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## 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](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.*

[FR Doc. 04-86 Filed 1-6-04; 8:45 am]

**BILLING CODE 6560-50-S**

## 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](http://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](mailto: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.).

• A novel cumulative risk assessment method, Cumulative Relative Potency Factors, is advanced that integrates the principles of dose addition and response addition to produce multiple-route, chemical mixture risk estimates using total absorbed doses.

The report acknowledges the need for additional research, such as, to conduct a more complete uncertainty and sensitivity analysis on the exposure estimates, and to conduct a more comprehensive analysis of toxic mode of action for the DBPs. This report makes two significant contributions to the science. First, external exposure modeling is conducted and linked with physiologically-based pharmacokinetic modeling to produce internal dose measures of drinking water disinfection by-products (DBPs) for multiple route exposures to be used in mixture risk assessments. Thus, a comprehensive exposure estimate is made for 13 of the major DBPs of concern, including the four trihalomethanes and five haloacetic acids that are currently regulated. Second, a mixtures risk assessment method, based on additivity concepts is proposed to logically evaluate human health risks using total internal doses and oral toxicology dose-response data based on knowledge or assumptions regarding toxic mode of action. This new method is a novel approach to evaluating multiple route exposures that can be generalized for the evaluation of other environmental mixtures.

Dated: December 23, 2003.

**Peter W. Preuss,**

*Director, National Center for Environmental Assessment.*

[FR Doc. 04-322 Filed 1-6-04; 8:45 am]

**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-7607-8]

### Developing Relative Potency Factors for Pesticide Mixtures: Biostatistical Analyses of Joint Dose-Response

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of availability.

**SUMMARY:** This notice announces the availability of a final report titled, "Developing Relative Potency Factors for Pesticide Mixtures: Biostatistical Analyses of Joint Dose-Response (EPA/600/R-03-052F)," 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](http://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 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](mailto:nceadc.comment@epa.gov).

**SUPPLEMENTARY INFORMATION:** In 1996, the Food Quality Protection Act and the Safe Drinking Water Act Amendments were passed, each requiring the EPA to consider the risk assessment of chemical mixtures. This report responds to the need for risk assessment research on pesticide mixtures and on chemicals of concern in drinking water. The Relative Potency Factor (RPF) approach is a general methodology for applying dose addition to mixtures of chemicals that produce toxicity by the same toxic mode of action. The current report develops biological concepts and statistical procedures for improving applications of the RPF approach, advancing the theoretical basis for RPF-based risk assessments. New quantitative methods that extend the application of RPFs are shown, addressing the important question of how to assess a mixture containing some chemicals that share a common toxic mode of action and other chemicals that do not. This research was undertaken to continue exploring and developing mixture risk assessment strategies beyond current applications and is intended to enrich the available library of mixture risk assessment methods for future applications of RPF-based risk assessments. This report provides a new set of methods to handle groups of chemicals with more than one toxic mode of action represented. Dose-response modeling techniques are shown, and two algorithms are provided for grouping chemicals into mode of action subclasses that can be modeled with a common slope parameter. The report details approaches to estimate health risks based on the mode of action

subclasses and shows a conceptual approach for estimating a Reference Dose for a mixture using these methods.

Dated: December 23, 2003.

**Peter W. Preuss,**

*Director, National Center for Environmental Assessment.*

[FR Doc. 04-321 Filed 1-6-04; 8:45 am]

**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-7608-1]

### Analysis of Laboratory and Field Studies of Reproductive Toxicity in Birds Exposed to Dioxin-Like Compounds for Use in Ecological Risk Assessment

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of availability.

**SUMMARY:** This notice announces the availability of a final report titled, Analysis of Laboratory and Field Studies of Reproductive Toxicity in Birds Exposed to Dioxin-Like Compounds for Use in Ecological Risk Assessment (EPA/600/R-03/114F), 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 (<http://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 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](mailto:nceadc.comment@epa.gov).

**SUPPLEMENTARY INFORMATION:** Coplanar PCBs and other dioxin-like chemicals are common environmental contaminants and risks to wildlife are a significant issue as demonstrated by