Ab1 and Cry35Ab1 test materials derived from microbial cultures were 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. When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Ref. 3). Since no treatment-related adverse effects were shown to be caused by Cry34Ab1 and Cry35Ab1 proteins, even at relatively high dose levels (greater than 5,000 mg/kg based upon a dosage of a 1:4.6 ratio mixture of (54% pure) Cry34Ab1 and (37% pure) Cry35Ab1 proteins and greater than 2,000 mg/kg for an equimolar mixture (1:3) of the pure proteins), the Cry34Ab1 and Cry35Ab1 proteins are 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). 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).

Although Cry34Ab1 and Cry35Ab1 expression level data were submitted, 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. Both: (1) Available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers including infants and children); and (2) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives, are generally recognized as appropriate for the use of animal experimentation data were not evaluated. The lack of mammalian toxicity at high levels of exposure to the Cry34Ab1 and Cry35Ab1 proteins demonstrates 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 Cry34Ab1 and Cry35Ab1 proteins in corn have been exempted under the blanket exemption for all nucleic acids (40 CFR 174.175).

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 protein 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 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 these plant-incorporated protectants at this time.

B. Analytical Method

A validated method for extraction and direct enzyme linked immunosorbent assay analysis of Cry34Ab1 in corn grain has been submitted and found acceptable by the Agency.

C. Codex Maximum Residue Level

No Codex maximum residue levels exists for the plant-incorporated protectants *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their 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), 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–2003–0154 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 5, 2003.

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 (1900C), 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 Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0154, to: Public Information and Records Integrity Branch, Information Resources and Services 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 Unit I.B.1. 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. References

1. Astwood J.D., Leach, J.N. and Fuch, R.L. (1996) ''Stability of Food Allergens to Digestion *In Vitro*.'' *Nature Biotech*. 14:1269–1273.

2. Fu, T-J, Abbott, U.R., Hatzos, C. (2002) ''Digestibility of Food Allergens and Nonallergenic Proteins in Simulated Gastric Fluid and Simulated Intestinal Fluid - A Comparative Study.'' *J. Agric. Food Chem.* 50:7154–7160.

3. Sjoblad, Roy D., et al. (1992) ''Toxicological Considerations for Protein Components of Biological Pesticide Products.'' *Regulatory Toxicology and Pharmacology* 15L, 3–9.

X. 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.

XI. 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 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 23, 2003.

James Jones,

Director, Office of Pesticide Programs.

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

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

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

■ 2. Section 180.1242 is added to subpart D to read as follows:

§ 180.1242 Bacillus thuringiensis Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production in corn; temporary exemption from the requirement of a tolerance.

Bacillus thuringiensis Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production in corn are temporarily exempted from the requirement of a tolerance when used as plant-incorporated protectants in the food and feed commodities of field corn, sweet corn and popcorn. 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 permits 68467–EUP–3, 68467–EUP–5, 68467–EUP–T(7), 68467–EUP–I(8), 29964–EUP–1, 29964–EUP–3, 29964–EUP–U(4), and 29964–EUP–L(5) which may be issued and amended/extended 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 April 30, 2006. This temporary exemption from the requirement of a tolerance may be revoked at any time 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.

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