

US EPA ARCHIVE DOCUMENT

DISCLOSURE OF REVIEWS OF PESTICIDE TEST DATA
SUBMITTED BY APPLICANTS AND REGISTRANTS

Background.

A. Data. EPA's Office of Pesticide Programs (OPP), other EPA offices, and EPA contractors prepare reviews of data received under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. This class determination, made under 40 CFR § 2.207, concerns the extent to which certain of these reviews may be disclosed publicly by EPA and the procedures that EPA may use to make disclosures.

Businesses which are applying for registration of pesticide products or for experimental use permits or emergency exemptions, or which hold registrations, submit test data to OPP for the purpose of satisfying requirements of FIFRA. (Some such data is submitted for the additional purpose of satisfying requirements imposed under the Federal Food, Drug & Cosmetic Act, 21 U.S.C. 321 et seq.; EPA's regulations, 40 CFR § 2.307(b), require such data to be treated as data submitted under FIFRA.)

EPA may not withhold information from disclosure for reasons of business confidentiality if a statute specifically requires disclosure of the information. To the extent information submitted under FIFRA concerns any test or experiment on a registered (or previously registered) pesticide or any of its ingredients, FIFRA Sections 10(d) and 10(g) largely govern the extent to which the information may be disclosed to members of the public. FIFRA Section 10(d)(1) [7 U.S.C. 136h(d)(1)] states:

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, or degradation products, and any information concerning the effects 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, shall be available for disclosure to the public; Provided, That the use

of such data for any registration purpose shall be governed by section 3 of this act [7 U.S.C. 136a]; Provided further, That this paragraph does not authorize the disclosure of any information that--

(A) discloses manufacturing or quality control processes,

(B) discloses the details of any methods for testing, detecting, or measuring the quality 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. [Emphasis added.]

Section 10(d)(2) provides that information concerning the production, distribution, sale, or inventories of a pesticide may be entitled to confidential treatment.

Therefore, if the data in question concern tests or experiments on a registered or previously registered pesticide product or any ingredient, impurity, or degradation product of a registered or previously registered pesticide product, FIFRA Section 10(d) and 40 CFR § 2.208 provide that those data are disclosable to most members of the public subject to Section 10(g). However, those portions of the data described by paragraph (A), (B), or (C) of Section 10(d)(1), or described by Section 10(d)(2), may be entitled to protection from disclosure as confidential business information.

Despite the provisions of Section 10(d), FIFRA Section 10(g) limits EPA's right to disclose to some persons data which is otherwise disclosable under Section 10(d). Section 10(g) [7 U.S.C. 136h(g)] states in pertinent part:

The Administrator shall not knowingly disclose information submitted by an applicant or registrant under this Act to any employee or agent of any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States or to any other person who intends to deliver such data to such foreign or multinational business or entity unless the applicant or registrant has consented to such disclosure.

B. Reviews of data. EPA employees and EPA contractors prepare reviews of the data described in paragraph A for use by EPA in making or explaining various decisions under FIFRA. In some cases, the review concerns a particular study. In other cases, data from a number of studies (which may have been submitted by different businesses) are reviewed, and conclusions are drawn from the combined data.

EPA receives many requests for disclosure of these reviews of data. EPA also desires to clarify the extent to which it may disclose such reviews for its own purposes. In a memorandum to the Office of General Counsel dated May 28, 1985, OPP stated:

We have an imperative need to freely disclose our evaluations of registrant-submitted data and present our conclusions and the reasons for our decisions. We wish to explain our decisions by sharing data reviews freely with all interested parties.

OPP recommended that these reviews of pesticide data be treated as disclosable to any person, without regard to Section 10(g), if the reviews (1) concern data that would be disclosable under FIFRA Section 10(d)(1), and (2) have been carefully scrutinized by OPP to ensure that they contain no data entitled to confidential treatment under FIFRA Section 10(d)(1)(A), (B), or (C). OPP further suggested that it would be proper to disclose such reviews without case-by-case prior notification to the submitter(s) of the item(s) of data which are the subject of the reviews, if a one-time notice were provided. Finally, OPP requested that the Office of General Counsel consider issuing a class determination concerning these matters.

Findings.

Under 40 CFR § 2.207 I have authority to issue class determinations concerning entitlement of business information to confidential treatment. In the case of pesticide data reviews, I find that:

(1) EPA possesses (and will continue to generate) a large number of reviews, prepared by EPA employees or by EPA contractors, of data submitted under FIFRA by registrants, applicants for registration, applicants for experimental use permits, and applicants for emergency exemptions.

(2) To the extent that the reviews concern submissions (or portions thereof) which are themselves disclosable under FIFRA Section 10(d), then disclosure of the reviews is mandatory. Reviews are disclosable without regard to FIFRA Section 10(g), provided that the reviews do not set forth essentially complete reports of the data or information submitted to the Agency.

Reviews of data concerning submissions which are themselves disclosable under FIFRA Section 10(d) therefore may properly be treated as a class.

(3) A class determination will serve the useful purpose of establishing the procedures and restrictions that will apply to the disclosure of pesticide data reviews, thereby allowing OPP to better conduct its future activities.

The Office of General Counsel has not been asked to decide, and these findings do not address, whether the underlying data on which the reviews are based may be the subject of a class determination. The conclusions reached in this determination with respect to disclosure of pesticide data reviews therefore do not control the disclosability of the underlying data.

Determinations.

I have determined that pesticide data reviews will be treated as follows:

I. The information covered by this class determination consists of each review, whether now existing or prepared at a future date:

(A) which was prepared by EPA personnel or prepared under an EPA-funded contract; and

(B) which, to the extent it contains or refers to any unpublished "business information" (as defined in 40 CFR § 2.201(c)), contains or refers only to data or information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide product or any of its separate ingredients, impurities, or degradation products, or concerning the effects of any such substance on any organism or the behavior of any such substance in the environment; and

(C) which does not contain (or from which has been deleted) any information the disclosure of which would disclose:

(1) manufacturing or quality control processes; or

(2) the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide product; or

(3) the identity or percentage quantity of any deliberately added inert ingredient of a pesticide product; or

(4) unpublished information concerning the production, distribution, sale, or inventories of a pesticide (such information might appear in reviews which discuss the amount of a pesticide sold or used in a given time, and thus might concern the "significance" of data from a test or experiment); and

(D) which does not contain or consist of any complete unpublished report submitted to EPA by an "affected business" (see definition at 40 CFR § 2.201(d)); and

(E) which does not contain or 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.

II. The information covered by this determination is not entitled to confidential treatment, because it consists entirely of information required by statute (FIFRA Section 10(d)) to be disclosed.

III. The information covered by this determination is not subject to FIFRA Section 10(g), and thus may be disclosed to any person. Section 10(g) is intended to prevent a person from obtaining, under FIFRA, data generated at another person's expense and then using the data to obtain the approval of another country's government to manufacture, sell, or use pesticides in that country. See, e.g., Congressional Record, October 31, 1977, page H 11864 (daily ed.) (remarks of Congressman Fithian): "[Under new Section 10(g)], foreign competitors or multinational corporations could not legally obtain research data, paid for by others, and utilize it for registration abroad--where compensation would not have to be paid." Disclosure of EPA reviews of data (provided that they are truly reviews, and not essentially complete reports) will not be useful in obtaining approvals by governments of other countries. To the extent that such a country requires data to evaluate the request, it is unlikely to be satisfied with a review of data conducted by EPA; to the extent that such a country is willing to accept an EPA review in lieu of data, it is just as likely to accept other readily available information indicating EPA's position, such as evidence that EPA has registered the product. It should also be noted that EPA has for years published many quite comprehensive reviews of information submitted under FIFRA in various formats (e.g., registration standard science chapters, proposed and final regulations setting tolerances for pesticide residues on food, special review notices) without objection from data submitters that such publication violates FIFRA Section 10(g).

IV. If OPP concludes that a review clearly is covered by this determination, OPP need not follow the procedures set forth in 40 CFR § 2.204(c), (d)(1), and (e) (which provide affected businesses an opportunity to assert and attempt to substantiate a business confidentiality claim prior to EPA's final confidentiality determination). In most cases, OPP will be able to determine readily whether a review is described by paragraphs I.(A) and (B) above. With regard to paragraphs I.(C), (D), and (E) above, in most cases it also should be apparent from the face of the review whether its disclosure would reveal information described by FIFRA Section 10(d)(1)(A), (B), or (C) or 10(d)(2), and if so, what pre-disclosure deletions would be necessary. However, in any case where OPP has doubt on either score, the procedure set forth in 40 CFR § 2.204(d)(1) and (e) must be followed.

V. The pre-disclosure notice requirements in FIFRA Section 10(c) and 40 CFR §§ 2.204(d)(2), 2.205(f), and 2.307(d) and (e) may be satisfied, insofar as information covered by this determination is concerned, by:

(A) furnishing to each current registrant of a pesticide product, each current applicant for registration, and each other data submitter whose identity is now known to EPA a copy of this determination and a notice of the Agency's intent to disclose any and all information covered by this determination, in the form required by §§ 2.205(f) and 2.307, by certified mail, return receipt requested, or by personal delivery;

(B) publishing a copy of this determination and a copy of a notice of intent to disclose the information covered by this determination in the Federal Register; and

(C) continuing the current practice of requiring each person (other than a government agency) who applies for an experimental use permit or a registration to first obtain a company number, and furnishing to each person who applies for assignment of a company number:

(1) a copy of this determination; and

(2) a notice stating that disclosure of any review which EPA may prepare of any data submitted by the person under FIFRA will be governed by this determination, and that EPA will furnish no further notice prior to disclosure of such information.

September 24, 1985
Date

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