

### B. Product Identity and Chemistry

The Cry34Ab1 and Cry35Ab1 genes were isolated from *Bacillus thuringiensis* strain PS149B1 and modified before insertion into corn plants. The Cry34/35Ab1 ICP has been adequately characterized. Several safety studies were conducted using microbially produced test substances that contained 54% of the Cry34Ab1 (14 kDa) protein and 37% of the Cry35Ab1 (44 kDa) protein. Studies conducted to establish the equivalence of the Cry34/35Ab1 ICP obtained from corn or from a microbial source demonstrate that the materials are similar with respect to molecular weight, immunoreactivity, lack of post-translational modification (glycosylation) N-terminal amino acid sequence, and spectrum of bioactivity.

A qualitative analytical method (lateral flow immunoassay) for the detection of the Cry34Ab1 (14 kDa) protein has been submitted (MRID #45383401).

### C. Mammalian Toxicity Profile

Cry proteins have been deployed as safe and effective pest control agents in microbial *Bacillus thuringiensis* formulations for almost 40 years. There are currently 180 registered microbial *Bacillus thuringiensis* products in the United States for use in agriculture, forestry, and vector control. The numerous toxicology studies conducted with these microbial products show no significant adverse effects, and demonstrate that the products are practically non-toxic to mammals. An exemption from the requirement of a tolerance has been in place for these products since at least 1971 (40 CFR 180.1011).

Toxicology studies conducted to determine the toxicity of Cry34/35Ab1 ICP demonstrated that the proteins have very low toxicity. The acute oral LD<sub>50</sub> of Cry34Ab1 (14 kDa) is greater than 5,000 milligrams/kilogram (mg/kg), and at 54% purity, the acute LD<sub>50</sub> for pure protein is greater than 2,700 mg/kg. The acute oral LD<sub>50</sub> of Cry35Ab1 (44 kDa) is greater than 5,000 mg/kg, and at 37% purity, the acute LD<sub>50</sub> for pure protein is greater than 1,850 mg/kg in male mice when the proteins were tested individually. When tested as a mixture (1:3 molar ratio of Cry34Ab1:Cry35Ab1 proteins), the acute oral LD<sub>50</sub> of PS149B1 Cry34/35Ab1 proteins in male and female mice is greater than 5,000 mg/kg, and greater than 2,000 mg/kg of an equimolar (1:3) mixture of pure proteins.

In *in vitro* studies, Cry34/35Ab1 ICP exhibited a high rate of digestibility under simulated gastric conditions

(referred to as SGF) in the presence of pepsin. The Cry34Ab1 (14 kDa protein) was greater than 90% digested in SGF 6.2 minutes. The Cry35Ab1 (44 kDa protein) was greater than 97% digested in less than 5 minutes. Also, thermolability testing results showed that the ICP was deactivated following exposure to 60 °C, 75 °C, and 90 °C for 30 minutes. A search of relevant data bases indicated that the amino acid sequences of the Cry34/35Ab1 ICP exhibit no significant homology to the sequences of known protein allergens. Thus, Cry34/35Ab1 ICP is highly unlikely to exhibit an allergic response.

The genetic material necessary for the production of the Cry34/35Ab1 ICP is nucleic acid (DNA) which is common to all forms of plant and animal life. There are no known instances where nucleic acids have caused toxic effects as a result of dietary exposure.

Collectively, the available data on Cry34/35Ab1 ICP along with the safe use history of microbial *Bacillus thuringiensis* products establishes the safety of the plant-incorporated protectant *B.t.* Cry34/35Ab1 ICP and the genetic material necessary for its production in all raw agricultural commodities.

### D. Aggregate Exposure

Because *B.t.* Cry34/35Ab1 ICP is expressed in minute quantities and is retained within the plant, there is virtually no potential for dermal or inhalation exposure to the protein. Significant dietary exposure to Cry34/35Ab1 ICP is unlikely to occur. Dietary exposures at very low levels, via ingestion of processed commodities, although, they may occur, are unlikely to be problematic because of the low toxicity and the high degree of digestibility of the protein. In addition, the protein is not likely to be present in drinking water because the protein is deployed in minute quantities within the plant, and studies demonstrate that Cry34/35Ab1 ICP is rapidly degraded in soil. In summary, the potential for significant aggregate exposure to Cry34/35Ab1 is highly unlikely.

### E. Cumulative Exposure

Common modes of toxicity are not relevant to consideration of the cumulative exposure to *B.t.* Cry34/35Ab1 ICP. The product has demonstrated low toxicity, and these effects do not appear to be cumulative with any other known compounds.

### F. Safety Determination

1. *U.S. population.* The deployment of the product in minute quantities within the plant, the very low toxicity of the

product, the lack of allergenic potential, and the high degree of digestibility of the proteins, are all factors in support of Mycogen/Dow AgroSciences' assertion that no significant risk is posed by exposure of the U.S. population to *B.t.* Cry34/35Ab1 ICP.

2. *Infants and children.* Non-dietary exposure to infants and children is not anticipated, due to the proposed use pattern of the product. Due to the very low toxicity of the product, the lack of allergenic potential, and the high degree of digestibility of the proteins, dietary exposure is anticipated to be at very low levels and is not anticipated to pose any harm to infants and children.

### G. Effects on the Immune and Endocrine System

Given the high degree of digestibility of the Cry34/35Ab1 ICP, no chronic effects are expected. Cry34/35Ab1 ICP, or metabolites of the ICP are not known to, or are expected to have any effect on the immune or endocrine systems. Proteins in general are not carcinogenic, therefore, no carcinogenic risk is associated with the Cry34/35Ab1 ICP.

### H. Existing Tolerances or Exemptions from Tolerance

There are no existing tolerances or exemptions from tolerance for *B.t.* Cry34/35Ab1 ICP.

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BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0016; FRL-7289-3]

### Experimental Use Permit; Receipt of Application

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

**SUMMARY:** This notice announces receipt of an application 68467-EUP-4 from Mycogen Seeds/Dow Agrosciences LLC requesting an experimental use permit (EUP) amendment/extension for *Bacillus thuringiensis* moCry1F protein and the genetic material necessary for its production (plasmid insert PHP 12537) in corn. The Agency has determined that the application may be of regional and national significance. Therefore, in accordance with 40 CFR 172.11(a), the Agency is soliciting comments on this application.

**DATES:** Comments, identified by docket ID number OPP-2003-0016, must be received on or before April 7, 2003.

**ADDRESSES:** Comments may be submitted electronically, by mail, or

through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8715; e-mail address: [mendelsohn.mike@epa.gov](mailto:mendelsohn.mike@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

This action is directed to the public in general. This action may, however, be of interest to those persons who are interested in agricultural biotechnology or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. 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-2003-0016. 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/>.

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. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. 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. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's

electronic public docket along with a brief description written by the docket staff.

*C. How and To Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2003-0016. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to [opp-docket@epa.gov](mailto:opp-docket@epa.gov), Attention: Docket ID Number OPP-

2003-0016. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2003-0016.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP-2003-0016. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

#### *D. How Should I Submit CBI To the Agency?*

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI.

Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

#### *E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the notice.
7. Make sure to submit your comments by the deadline in this document.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

#### **II. Background**

Mycogen Seeds/Dow AgroSciences LLC has applied to amend/extend 68467-EUP-4 for *Bacillus thuringiensis* moCry1F protein and the genetic material necessary for its production (plasmid insert PHP 12537) in corn to allow the planting of 291 acres of field corn to conduct insect resistance management, agronomic observation, breeding and observation nursery, efficacy, maize demonstration, and herbicide tolerance study trials. The Mycogen Seeds' program is authorized in the States of California, Colorado, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New York, North Dakota, Ohio, Oklahoma, Pennsylvania, South Dakota, Texas, Virginia, and Wisconsin and the Commonwealth of Puerto Rico. The original notice of approval for this EUP published in the **Federal Register** on June 26, 2002 (67 FR 43115) (FRL-7182-2).

#### **III. What Action is the Agency Taking?**

Following the review of the Mycogen Seeds/Dow Agrosciences LLC application and any comments and data received in response to this notice, EPA

will decide whether to issue or deny the EUP request. Any issuance of the EUP will be announced in the **Federal Register**.

#### **IV. What is the Agency's Authority for Taking this Action?**

The specific legal authority for EPA to take this action is under FIFRA section 5.

#### **List of Subjects**

Environmental protection,  
Experimental use permits.

Dated: February 28, 2003.

**Janet L. Andersen,**

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

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#### **ENVIRONMENTAL PROTECTION AGENCY**

[FRL-7459-6]

#### **Proposed Administrative Peripheral Party, Inability To Pay, Cash-out Agreement Under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 Regarding the Meadowlands Plating & Finishing Site, East Rutherford, NJ**

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of proposed administrative cash-out agreement and opportunity for public comment.

**SUMMARY:** The Environmental Protection Agency ("EPA") is proposing to enter into an administrative settlement to resolve claims under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended ("CERCLA"), 42 U.S.C. "9601 *et seq.* In accordance with EPA guidance, notice is hereby given of a proposed administrative settlement pursuant to section 122(h)(1) of CERCLA concerning the Meadowlands Plating & Finishing Site, located in East Rutherford, New Jersey. Notice is being published to inform the public of the proposed settlement and of the opportunity to comment. This settlement is intended to resolve a responsible party's civil liability for response costs incurred by EPA at the Meadowlands Plating & Finishing Site. CERCLA provides EPA the authority to settle certain claims for response costs incurred by the United States with the approval of the Attorney General of the United States.