

US EPA ARCHIVE DOCUMENT

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF GENERAL COUNSEL
FINANCE AND OPERATIONS LAW OFFICE

CLASS DETERMINATION 1-99

DISCLOSURE OF INFORMATION OBTAINED UNDER SECTION 6(a)(2) OF THE
FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT REGARDING
UNREASONABLE ADVERSE EFFECTS OF PESTICIDES ON THE ENVIRONMENT

BACKGROUND:

Section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires that "[i]f at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator." Information received by EPA's Office of Pesticide Programs (OPP) pursuant to section 6(a)(2) includes reports of adverse effects related to product usage, product defects, or lack of product efficacy, as well as new information derived from scientific studies. Other EPA offices may on occasion make use of section 6(a)(2) information in furtherance of their mission. EPA promulgated a rule setting forth procedures for filing section 6(a)(2) submissions. 62 FR 49370 (September 19, 1997).

Submissions under section 6(a)(2) are sometimes claimed as confidential. The confidentiality of information submitted pursuant to FIFRA is governed by FIFRA section 10. Section 10(b) provides that EPA shall not make public "trade secrets or commercial or financial information obtained from a person and privileged or confidential." Section 10(d)(1) of FIFRA, however, limits the reach of section 10(b) in that it 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 unless the information (A) discloses manufacturing or quality control processes, (B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or (C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide, unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment. In other words, safety and efficacy information submitted to an agency and pertaining to a registered (or previously registered) pesticide must be disclosed unless the information fits in one of categories (A) - (C), and even then may be disclosed, if necessary, to protect against an unreasonable risk of injury to health or the environment.

In addition, section 10(g) prohibits EPA from releasing information submitted under FIFRA to any business or other entity engaged in the production, sale or distribution of pesticide products in countries other than the United States unless the submitter of the information has consented to such disclosure, or the Agency has obtained an affirmation from the requestor that the person is not, and will not deliver the information to, a business or entity engaged in such activities. Section 10(g) was designed to prevent businesses or other entities from obtaining proprietary data in support of pesticide registration from EPA and gaining market entry in foreign countries without contributing to the costs of developing the data necessary to do so. (See EPA Class Determination 3-85, Disclosure of Reviews of Pesticide Test Data; 50 FR 48833, November 27, 1985, for a more detailed discussion of the intent of section 10(g)). Accordingly, EPA has only applied the section 10(g) disclosure limitations to information that supports pesticide registration, such as test data. Other information such as registration applications, product labeling and general offers to pay data compensation would not be included in this category.

EPA receives many requests for disclosure of adverse effects information. EPA also desires to clarify the extent to which it may disclose such information on its own initiative. As an example, the Agency is contemplating making adverse effects information reports available on the Internet, in keeping with Agency policies concerning enhanced public access to environmental information.

DEFINITION

For purposes of this class determination, "safety and efficacy information" means all information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, contaminants, or degradation products (including metabolites), and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil; and studies on persistence, translocation and fate in the environment, and metabolism. This includes not only formal studies, but any other information, such as incident reports, that meets the criteria of this paragraph. The subject chemical may be the active ingredient of a pesticide, an inert ingredient, an impurity or contaminant, or a degradation product (including metabolites).

FINDINGS

The General Counsel has delegated to me the authority to issue class determinations under 40 CFR 2.207 concerning entitlement of business information to confidential treatment. In the case of information required to be submitted to EPA under FIFRA section 6(a)(2), I find that:

(1) EPA possesses and will obtain related items of business information. Such information may be subject to business confidentiality claims.

(2) Characteristics common to all such items of information will necessarily result in identical treatment for each such item under one or more of the provisions in 40 CFR part 2, subpart B, as follows: Information contained in submissions under section 6(a)(2) of FIFRA that constitutes safety and efficacy information, unless it is information described by paragraph (A), (B), or (C) of section 10(d)(1), is required to be available for disclosure to the public under FIFRA section 10(d)(1), subject to section 10(g), and, therefore, is not entitled to confidential treatment. It is, therefore, proper to treat all such items as a class for one or more purposes under 40 CFR part 2, subpart B.

(3) A class determination will serve the useful purpose of establishing the procedures and restrictions that will apply to the disclosure to the public of information contained in submissions under FIFRA section 6(a)(2), thereby allowing EPA offices to better conduct their future activities, and to respond more quickly and efficiently to requests for information included in the class. It will also simplify publication of information on the Internet and through other means.

DETERMINATIONS

I. The information covered by this class determination consists of all safety and efficacy information, whether such information is now in EPA's possession or is acquired at a future date:

- (A) that was submitted to EPA by a pesticide registrant or former registrant pursuant to section 6(a)(2) of FIFRA;
- (B) that is submitted subject to a business confidentiality claim; and
- (C) that does not contain (or from which has been deleted) any information that:
 - (1) discloses manufacturing or quality control processes;
 - (2) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide; or
 - (3) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide.

The information may pertain to a pesticide that is currently registered or one that was previously registered. Information pertaining to pesticides which have never been registered (for example, data accompanying pending applications for registration of new ingredients) is not included within the class. Information pertaining to pending applications for new uses of an existing pesticide is included within the class, because it pertains to a "registered or previously registered pesticide."

II. Because the information covered by this class determination must be made available for disclosure under FIFRA section 10(d)(1), which is an express limitation of the protection provided under section 10(b), such information is not entitled to confidential treatment under FIFRA.

III. The information described in paragraph I is divided into two subclasses:

- (A) Information which does not consist of any complete unpublished report of a study, test, or experiment submitted to EPA by an applicant or registrant under FIFRA, and which does not consist 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.
- (B) Information which consists of any 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.

Information in subclass A may be made available to the public without requiring the affirmation or consent required by FIFRA section 10(g). Information in subclass B may be provided to members of the public only pursuant to the requirements of section 10(g), including completion of the section 10(g) affirmation by the requestor or consent by the submitter of the report, as appropriate.

IV. If OPP (or another EPA office in possession of information submitted under FIFRA section 6(a)(2)) concludes that information is covered by this determination, the office need not follow the procedures set forth in 40 CFR 2.204(d)(1) and (e), which provide affected businesses an opportunity to substantiate a business confidentiality claim prior to EPA's final confidentiality determination.

This class determination may be implemented by an office disclosing information included in the class either in response to a request for that information or when making the information publicly available in the absence of a request. If the office determines that information included in the class has been claimed as confidential, the office must provide the submitter with a copy of this class determination and inform the submitter that the confidentiality claim is denied pursuant to this class determination, providing the submitter with thirty-days notice prior to release of the information (unless such notice had previously been provided), pursuant to procedures at 40 CFR 2.204(d)(2), 2.205(f) and 2.307(d).

Information claimed as confidential that is not included in the class must be handled according to procedures at 40 CFR part 2, subpart B, which may include substantiation of the claim by the submitter and a separate final confidentiality determination by the appropriate EPA legal office.

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