

EPA issued a notice, published in the **Federal Register** of January 13, 1995 (60 FR 3209) (FRL-4928-9), which announced that Ciba-Geigy Corporation (Ciba-Seeds), 3054 Cornwallis Road, P.O. Box 12257, Research Triangle Park, NC, 27709, (now Novartis Seeds), had submitted an application to register the transgenic plant pesticide B.t.k. CryIA(b) Insect Control Protein as Produced in Corn (EPA File Symbol 66736-R) containing the active ingredient *Bacillus thuringiensis* delta-endotoxin as produced in corn by a cryIA(b) gene and its controlling sequences as found on plasmid vector pCIB4431 0.0001-0.0018 percent total plant protein an active ingredient not included in any previously registered product.

The application was approved on August 9, 1995, and was published in the **Federal Register** of February 14, 1996 (61 FR 5768) (FRL-4980-5), involving a changed use pattern, to include in its presently registered use, a new use for full commercial use in field corn (EPA Registration Number 66736-1). The registration was conditionally amended to allow additional use of the product for food and feed in field corn in accordance with FIFRA section 3(c)(7)(B).

On March 17, 1998 the amendment of this registration was approved as "*Bacillus Thuringiensis* European Corn Borer Control Protein" to include popcorn, containing the active ingredient *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production (pCIB4431 in corn) involving a changed use pattern. This use is conditional and requires insect resistance data management, USDA NC-205 guidelines for refuge must be followed for popcorn, and monitoring for resistance management of the registration.

A conditional registration may be granted under section 3(c)(7)(B) of FIFRA for a product involving a changed use pattern where certain data are lacking, on condition that such data are received as specified by EPA and the applicant has submitted satisfactory data pertaining to the proposed additional use and the amended registration would not significantly increase the risk of any unreasonable adverse effect.

The Agency has considered the available data on the risks associated with the proposed use of *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production (pCIB4431 in corn), and information on social, economic, and environmental benefits to be derived

from such use. Based on these reviews, the Agency was able to make basic environmental, health, and safety determinations which show that use of *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production (pCIB4431 in corn) consistent with the terms and conditions of registration during the period of conditional registration will not significantly increase the risk of unreasonable adverse effect on the environment. These products are conditionally registered in accordance with FIFRA section 3(c)(7)(B).

If the conditions are not complied with the registration will be subject to cancellation in accordance with FIFRA section 6(e). The registration will automatically expire on midnight April 1, 2001.

More detailed information on the conditional registration is contained in an EPA Pesticide Fact Sheet on *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production (pCIB4431 in corn).

A copy of this fact sheet, which provides a summary description of the chemical, use patterns and formulations, science findings, and the Agency's regulatory position and rationale, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label, the list of data references, the data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are available for public inspection in the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 119, CM #2, Arlington, VA 22202 (703-305-5805). Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A-101), 401 M St., SW., Washington, DC 20460. Such requests should: (1) Identify the product name and registration number and (2) specify the data or information desired.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pests, Product registration.

Dated: July 28, 1998.

Janet L. Andersen,

Director, Biopesticides Pollution Prevention Division, Office of Pesticide Programs.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-00542; FRL-5797-9]

Guidance for Identifying Pesticides That Have a Common Mechanism of Toxicity; Notice of Availability and Solicitation of Public Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability and solicitation of public comments.

SUMMARY: EPA is soliciting comments on a proposed pesticide policy guidance document entitled "Guidance for Identifying Pesticide Chemicals That Have a Common Mechanism of Toxicity, for Use in Assessing the Cumulative Toxic Effects of Pesticides." This proposed guidance document was developed from a background document that was announced and made available to the public for comment, and discussed publicly at the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Science Advisory Panel (SAP) meeting of March 19-20, 1997. Interested parties may request a copy of the Agency's proposed guidance document as set forth in the ADDRESSES unit of this Notice.

DATES: Comments must be received by September 8, 1998.

ADDRESSES: By mail, submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, deliver comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under Unit IV. of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted as a comment concerning this document 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 comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. The public docket is available for public inspection in Rm. 119 at the Virginia address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

This Notice and the proposed guidance document described herein are available by mail or electronically. To obtain electronic copies follow the instructions listed under Unit I. of this document. To obtain copies by mail contact: Elizabeth Doyle, Office of Pesticide Programs, Health Effects Division (7509C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 718G, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 308-2722, e-mail: doyle.elizabeth@epamail.epa.gov.

FOR FURTHER INFORMATION CONTACT: Elizabeth Doyle at the address or telephone number listed above.

SUPPLEMENTARY INFORMATION:

I. Electronic Availability

A. Internet

Electronic copies of this document and the guidance document are available from the EPA Home Page at the Federal Register--Environmental Documents entry for this document under "Laws and Regulations" (<http://www.epa.gov/fedrgstr/>). Copies are also available electronically from EPA's Office of Pesticide Programs Home Page (<http://www.epa.gov/pesticides>) under "FQPA, Science Issues."

B. Fax-On-Demand

Using a faxphone call 202-401-0527 and select item 6055 for a copy of the guidance document.

II. Background

This **Federal Register** notice announces the availability of the proposed EPA pesticide policy guidance document entitled "Guidance for Identifying Pesticide Chemicals That Have a Common Mechanism of Toxicity, for Use in Assessing the Cumulative Toxic Effects of Pesticides." This guidance document was developed by EPA in response to the recent amendments to FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA) as promulgated by the Food Quality Protection Act of 1996 (FQPA). These amendments require EPA to consider in their process of determining safety of a

given pesticide the possibility of cumulative toxic effects resulting from aggregate exposure to the pesticide and other pesticides that are toxic from a common mechanism. Hence, in assessing the risks posed by a given pesticide, EPA must also assess the combined risks to human health that can result from exposure to the pesticide and other pesticides that have a common mechanism of toxicity. The guidance document describes the approach that EPA will use for identifying and categorizing pesticide chemicals that have common mechanisms of toxicity for purposes of assessing the cumulative toxic effects of such pesticides. Specifically, the proposed guidance document describes:

- EPA's interpretation of common mechanism of toxicity with respect to making a determination of safety under FFDCA as amended by FQPA.
- The specific steps that need to be taken for identifying, inferring, or refuting a common mechanism of toxicity.
- The types of data (and their sources) that are needed for doing so.
- How these data are to be used in making decisions regarding common mechanisms of toxicity.
- Factors that will be considered when conducting combined risk assessments that characterize whether or not cumulative toxic effects can reasonably be expected to occur following exposure to two or more pesticide substances that are toxic from a common mechanism.

III. Comments

All public comments concerning the background document were presented to the FIFRA Scientific Advisory Panel prior to the March 1997 meeting. The background document and comments were discussed openly at the meeting. Changes recommended by the Panel concerning the background document were fully considered by EPA when finalizing the guidance document. The recommended changes, as well as a summary of the Agency's responses to the changes, are filed in public docket.

IV. Public Record and Electronic Submissions

The official record for this action, as well as the public version, has been established for this action under docket control number "OPP-00542" (including comments and data 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 8:30

a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the Virginia address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at:
opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number "OPP-00542." Electronic comments on this document may be filed online at many Federal Depository Libraries.

List of Subjects

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

Dated: July 23, 1998.

Stephen L. Johnson,
Acting Director, Office of Pesticide Programs.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-6137-3]

Announcement of Small System Compliance Technology Lists for Existing National Primary Drinking Water Regulations and Findings Concerning Variance Technologies

AGENCY: Environmental Protection Agency.

ACTION: Notice of lists of technologies and upcoming release of guidance and supporting documents.

SUMMARY: The Environmental Protection Agency (EPA) announces the Small System Compliance Technology Lists and the upcoming release of three guidance documents and three supporting documents. These lists, guidance and supporting documents are related to the provisions in the Safe Drinking Water Act (SDWA), as amended in 1996. The three guidance documents are: EPA-815-R-98-001, Small System Compliance Technology List for the Surface Water Treatment Rule and Total Coliform Rule which includes an update of the existing document-EPA 815-R-97-002; EPA-815-R-98-002, Small System Compliance Technology List for the