

absorption factor of 12% from a dermal penetration study in rats submitted by Bayer (MRID #44538505) was used. Based on the assumptions below and the default factors from the SOP, a MOE of 2,299 (Exp=0.07 mg/kg/day) is obtained for adult females. This is well above the level of concern (LOC) for propamocarb hydrochloride based on a MOE of 100. This analysis is a very conservative estimate based on EPA screening level procedures. Actual exposures are likely to be much lower, if they occur at all.

#### D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The precise mechanism of toxicity for propamocarb hydrochloride is unknown. Although a member of the carbamate group of pesticides, propamocarb hydrochloride is not an *n*-methyl carbamate, and demonstrated no inhibitory effects on blood or brain cholinesterase following either acute or repeated oral administrations to rats and dogs. *In vitro* studies using rat or dog blood plasma showed very slight cholinesterase inhibitory effects only at extremely high dose levels, equivalent to about 2,200 mg/kg bodyweight. This level is 20,000X the established RfD for propamocarb hydrochloride. Thus, no cumulative effects with other carbamates are anticipated. There is no other available data to determine whether propamocarb hydrochloride has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, propamocarb hydrochloride does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance petition, therefore, it has not been assumed that propamocarb hydrochloride has a common mechanism of toxicity with other substances.

#### E. Safety Determination

1. *U.S. population.* Using the conservative assumptions described above, based on the completeness and reliability of the toxicity data, it is concluded that chronic dietary exposure to the proposed uses of propamocarb hydrochloride will utilize at most 18% of the chronic reference dose for the

U.S. population. The actual exposure is likely to be much less as more realistic data and models are developed. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risk to human health. The acute population of concern, female 13+ utilizes 7% of the acute RfD. Again, this is a Tier I highly conservative assessment and actual exposure is likely to be far less. A very conservative "worst-case" aggregate assessment for females 13+ results in utilization of 11% of the RfD. DWLOCs based on the dietary and aggregate exposures are greater than highly conservative estimated levels, and would be expected to be well below the 100% level of the RfD, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure (food, drinking water, and non-dietary) to residues of propamocarb hydrochloride.

2. *Infants and children.* No treatment-related effects to either parental animals or offspring were noted in either a 3-generation rat reproduction study at dose levels up to 1,000 ppm (33.3 mg/kg/day) or a 2-generation rat reproduction study at dose levels up to 1,250 ppm (81 mg/kg/day in males, 127 mg/kg/day in females). No evidence of teratogenicity was noted in either rat or rabbit developmental toxicity studies, even at maternally toxic dose levels. Increased post-implantation loss was noted in the rabbit study, but only at maternally toxic dose levels. The NOAEL for both maternal and developmental toxicity in rabbits was 150 mg/kg/day.

Decreased fetal weights, increased post-implantation loss and retarded ossification were noted in rats, and the developmental NOAEL of 221 mg/kg/day was lower than the maternal NOAEL of 740 mg/kg/day.

FFDCA section 408 provides that the Agency may apply an additional safety factor for infants and children to account for prenatal and postnatal toxicity or incompleteness of the database. The toxicology database for propamocarb hydrochloride regarding potential prenatal and postnatal effects in children is complete according to existing Agency data requirements and does not indicate any particular developmental or reproductive concerns, therefore an additional UF to protect infants and children is not needed. Using the conservative assumptions described in the exposure section above, the percent of the chronic RfD that will be used for exposure to

residues of propamocarb hydrochloride in food for children 1 to 6 (the most highly exposed sub group) is 24%. Infants utilize 4% of the chronic RfD. There are no chronic non-dietary concerns for infants and children.

All DWLOCs are higher than the worst case DWECs and are expected to use well below 100% of the RfD. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of propamocarb hydrochloride.

#### F. International Tolerances

The Codex Alimentarius Commission (Codex) has established tolerances (maximum residue levels) for propamocarb hydrochloride in the following raw agricultural commodities: Beetroot at 0.2 ppm, brussel sprouts at 1.0 ppm, cabbage (head) at 0.1 ppm, cauliflower at 0.2 ppm, celery at 0.2 ppm, cucumber at 2.0 ppm, lettuce (head) at 10 ppm, pepper (sweet) at 1.0 ppm, radish at 5.0 ppm, strawberry at 0.1 ppm and tomato at 1.0 ppm.

[FR Doc. E4-464 Filed 3-9-04; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0055; FRL-7346-6]

### Experimental Use Permit; Receipt of Amendment/Extension Applications

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces receipt of applications 68467-EUP-7 and 29964-EUP-5 from Mycogen Seeds c/o Dow Agrosciences LLC and Pioneer Hi-Bred International requesting experimental use permit (EUP) amendment/extensions for *Bacillus thuringiensis* Cry34/35Ab1 protein and the genetic material necessary for its production (from the insert of plasmid PHP 17662) in corn. The Agency has determined that the applications may be of regional and national significance. Therefore, in accordance with 40 CFR 172.11(a), the Agency is soliciting comments on the applications.

**DATES:** Comments, identified by docket ID number OPP-2004-0055, must be received on or before April 9, 2004.

**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-2004-0055. 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-2004-0055. 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-2004-0055. 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-2004-0055.

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-2004-0055. 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**

In the **Federal Register** of January 6, 2004 (69 FR 658) (FRL-7328-5), EPA announced the issuance of the EUPs 68467-EUP-7 and 29964-EUP-5 to Mycogen Seeds c/o Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268-1054 and Pioneer Hi-Bred International, P.O. Box 552, Johnston, IA 50131-0552. Mycogen Seeds c/o Dow AgroSciences and Pioneer Hi-Bred have requested to amend and extend these EUPs through April 30, 2006, for *Bacillus thuringiensis* Cry34/35Ab1 protein and the genetic material necessary for its production (from the insert of plasmid PHP 17662) in corn.

For Mycogen Seeds/Dow AgroSciences LLC, 1,177 acres are proposed during the 2004 season and 7,687 acres are proposed for the 2005 season under EUP 68467-EUP-7 for testing in Arizona, Colorado, Delaware, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Missouri, Nebraska, New Jersey, New York, North Dakota, Ohio, Pennsylvania, Puerto Rico, South Dakota, Tennessee, Texas, Vermont, and Wisconsin. Testing is to include maize breeding and observation nursery, maize agronomic observation, herbicide tolerance, maize efficacy, insect

resistance management, and maize demonstration trials.

For Pioneer Hi-Bred International, 9,050 acres are proposed during the 2004 season and 13,050 acres are proposed for the 2005 season under EUP 29964-EUP-5 for testing in Alabama, Arizona, California, Colorado, Delaware, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, North Dakota, Ohio, Pennsylvania, Puerto Rico, South Dakota, Tennessee, Texas, Washington, and Wisconsin. Testing is to include insect resistance management, maize agronomic observation, maize breeding and observation, maize demonstration, maize efficacy, maize research seed production, maize inbred seed increase, maize regulatory studies, non-target organism, and herbicide tolerance trials.

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

Following the review of the Mycogen Seeds c/o Dow AgroSciences LLC and Pioneer Hi-Bred International applications and any comments and data received in response to this notice, EPA will decide whether to issue or deny the EUP requests for the EUP programs, and if issued, the conditions under which it is to be conducted. Any issuance of EUPs 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 26, 2004.

**Janet L. Andersen,**

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

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## **ENVIRONMENTAL PROTECTION AGENCY**

[FRL-7633-6]

### **Development Plan for the Causal Analysis/Diagnosis Decision Information System (CADDIS)**

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of availability.

**SUMMARY:** This notice announces the availability of a final report titled,