

§ 180.1175 [Removed]

3. Section 180.1175 is removed.

[FR Doc. 97-9373 Filed 4-10-97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-300462; FRL-5596-7]

RIN 2070-AB78

Bacillus Thuringiensis Subspecies Kurstaki CryIA(c) and the Genetic Material Necessary for Its Production in All Plants; Exemption From the Requirement of a Tolerance on All Raw Agricultural Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of the plant-pesticides CryIA(c) and the genetic material necessary for its production in all plants when used as plant-pesticides in or on all raw agricultural commodities. Dekalb Genetics Corporation submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act of 1996 requesting the exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of this plant-pesticides in or on all raw agricultural commodities.

EFFECTIVE DATE: This regulation becomes effective on April 11, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300462], 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 docket 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.

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 control number [OPP-300462]. 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 in Unit VIII. of this preamble.

FOR FURTHER INFORMATION CONTACT: By mail: Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 5th Floor Crystal Station, 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8715; email: mendelsohn.mike@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 24, 1997 (62 FR 3682)(FRL-5380-2), EPA issued a notice pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d) announcing the filing of a pesticide petition for an exemption from the requirement of a tolerance by Dekalb Genetics Corporation (Dekalb), 3100 Sycamore Road, Dekalb, IL 60115. The notice contained a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (Pub. L. 104-170). The petition requested that an exemption from the requirement of a tolerance be established for the plant-pesticides *Bacillus thuringiensis* subspecies *kurstaki* CryIA(c) [CryIA(c)] and the genetic material necessary for its production in plants in or on all raw agricultural commodities (RACS). There were no comments or requests for referral to an advisory committee received in response to the notices of filing. The data submitted in the petition and other relevant material have been evaluated. The toxicology

and other data listed below were considered in support of this exemption from the requirement of a tolerance.

I. Toxicological Profile

The data submitted regarding potential health effects of CryIA(c) include information on the characterization of the expressed protein in corn, the acute oral toxicity of CryIA(c), and *in vitro* digestibility studies of the protein. 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. The acute oral toxicity test of bacterially-derived CryIA(c) protein showed no test substance related deaths at a dose of 5,000 mg/kg. Although CryIA(c) expression level data were required for an environmental fate and effects assessment, residue chemistry data were not required for a human health effects assessment of the subject plant-pesticides 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 because the lack of mammalian toxicity at high levels of exposure demonstrate the safety of the product at levels above possible maximum exposure levels. This is similar to the Agency position regarding toxicity and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which these plant-pesticides are 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 acute oral toxicity data submitted support the prediction that the CryIA(c) protein would be non-toxic to humans. When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels [Sjogblad, 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-pesticides, even at relatively high dose

levels, the CryIA(c) delta-endotoxin protein is not considered toxic.

Adequate information was submitted to show that the CryIA(c) test material derived from microbial cultures was biochemically and, functionally similar to the protein produced by the plant-pesticide ingredient in corn. Production of microbially produced protein was chosen in order to obtain sufficient material for testing. In addition, the *in vitro* digestibility studies indicate the proteins would be rapidly degraded following ingestion.

The genetic material necessary for the production of the plant-pesticides active and inert ingredients are the nucleic acids (DNA) which comprise (1) genetic material encoding these proteins and (2) their regulatory regions. "Regulatory regions" are the genetic material that control the expression of the genetic material encoding the proteins, 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 as a component of food. These ubiquitous nucleic acids as they appear in the subject active ingredients has been adequately characterized by the applicant. Therefore, no mammalian toxicity is anticipated from dietary exposure to the genetic material necessary for the production of the subject active and inert plant pesticidal ingredients.

II. Sensitivity of Subgroups

The Agency has considered available information on the variability of the sensitivities of major identifiable subgroups of consumers including infants and children and the physiological differences between infants and children and adults and effects of *in utero* exposure to the plant-pesticides. Since CryIA(c) is a protein, allergenic sensitivities were considered. Current scientific knowledge suggests that common food allergens tend to be resistant to degradation by heat, acid, and proteases, are glycosylated and present at high concentrations in the food. Data has been submitted which demonstrate that the CryIA(c) delta-endotoxin is rapidly degraded by gastric fluid *in vitro* and is non-glycosylated. Studies submitted to EPA done in laboratory animals have not indicated any potential for allergic reactions to *Bacillus thuringiensis* or its components, including the delta-endotoxin in the crystal protein. 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 claiming allergic reactions. However, the Agency determined these reactions were not due to *Bacillus thuringiensis* itself or any of the Cry toxins. Thus, the potential for the CryIA(c) protein to be a food allergen is minimal.

III. Cumulative Effects

The Agency 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-pesticides, there are no cumulative effects.

IV. Aggregate Exposures

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-pesticides chemical residue, and exposure from non-occupational sources. Exposure via the skin or inhalation is not likely since the plant-pesticides are 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 drinking water. However a lack of mammalian toxicity and the digestibility of the plant-pesticides has been demonstrated. The use sites for CryIA(c) delta endotoxin are all agricultural for control of lepidopteran 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.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a

different margin of exposure (safety) will be safe for infants and children. In this instance, EPA believes there is reliable data to support the conclusion that the plant-pesticides are not toxic to mammals, including infants and children and thus there are no threshold effects of concern. As a result, the provision requiring an additional margin of exposure does not apply.

V. Endocrine Effects

EPA does not have any information regarding endocrine effects on these pesticides at this time. The Agency is not requiring information on the endocrine effects of these plant-pesticides at this time; and Congress allowed 3 years after August 3, 1996, for the Agency to implement a screening and testing program with respect to endocrine effects.

VI. 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 CryIA(c) protein and the genetic material necessary for its production. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

The Agency has arrived at this conclusion because, as discussed above, no toxicity to mammals has been observed for the plant-pesticides. As a result, EPA establishes an exemption from tolerance requirements pursuant to FFDCA section 408(j)(3) for *Bacillus thuringiensis* CryIA(c) delta-endotoxin and the genetic material necessary for its production in all plants.

Bacillus thuringiensis subspecies *kurstaki* CryIA(c) delta-endotoxin and the genetic material necessary for its production in all plants are exempt from the requirement of a tolerance when used as plant-pesticides in all plant raw agricultural commodities. "Genetic material necessary for its production" means the genetic material which comprise (1) genetic material encoding the CryIA(c) delta-endotoxin and (2) its regulatory regions. "Regulatory regions" are the genetic material that control the expression of the genetic material encoding the CryIA(c) delta-endotoxin, such as promoters, terminators, and enhancers.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) 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 section 408 and in section 409.

However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by June 10, 1997 file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the Virginia address given under the **ADDRESSES** section (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 rulemaking. 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 (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 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

VIII. Public Docket

A record has been established for this rulemaking under docket control

number [OPP-300462]. A public version of this record, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 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.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing requests, EPA will transfer any copies of 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. The official rulemaking record is the paper record maintained at the address in ADDRESSES at the beginning of this document.

IX. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and since this action does not impose any information collection requirements subject to approval under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, or contain any "unfunded mandates" as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because exemptions from the requirement of a tolerance established on the basis of a petition under section 408(d) of FFDCA do not require issuance of a proposed rule, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 604(a), do not apply. Prior to the recent amendment of the FFDCA, EPA had treated such rulemakings as subject to the RFA; however, the amendments to the FFDCA clarify that no proposal is required for such rulemakings and hence that the RFA is inapplicable. Nonetheless, the Agency has previously

assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded as a generic matter, that there is no adverse impact (46 FR 24950, May 4, 1981).

Pursuant to 5 U.S.C. 801(a)(1)(A), EPA submitted 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 General Accounting Office prior to publication of the rule in today's **Federal Register**. This 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: March 25, 1997.

Daniel M. Barolo,

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. 346a and 371.

2. Section 180.1155 is revised to read as follows:

§ 180.1155 *Bacillus thuringiensis* subspecies *kurstaki* CryIA(c) and the genetic material necessary for its production in all plants; exemption from the requirement of a tolerance.

Bacillus thuringiensis subspecies *kurstaki* CryIA(c) delta-endotoxin and the genetic material necessary for its production in all plants are exempt from the requirement of a tolerance when used as plant-pesticides in all plant raw agricultural commodities. "Genetic material necessary for its production" means the genetic material which comprise genetic material encoding the CryIA(c) delta-endotoxin and its regulatory regions. "Regulatory regions" are the genetic material that control the expression of the genetic material encoding the CryIA(c) delta-endotoxin, such as promoters, terminators, and enhancers.

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