

## **Attachment E**

Class Determination Regarding Confidentiality of 6(a)(2) Information  
<http://www.epa.gov/fedrgstr/EPA-PEST/1999/December/Day-15/p32185.pdf>



## U.S. Environmental Protection Agency

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## AGENCY : Environmental Protection Agency (EPA).

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-100152; FRL-6392-4]

Disclosure of Information Obtained Regarding Unreasonable Adverse Effects of Pesticides on the Environment; Class Determination

AGENCY : Environmental Protection Agency (EPA).

ACTION: Notice of Availability.

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SUMMARY: This document announces a class determination by EPA that safety and efficacy information submitted under section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) is not entitled to confidential treatment. This determination will enable EPA offices to respond more quickly and efficiently to requests for information submitted under section 6(a)(2).

DATES: The class determination took effect upon its issuance, on September 28, 1999.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Kathryn S. Bouve, 6(a)(2) Officer, Office of Pesticide Programs (7502C), U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location: Information Services Branch, CM #2, 2d floor, 1921 Jefferson Davis Hwy., Arlington, VA. Telephone: (703) 305-5032; e-mail: bouve.kate@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

You may be potentially affected by this action if you are a pesticide registrant, i.e., any person who holds, or ever held, a registration for a pesticide product issued under section 3 or section 24(c) of FIFRA. Potentially affected categories and entities may include but are not limited to:

| Categories    | NAICS | Examples of Potentially Affected Entities |
|---------------|-------|---|
| Industry..... | 32532 | Pesticide manufacturing                   |

This listing is not exhaustive, but is a guide to entities likely to be regulated by this action. The North American Industrial Classification System (NAICS) codes will assist you in determining whether this action applies to you. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the FOR FURTHER INFORMATION CONTACT section.

## II. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. Electronically. You may obtain copies of this document and certain other available support documents from the EPA Internet Home Page at <http://www.epa.gov/>. On the Home Page select ``Laws and Regulations'' and then look up the entry for this document under the ``Federal Register- Environmental Documents.'' You can also go directly to the ``Federal Register'' listings at <http://www.epa.gov/homepage/fedrgstr/>.

2. In person. The Agency has established an official record for this action under docket control number OPP-100152. The official record consists of the documents specifically referenced in this action and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is 703-305-5805.

3. Fax on demand. Using a faxphone call (202) 401-0527 and select item 6045 for a copy of Class Determination 1-99.

## III. What Is the Determination Announced in this Document?

On September 28, 1999, EPA issued Class Determination 1-99. In the Class Determination the Agency determined that safety and efficacy information submitted pursuant to FIFRA section 6(a)(2) is not entitled to confidential treatment, and that if such information is submitted to EPA under a claim of business confidentiality it may nonetheless be disclosed to the public, subject to the provisions of FIFRA section 10(g). This determination covers information both currently in the

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Agency's possession and submitted in the future.

A. What is Section 6(a)(2) of FIFRA?

On September 19, 1997, EPA published in the Federal Register (62 FR 49370) (FRL-5739-1) a rule implementing section 6(a)(2) of FIFRA. This rule is codified at 40 CFR part 159, subpart D. As explained more fully in the 1997 Federal Register rule, under FIFRA section 6(a)(2) pesticide registrants are required to submit to EPA reports of adverse effects related to product usage, product defects, or lack of product efficacy, as well as new information derived from scientific studies which pertain to unreasonable adverse effects of pesticides on the environment.

B. What is Safety and Efficacy Information?

Section 10(d)(1) of FIFRA requires disclosure to the public of all information regarding the effects of any registered or previously registered pesticide on any organism or the behavior of any such pesticide in the environment (subject to certain exceptions, discussed in the class determination). EPA has used the term "safety and efficacy information" as a label for the information required to be disclosed by section 10(d)(1). Information submitted under section 6(a)(2) is largely safety and efficacy information.

C. What is Section 10(g) of FIFRA?

Section 10(g) protects the proprietary rights of pesticide registrants and applicants in data submitted to support applications for pesticide registration, by limiting disclosure of such data to persons who affirm that they are not, and will not deliver the information to, a business engaged in the production, sale or distribution of pesticide products in countries other than the United States (except when the data submitter has consented to such disclosure). In Class Determination 3-85, Disclosure of Reviews of Pesticide Test Data (50 FR 48833, November 27, 1985), EPA announced its interpretation that section 10(g) applies to information which consists of a complete unpublished report of a study, test, or experiment submitted to EPA by an applicant or registrant under FIFRA, or which consists of excerpts or restatements of any such report which reveal the full methodology and complete results of the study, test, or experiment, and all explanatory information necessary to understand the methodology or interpret the results, and that section 10(g) does not apply to information of a more summary nature.

D. Why has EPA Issued the Class Determination and Published Notice in the Federal Register?

Under EPA confidentiality regulations at 40 CFR 2.207, the Agency may issue determinations regarding the application of the confidentiality regulations to an entire class, when such a determination serves a useful purpose. In this case, a class determination promoting expeditious processing of section 6(a)(2) information subject to confidentiality claims will assist the Agency in responding to requests for this information and in making the information more widely available. Because under section 2.207 one of the purposes of issuing a class determination is to make known the Agency's position regarding the manner in which information within the class will be treated, EPA is publishing notice of the class determination in the Federal Register.

List of Subjects

Environmental protection.

Dated: December 7, 1999.

Marcia E. Mulkey,  
Director, Office of Pesticide Programs.

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