

material necessary for its production (vector ZMIR13L) in corn MON 863 and *Bacillus thuringiensis* Cry1Ab delta-endotoxin and the genetic material necessary for its production (vector PV-ZMCT01) in corn MON810 on 2,304 acres for breeding and observation nursery, inbred seed increase production, line per se and hybrid yield, insect efficacy, product characterization and performance/labeling, insect resistance management, non-target organism and benefit, and seed treatment trials. The program is authorized only in the States of Alabama, Arizona, California, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Missouri, Mississippi, Montana, North Carolina, North Dakota, Nebraska, New Mexico, New York, Ohio, Oklahoma, Pennsylvania, Puerto Rico, South Dakota, Tennessee, Texas, Utah, Virginia, and Wisconsin. The EUP is effective from June 20, 2003 to December 31, 2003. Tolerance exemptions have been established for residues of the active ingredients in or on corn. In the **Federal Register** of April 23, 2003 (68 FR 19995) (FRL-7301-9), EPA announced the receipt of application for this EUP. No comments were received in response to the **Federal Register** notice.

524-EUP-96. Issuance. Monsanto Company, 800 N. Lindberg Blvd., St. Louis, MO 63167. This EUP allows the use of the plant-incorporated protectants ZMIR39 x MON810 combined insecticidal trait stacked corn hybrids along with ZMIR39 and MON810 corn hybrids; *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production (vector ZMIR39) in corn ZMIR39 and *Bacillus thuringiensis* Cry1Ab delta-endotoxin and the genetic material necessary for its production (vector PV-ZMCT01) in corn MON810 on 829.7 acres of field corn for breeding and observation nursery, inbred seed increase production, line per se and hybrid yield, insect efficacy, product characterization and performance/labeling, insect resistance management, non-target organism and benefit, seed treatment, swine growth and feed efficiency, dairy cattle feed efficiency, beef cattle growth and feed efficiency, and cattle grazing feed efficiency trials. The program is authorized only in the States of Alabama, California, Colorado, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Mexico, New York,

North Carolina, Ohio, Pennsylvania, Puerto Rico, South Dakota, Tennessee, Texas, Virginia, and Wisconsin. The EUP is effective from July 2, 2003 to December 31, 2003. Tolerance exemptions have been established for residues of the active ingredients in or on corn.

In the **Federal Register** of April 2, 2003 (68 FR 16050) (FRL-7286-2), EPA announced the receipt of application for this EUP. One comment, by the Sierra Club, was received in response to the **Federal Register** notice. The Sierra Club commented that EPA should require additional testing requirements in order to look for reproductive and chronic effects in the animal feeding trials. The Cry3Bb1 protein has not been shown to be toxic to humans and the Agency concluded on May 11, 2001 (66 FR 24061) (FRL-6781-6), that there is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to the Cry3Bb1 protein and the genetic material necessary for their production in corn (40 CFR 180.1214). Accordingly, the Agency does not agree that such additional testing as requested by the Sierra Club is necessary. Nevertheless, although the Agency is not requiring Monsanto to modify its experimental program as requested by the Sierra Club in their comments, Monsanto must immediately notify the Agency of any findings from the experimental uses that have a bearing on safety (i.e., reporting to the Agency of any adverse effects from the use of, or exposure to, the pesticide is required).

Authority: 7 U.S.C. 136c.

List of Subjects

Environmental protection,
Experimental use permits.

Dated: December 19, 2003.

Janet L. Andersen,

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

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0299; FRL-7326-3]

Issuance of an Experimental Use Permit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted an experimental use permit (EUP) to the following pesticide applicant. An EUP permits use of a pesticide for experimental or research purposes only in accordance with the limitations in the permit.

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.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, 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 information in this action, 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-2003-0299. 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, CrystalMall #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. 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. Once in the system, select "search," then key in the appropriate docket ID number.

II. EUP

EPA has issued the following EUP: 68467-EUP-4. Extension/amendment. Mycogen Seeds, c/o Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268-1054. This EUP allows the use of the plant-incorporated protectant *Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (from the insert of plasmid PHP12537) in corn (moCry1F corn) on 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 program is authorized only in the States of Hawaii, Illinois, Indiana, Iowa, Kentucky, Louisiana, Minnesota, Mississippi, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin and the Commonwealth of Puerto Rico. EUP plantings are effective from April 11, 2003 to March 31, 2004.

In the **Federal Register** of March 7, 2003 (68 FR 11103) (FRL-7289-3), EPA announced the notice of receipt for the amendment/extension application (docket identification number OPP-2003-0016). Fifteen public comments were received in response to the notice. Commenters requested EPA not to issue the amendment/extension and expressed concern regarding food and environmental safety, gene flow, impacts on organic production, and the level of government oversight. First, moCry1F corn is covered by the tolerance exemption that permits Cry1F corn in food, 40 CFR 180.1217, (66 FR 30321) (FRL-6783-3). In granting that tolerance exemption, the Agency concluded that there is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to the Cry1F protein and the genetic material necessary for its production. In addition, the approved experimental program submitted by Mycogen Seeds, c/o Dow AgroSciences LLC requires the destruction of seed or plant material resulting from this permit that are not saved for future research, analysis, or future plantings. This EUP

was limited to 291 acres and moCry1F corn produces the Cry1F protein whose non-target organism toxicity was evaluated during the *Bt* Crops Reassessment in October 2001 (October 15, 2001 Plant-Incorporated Protectants Biopesticide Registration Action Document (pages II.C38-C44, VI.2), http://www.epa.gov/pesticides/biopesticides/pips/bt_brad.htm). In the Cry1F ecological effects testing done, no treatment-related effects were observed in bobwhite quail fed Cry1F corn as part of their diet. No measurable deleterious effects from the Cry1F protein on honey bees, parasitic wasps, ladybird beetles, green lacewings, collembola (springtails), earthworms, daphnia, and monarch butterflies were observed in submitted studies. The reassessment document also addresses the concern raised regarding impacts on organic production in its benefits section (II.E2-6). EPA's regional offices currently cooperate with State agencies in the enforcement of plant-incorporated protectant EUPs.

Authority: 7 U.S.C. 136c.

List of Subjects

Environmental protection,
Experimental use permits.

Dated: December 19, 2003.

Janet L. Andersen,

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

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-7607-9]

The Feasibility of Performing Cumulative Risk Assessments for Mixtures of Disinfection By-Products in Drinking Water

AGENCY: Environmental Protection
Agency.

ACTION: Notice of availability.

SUMMARY: This notice announces the availability of a final report titled, "The Feasibility of Performing Cumulative Risk Assessments for Mixtures of Disinfection By-Products in Drinking Water (EPA/600/R-03-051F)," which was prepared by the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA) of the Office of Research and Development (ORD).

DATES: This document will be available on or about January 7, 2004.

ADDRESSES: The document will be made available electronically through the NCEA Web site (www.epa.gov/ncea). A limited number of paper copies will be available from the EPA's National Service Center for Environmental Publications (NSCEP), P.O. Box 42419, Cincinnati, OH 45242; telephone: 1-800-490-9198 or 513-489-8190; facsimile: 513-489-8695. Please provide your name, your mailing address, the title and the EPA number of the requested publication.

FOR FURTHER INFORMATION CONTACT: The Technical Information Staff, National Center for Environmental Assessment/ Cincinnati, Ohio office (MS-117), U.S. Environmental Protection Agency, 26 W. Martin Luther King Drive, Cincinnati, OH 45268. Telephone: 513-569-7257; fax: 513-569-7475; e-mail: nceadc.comment@epa.gov.

SUPPLEMENTARY INFORMATION: In 1996, the Safe Drinking Water Act Amendments were passed, requiring the EPA to consider the risk assessment of contaminant mixtures in drinking water and prompting this current research on disinfection by-product (DBP) mixtures. Humans are exposed daily to hundreds of DBPs via oral, dermal, and inhalation routes. Some positive epidemiologic studies suggest cancer and reproductive/developmental effects are associated with consumption of chlorinated drinking water. However, in other epidemiologic studies significant health effects have not been observed, and current single-chemical toxicology studies fail to corroborate epidemiologic findings. Furthermore, human health risk estimates made using animal data based only on oral exposures do not reflect the same magnitude of risks found in positive epidemiologic studies. Thus, it is hypothesized that this difference can be accounted for by evaluating simultaneous exposures to multiple DBPs via all three exposure routes. This report addresses the feasibility of such an assessment, yielding the following interim results:

- Exposure estimates are made for an adult female and an adult male, each of reproductive age, and for a child (age 6) of total absorbed doses inclusive of exposures via oral, dermal and inhalation routes.
- Estimates are made for 13 major DBPs, accounting for human activity patterns that affect contact time with drinking water (e.g., tap water consumed, time spent showering, building characteristics) and physicochemical properties of the DBPs (inhalation rates, skin permeability rates, blood:air partition coefficients, etc.).