VI. Procedural Determinations

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA [30 U.S.C. 1292(d)] provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 948

Intergovernmental relations, Surface mining, Underground mining.

Dated: August 10, 1995.

Michael K. Robinson,

Acting Regional Director, Appalachian Regional Coordinating Center.

For the reasons set out in the preamble, Title 30, Chapter VII, Subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 948—WEST VIRGINIA

1. The authority citation for Part 948 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. Section 948.15 is amended by adding paragraph (n) to read:

§ 948.15 Approval of regulatory program amendments.

* * * * *

(n) The sections of the amendment submitted by West Virginia to OSM by letter dated July 30, 1993, as revised by submittals dated September 1, 1994, and May 16, 1995, pertaining to durable rock fills are approved effective August 16, 1995.

[FR Doc. 95–20272 Filed 8–15–95; 8:45 am]

BILLING CODE 4310–05–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[PP 4F4395/R2161; FRL–4971–3]

RIN 2070–AB78

Plant Pesticide Bacillus Thuringiensis CryIA(b) Delta-Endotoxin and the Genetic Material Necessary for its Production (Plasmid Vector pCIB4431) in Corn

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the plant pesticide active ingredient *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production (plasmid vector pCIB4431) in corn. A request for an exemption from the requirement of a tolerance was submitted by Ciba-Geigy Corp. (Ciba Seeds). This regulation eliminates the need to establish a maximum permissible level for residues of this plant pesticide in the raw agricultural commodities of field corn, sweet corn, and popcorn.

EFFECTIVE DATE: Effective on August 16, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 4F4395/R2161] and may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections shall be labeled ''tolerance petition fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number, [PP 4F4395/R2161]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Michael L. Mendelsohn, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Office location and telephone number: 5th Floor, CS #1, 2800 Crystal Drive, Arlington, VA 22202, Telephone No.: (703)-308-8715; e-mail: mendelsohn.michael@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Ciba Seeds has genetically modified corn plants to produce a truncated version of the pesticidal CryIA(b) delta-endotoxin protein (derived from the soil microbe *Bacillus thuringiensis*). EPA issued a notice, published in the **Federal Register** of February 1, 1995 (60 FR 6093), which announced that Ciba-Geigy Corp., P.O. Box 12257, Research Triangle Park, NC 27709-2257, had submitted a pesticide petition, PP 4F4395, to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), establish an exemption from the requirement of a tolerance for the plant pesticide *Bacillus thuringiensis* delta-endotoxin as produced in corn by a CryIA(b) gene and its controlling sequences as found on plasmid vector pCIB4431. EPA has assigned the active ingredient of this product the name *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production (plasmid vector pCIB4431) in corn. ''Genetic material necessary for its production'' means the genetic material which comprise (1) genetic material encoding the CryIA(b) delta-endotoxin and (2) its regulatory regions. ''Regulatory regions'' are the genetic materials that control the expression of the genetic material encoding the CryIA(b) delta-endotoxin, such as promoters, terminators, and enhancers.

There were no adverse comments or requests for referral to an advisory committee received in response to the notice of filing of the pesticide petition, PP 4F4395.

Product Analysis

Ciba Seeds submitted information which adequately described the truncated CryIA(b) delta-endotoxin as expressed in corn, along with data on the genetic material necessary for its production.

Product analysis data were submitted to show that microbially expressed and purified CryIA(b) delta-endotoxin used for mammalian toxicological testing purposes is not significantly different than the delta-endotoxin expressed in the plant. The following assays were used to determine the similarity of the microbially expressed and purified CryIA(b) delta-endotoxin and that produced in corn: SDS-PAGE, western blots, amino acid sequencing, certain tests for post-translational modifications, and insect bioactivity. These assays have demonstrated the truncated CryIA(b) delta-endotoxin expressed in corn and the tryptic digested CryIA(b) delta-endotoxin to be similar. The N-terminal amino acid sequences of both delta-endotoxins were found to be identical except that the plant produced delta-endotoxin had portions at the N-terminus deleted, perhaps due to internal plant proteases and a higher bioactivity. These differences were not considered toxicologically significant since they are not expected to change the activity of the deltaendotoxin in mammalian systems.

Toxicology Assessment

The toxicology data provided are sufficient to demonstrate that there are no foreseeable human health hazards likely to arise from the use of *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production (plasmid vector pCIB4431) when used as a plant pesticide in any corn plant.

The data Ciba Seeds submitted regarding potential health effects include information on the characterization of the expressed CryIA(b) delta-endotoxin in corn, the acute oral toxicity, and *in vitro* digestibility of the delta-endotoxin.

Toxicity

The Agency expects that proteins with no significant amino acid homology to known protein toxins and which are readily inactivated by heat or mild acidic conditions would also be readily degraded in an *in vitro* digestibility assay and have little likelihood for displaying oral toxicity.

The data submitted by Ciba Seeds support the prediction that the CryIA(b) protein would be nontoxic to humans. When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels [Sjobald, Roy D., et al. ''Toxicological Considerations for Protein Components of Biological Pesticide Products,'' *Regulatory Toxicology and Pharmacology*, 15, 3-9 (1992)]. Therefore, since no significant acute effects were observed, even at relatively high-dose levels, the CryIA(b) delta-endotoxin is not considered acutely or chronicly toxic. Adequate information was submitted to show that the test materials derived from microbial cultures were biochemically and insecticidally similar to the delta-endotoxin as produced by corn. Production of microbial produced CryIA(b) delta-endotoxin was chosen in order to obtain sufficient material for mammalian testing. In addition, the *in vitro* digestibility studies indicate the delta-endotoxin would be rapidly degraded following ingestion.

The genetic material necessary for the production of the *Bacillus thuringiensis* CryIA(b) delta endotoxin are the nucleic acids (DNA) which comprise (1) genetic material encoding the CryIA(b) delta-endotoxin and (2) its regulatory regions. ''Regulatory regions'' are the genetic material that control the expression of the genetic material encoding the CryIA(b) deltaendotoxin, such as promoters, terminators, and enhancers. DNA is common to all forms of plant and animal life, and the Agency knows of no instance where these nucleic acids have been associated with toxic effects related to their consumption. These ubiquitous nucleic acids as they appear in the subject active ingredient have been adequately characterized by the applicant. Therefore, no mammalian toxicity is expected from dietary exposure to the genetic material necessary for the production of the Bacillus thuringiensis CryIA(b) delta endotoxin in corn.

Allergenicity

Current scientific knowledge suggests that common food allergens tend to be resistant to degradation by heat, acid, and proteases and are glycosylated and present at high concentrations in the food. Ciba Seeds has submitted data to indicate that the CryIA(b) delta-endotoxin is rapidly degraded by gastric fluid *in vitro*, is not present as a major component of food (i.e., is not found in corn kernels and is not detectable in finished silage) and is apparently nonglycosylated or otherwise post-translationally modified when produced in plants.

Studies submitted to EPA done in laboratory animals also have not indicated any potential for allergic reactions to *B. thuringiensis* or its components, including the delta-endotoxin in the crystal protein. Recent *in vitro* studies also confirm that the delta endotoxin would be readily digestible *in vivo*, unlike known food allergens that are resistant to degradation.

Despite decades of widespread use of *Bacillus thuringiensis* as a pesticide (it has been registered since 1961), there have been no confirmed reports of immediate or delayed allergic reactions to the delta-endotoxin itself despite significant oral, dermal, and inhalation exposure to the microbial product. Several reports under FIFRA section 6(a)2 have been made for various *Bacillus thuringiensis* products with allergic reactions being reported. However, these reactions were

determined not to be due to *Bacillus thuringiensis* itself or any of the cry toxins.

Submitted Data

1. *Acute Oral Toxicity of Bacterially Produced CryIA(b) Delta- endotoxin* Five male and five female mice received a single dose of 3,280 mg/kg of CryIA(b) delta-endotoxin by oral gavage. No animals died, nor were there significant clinical signs as a result of the exposure. One female failed to gain weight between day 7 and day 14. All animals gained weight by the end of the study. Males gained more weight over the study than females. The LD_{50} was therefore greater than 3,280 mg/kg, the highest dose tested.

2. *In-Vitro Digestibility of CryIA(b) Delta-endotoxin*. The CryIA(b) delta-endotoxin from either corn or B.t.k. HD19 is rapidly degraded in the presence of pepsin. Using 1/1000 strength pepsin, a time course study shows that the introduced delta-endotoxin from either source degrades within 10 minutes to fragments that lack any immunorecognition in a western blot assay. While this study provides useful information demonstrating the digestibility of the CryIA(b) delta-endotoxin produced in corn, it is not yet a validated study for assessing protein toxicology. It is not clear whether lack of toxicity correlates with *in vitro* digestibility under the conditions of the assay. EPA was relying on this study to demonstrate rapid degradation of the delta-endotoxin.

3. *Acute Oral Toxicity of Corn Leaf Protein Extracted from Bt Corn*. Application of this study to dietary risk assessment is not possible because of extremely low doses administered, small test populations, and unexplained deaths occurring in both control and treated groups. Therefore, EPA is not relying on this study to support the tolerance exemption.

Residue Chemistry Data

Residue chemistry data were not required because of the lack of mammalian toxicity of this active ingredient. In the acute mouse oral toxicity study, the CryIA(b) delta-endotoxin was shown to have an LD_{50} greater than 3,280 mg/kg. When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels [Sjobald, Roy D., et al. ''Toxicological Considerations for Protein Components of Biological Pesticide Products,'' *Regulatory Toxicology and Pharmacology*, 15, 3-9 (1992)]. Therefore, since no significant acute effects were observed, even at relatively high dose levels, the CryIA(b) delta-endotoxin is not considered acutely or chronicly 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 pesticide was derived. [See 40 CFR 158.740(b)] For microbial products, further toxicity testing to verify the observed effects and clarify the source of the effects (Tiers II and III) and residue data are triggered by significant acute effects in studies such as the mouse oral toxicity study.

The genetic material necessary for the production of the *Bacillus thuringiensis* CryIA(b) delta endotoxin are the nucleic acids (DNA) which comprise: (1) genetic material encoding the CryIA(b) delta-endotoxin and (2) its regulatory regions. ''Regulatory regions'' are the genetic materials that control the expression of the genetic material encoding the CryIA(b) deltaendotoxin, such as promoters, terminators, and enhancers. As stated above, no mammalian toxicity is expected from dietary exposure to the genetic material necessary for the production of the *Bacillus thuringiensis* CryIA(b) delta endotoxin in corn. Therefore, no residue data are required in order to grant an exemption from the requirements of a tolerance for the plant pesticide, *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production (plasmid vector pCIB4431) in corn.

Conclusions

Based on the information considered, the Agency concludes that establishment of a tolerance is not necessary to protect the public health. Therefore, the exemption from tolerance is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rule making. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(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 as well as the other materials required by 40 CFR 178.27. A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number [PP 4F4395/R2161] (including objections and hearing requests submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Written objections and hearing requests, identified by the document control number [PP 4F4395/R2161], may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and hearing requests filed with the Hearing Clerk can be sent directly to EPA at:
opp-Docket@epamail.epa.gov

A copy of electronic objections and hearing requests filed with the Hearing Clerk must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all objections and hearing requests submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines ''significant'' as those actions likely to lead to a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

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

Dated: August 7, 1995.

Penelope A. Fenner-Crisp,

Acting Director, Office of Pesticide Programs.

PART 180—[AMENDED]

Therefore, 40 CFR part 180 is amended as follows:

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

Authority: 21 U.S.C. 346a and 371.

2. In subpart D, by adding new § 180.1152, to read as follows:

§ 180.1152 Bacillus thuringiensis CryIA(b) delta-endotoxin and the genetic material necessary for its production (plasmid vector pCIB4431) in corn; exemption from the requirement of a tolerance.

Bacillus thuringiensis CryIA(b) delta-endotoxin and the genetic material necessary for its production (plasmid vector pCIB4431) in corn is exempt from the requirement of a tolerance when used as a plant pesticide in the raw agricultural commodities of field corn, sweet corn, and popcorn. ''Genetic material necessary for its production'' means the genetic materials which comprise genetic material encoding the CryIA(b) delta-endotoxin and its regulatory regions. ''Regulatory regions'' are the genetic materials that control the expression of the genetic material encoding the CryIA(b) delta-endotoxin, such as promoters, terminators, and enhancers.

[FR Doc. 95–20014 Filed 8–15–95; 8:45 am]

BILLING CODE 6560–50–F

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40 CFR Part 180

[OPP–300390A; FRL–4967–6]

RIN 2070–AB78

Dimethoate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an import tolerance for total residues of the insecticide dimethoate including its oxygen analog in or on the raw agricultural commodity blueberries. EPA is issuing this regulation on its own initiative pursuant to a project to harmonize certain tolerances with those established by the Canadian government.

EFFECTIVE DATE: This regulation becomes effective August 16, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [OPP-300390A], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP-300390A]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Robert Forrest, Product Manager (PM) 14, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 259, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6600; e-mail: forrest.robert@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 23, 1995 (60 FR 32641), EPA issued a proposed rule that gave notice that on its own initiative and pursuant to section 408(e) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), EPA proposed to amend 40 CFR 180.204 by establishing an import tolerance for total residues of the insecticide dimethoate including its oxygen anaolog in or on the raw agricultural commodity blueberries at 1 part per million (ppm). As part of the Canada-U.S. Trade Agreement (CUSTA), and through the Pesticides Technical Working Group's Maximum Residue Limit (MRL) Harmonization Pilot Project, the Canadian government has requested that the U.S. establish a tolerance of 1 ppm for residues of dimethoate in or on blueberries. The insecticide is registered for use on blueberries in Canada, but not in the U.S. The Canadian tolerance is 1 ppm. The Agency has reviewed Canadian crop field trial residue data and determined that they are adequate to support an import tolerance.