

establishing a precedent for any future request for revision to any SIP. Each request for a revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Executive Order 12866

This action has been classified as a Table 3 action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214-2225). The Office of Management and Budget has exempted this regulatory action from review under Executive Order 12866.

Regulatory Flexibility

Under the Regulatory Flexibility Act, 5 U.S.C. Section 600 *et seq.*, USEPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities (5 U.S.C. Sections 603 and 604). Alternatively, USEPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000. This approval does not create any new requirements.

Therefore, I certify that this action does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the Act, preparation of the regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of the State action. The Act forbids USEPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S. EPA*, 427 U.S. 246, 256-66 (1976).

Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, USEPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of \$100 million or more. Under section 205, USEPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires USEPA to establish a plan for informing and advising any small governments that may be

significantly or uniquely impacted by the rule.

The USEPA has determined that the approval action promulgated today does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector.

This Federal action approves pre-existing requirements under State or local law, and imposes no new Federal requirements. Accordingly, no additional costs to State, local, or tribal governments, or the private sector, result from this action.

Petitions for Judicial Review

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 13, 1995. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such a rule. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: August 17, 1995.

Valdas V. Adamkus,

Regional Administrator.

40 CFR part 81 is amended as follows:

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401-7671q.

§ 81.350 [Amended]

2. In § 81.350 the table entitled "Wisconsin-TSP" is removed.

[FR Doc. 95-22620 Filed 9-12-95; 8:45 am]

BILLING CODE 6560-50-P

40 CFR Part 180

[PP 4F4389/R2163; FRL-4973-3]

RIN 2070-AB78

CryIA(c) and CryIC Derived Delta Endotoxins of *Bacillus Thuringiensis* Encapsulated in Killed *Pseudomonas fluorescens*; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of CryIA(c) and CryIC derived *Pseudomonas fluorescens* (MATTCH Biosecticide) in or on all raw agricultural commodities. Mycogen Corp. submitted a request for an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of this pesticide in or on all raw agricultural commodities.

EFFECTIVE DATE: Effective on September 13, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 4F4389/R2163], 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 4F4389/R2163]. 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: Willie H. Nelson, 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, 703-308-8715; e-mail: nelson.willie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 17, 1995, EPA issued a notice that Mycogen Corp., 4980 Carroll Canyon Rd., San Diego, CA 92121, had submitted a pesticide petition (PP 4F4389) 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 a blend of CryIA(c) and CryIC derived delta-endotoxins of pesticide *Bacillus thuringiensis* encapsulated in killed *Pseudomonas fluorescens* for all raw agricultural commodities (RAC's) when used in accordance with good agricultural practices.

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 4F4389.

Product Analysis

Mycogen Corp. submitted information which adequately described its product (MATTCH). This product consists of a mixture of two lepidopteran active toxins derived from naturally occurring delta endotoxins as found in *Bacillus thuringiensis*. Delta endotoxins active against lepidopteran species are formed as protoxins that are activated in the alkaline gut environment of the insect. The active toxins in this product are referred to by Mycogen Corp. as CryIA(c) and CryIC due to their amino acid sequence similarity to these toxins. The protoxin portion of these derived toxins comes from another CryI protein. These are produced in *Pseudomonas fluorescens*.

The data submitted in the petition and all other relevant material have been evaluated. The toxicological data considered in support of the exemption from the requirement of a tolerance

include the following: an acute oral toxicity/pathogenicity study, an *in-vitro* digestibility study, and abridged data from Mycogen's previously registered MVP product.

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 CryIA(c) and CryIC derived delta-endotoxins of *Bacillus thuringiensis* encapsulated in killed *Pseudomonas fluorescens*.

Mycogen's data on potential health effects include information on the characterization of the expressed CryIA(c) and CryIC derived delta-endotoxin, the acute oral toxicity, and the *in vitro* digestibility of the delta-endotoxin. No potential health effects are expected from the use of this product.

Toxicity

The Agency expects that proteins with no significant amino acid homology to known mammalian 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 of displaying oral toxicity in laboratory rodents.

Mycogen's data support the prediction that the CryIA(c) and CryIC proteins 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(c) and CryIC delta-endotoxins are not considered acutely or chronically toxic. In addition, the *in vitro* digestibility studies indicate the delta-endotoxin would be rapidly degraded following ingestion.

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.

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 CryIC delta-endotoxin was shown to have an LD₅₀ greater than 5,050 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 CryIC delta-endotoxin is not considered acutely or chronically 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, III) and residue data are triggered by significant acute effects in studies such as the mouse oral toxicity study.

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 the requirement of a 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, 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 of 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 4F4389/R2163] (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 4F4389/R2163], 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 in 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 recordkeeping requirements.

Dated: August 31, 1995.

Daniel M. Barolo,

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 § 180.1154, to read as follows:

§ 180.1154 CryIA(c) and CryIC derived Delta-Endotoxins of *Bacillus thuringiensis* var. *kurstaki* Encapsulated in killed *Pseudomonas fluorescens*, and the expression plasmid and cloning vector genetic constructs.

CryIA(c) and CryIC derived delta-endotoxins of *Bacillus thuringiensis* var. *kurstaki* encapsulated in killed *Pseudomonas fluorescens* and the expression plasmid and cloning vector genetic constructs are exempt from the requirement of a tolerance when used in or on all raw agricultural commodities.

[FR Doc. 95-22617 Filed 9-12-95; 8:45 am]

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40 CFR Part 300

[FRL-5294-3]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List Update

AGENCY: Environmental Protection Agency.

ACTION: Notice of deletion of the Jackson Township Landfill Superfund Site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) Region II announces the deletion of the Jackson Township Landfill Superfund site (Site) in Ocean County, New Jersey from the National Priorities List (NPL). The NPL is Appendix B of 40 CFR Part 300, the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. EPA and the State of New Jersey have determined that all appropriate Fund-financed responses under CERCLA have been implemented at the Site and that no further cleanup by responsible parties is appropriate. Moreover, EPA and the State of New Jersey have determined that remedial actions conducted at the Site to date remain protective of public health, welfare, and the environment.

EFFECTIVE DATE: September 13, 1995.

ADDRESSES: Comprehensive information on this site is available at the following addresses:

Jackson Township Municipal Complex,
RD#4, Box 1000, Jackson, NJ 08527,
Phone: (908) 928-1200

Ocean County Library, 101 Washington Street, Toms River, NJ 08753, Phone: (908) 349-6200.

FOR FURTHER INFORMATION CONTACT: Mr. Joseph Gowers, Remedial Project Manager, U.S. Environmental Protection