Pesticide Registration Manual:

Chapter 15 - Submitting Data and Confidential Business Information

Submitting Data and Confidential Business Information

This chapter includes information on how to submit data as well as special considerations concerning what data and information can be considered to be confidential business information.

Overview

Section 10 of FIFRA provides applicants with the ability to claim information as confidential, and requires EPA to protect information, which, in the Administrator's judgment, is entitled to confidential treatment.

Conversely, FIFRA section 10(d)(1) also provides that safety and efficacy information must be made available to the public. The exceptions to this mandatory disclosure requirement are listed in FIFRA section 10(d)(1)(A), (B), and (C).

The procedures for asserting confidentiality claims for safety and efficacy information are described in 40 CFR 158.33, 40 CFR 161.33, and PR Notice 2011-3.

Synopsis of FIFRA Section 10

Confidential Business Information

Section 10 of FIFRA specifies how and to what extent information submitted to the Agency under FIFRA may be afforded protection as confidential business information (CBI). FIFRA section 10(b) protects from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." Certain annual facility data are also granted confidentiality under section 7(d).

However, FIFRA section 10(d)(1) limits the types of data that may be claimed confidential. Safety and efficacy data (such as studies submitted to the Agency) on registered or previously registered pesticides are not considered CBI and must be made available to the public. However, certain information is excluded from the definition of safety and efficacy data, and may therefore be claimed as CBI. These include the following:

- information that discloses manufacturing or quality control processes (FIFRA 10(d)(1)(A));
- information that discloses methods for testing and measuring the quantity of deliberately added inert ingredients (FIFRA 10(d)(1)(B)); and
- information that discloses the identity or percentage quantity of deliberately added inert ingredients (FIFRA 10(d)(1)(C)).

On rare occasions it may be necessary to reveal, under the authority of section 10(b), to federal agencies in public hearings or in findings of fact issued by EPA, formulas of products, even if confidential, to carry out other provisions of FIFRA, e.g., in cancellation or suspension hearings.

FIFRA section 10(e) permits EPA to give submitted confidential business information (CBI) to its contractors who are helping to do the work of the Agency. Such contractors are bound to protect this information to the same extent as EPA staff. The Agency will notify submitters of CBI whenever their data will be shared with a contractor. This is usually done by publishing a Notice in the *Federal Register* and always precedes giving the CBI to the contractor.

FIFRA section 10(g) prohibits the disclosure of certain information submitted by an applicant or registrant to any representative of a multinational pesticide producer or to anybody who intends to deliver such information to a multinational pesticide producer. Those persons may see certain abstracted data, or may view unabstracted data without copying.

FIFRA provides that, in certain circumstances, the EPA Administrator may disclose information that is otherwise protected. Such action is rare, and is described in FIFRA sections 10(b), 10(d)(3), 10(g), and 12(a)(2)(D).

The preceding section provides a brief overview of certain points regarding CBI. For more detailed information on policies related to EPA's handling of CBI, and allowances regarding CBI, refer to:

- FIFRA sections 7, 10, and 12
- 40 CFR Part 2

Procedures for Submitting Data

When data are submitted to the Agency, they are reviewed to determine whether they meet the data-formatting requirements in 40 CFR 158.32-33, 40 CFR 161.32-33, and PR Notice 2011-3. The submitter will be notified of the results of this screening process.

Each study that meets the formatting requirements will be assigned a Master Record Identification Number (MRID) number and entered into OPP's data archive. These studies may then be retrieved at any time by referring to the MRID number. Refer to these MRID numbers instead of submitting additional copies of the studies to support additional applications for registration.

Please refer to 40 CFR 158.32-33, 40 CFR 161.32-33, and PR Notice 2011-3 for a more detailed discussion on how to format data submissions.

Data submitted for certain actions may be submitted electronically as discussed in the guidance on electronic submission. Applicants are advised to follow this guidance closely and contact EPA before developing their electronic submission.

- Contact OPP's Information Services Branch in the Information Technology & Resources Management Division for assistance and additional information on data-formatting procedures.

Data Formatting

The following paragraphs summarize the major data-formatting requirements.

- Reminder: Each study should be submitted in triplicate. Data submitted for certain actions may be submitted electronically as discussed in the guidance on electronic submission. Applicants are advised to follow this guidance closely and contact EPA before developing their electronic submission.
- Note: EPA Forms 8570-36 (Summary of Physical/Chemical Properties) and 8570-37 (Self-Certification Statement for Physical/Chemical Properties) should be placed in the study portion of an application package if they are applicable to that action. Information on self certification of product chemistry data is available in PR Notice 98-1.

Transmittal Document

Each submission of data to the Agency must include a transmittal document. At a minimum, the transmittal document should include the name of the data submitter (or submitters, if more than one), the regulatory action the data are submitted in support of, and a listing of the data. The transmittal document can be a stand-alone document or may be incorporated into the cover letter for the action, at the submitter's option but may not include any confidential business information. A representative example of a stand-alone transmittal document can be found in PR Notice 86-5.

- Ensure that all studies physically included in the submission are itemized.

EPA will send submitters an annotated copy of the transmittal document, provided the studies are accepted, with the corresponding MRID numbers. Please refer to PR Notice 2011-3 for a sample transmittal document.

Studies Must be Bound Separately

Each study should be separately bound on 8.5 x 11-inch paper, single-sided, with black and white printing. All bindings should be secure, but easily removable to permit imaging.

Supplements to Previously Submitted Studies

Whenever information is submitted to supplement a previously submitted study, whether in response to a request by EPA or on the data submitter's own initiative, it must be prepared in the format required by 40 CFR 158.32-33, 40 CFR 161.32-33, and by PR Notice 86-5.

Replacement Pages for Previously Submitted Studies

EPA will not accept unbound, unformatted, individual replacement pages or inadvertently omitted pages sent in for inclusion in previously submitted studies. However, EPA will accept a complete replacement version of the study that meets all the requirements 40 CFR 158.32-33 and of 40 CFR 161.32-33, and by PR Notice 2011-3.

- When submitting a complete replacement study, the title page of the replacement study should clearly identify the previously submitted study it replaces and include that study's MRID number.

The transmittal for the replacement study should fully explain both the relationship of the newly submitted study to the original study and the specific differences between the two versions. This will allow EPA reviewers to quickly discern whether or not the replacement study will significantly affect a review already under way or completed.

Statement of Data Confidentiality Claims

Each study submitted must include a Confidentiality Statement. The exact text of one of the two alternative forms of the statement (either the "Statement of No Data Confidentiality Claims" or "Statement of Data Confidentiality Claims") must appear on page 2 of the study (Refer to 40 CFR 158.33, 40 CFR 161.33, and PR Notice 2011-3.

When data are submitted, confidential data must be physically separated from the rest of the data (study) and placed in a confidential attachment at the back of the study report to enable the Agency to quickly identify the confidential data and to cross-reference it with the citations in the report.

Confidential Business Information Claims for Plant-Incorporated Protectant Submissions

Although it is strongly recommended that the submitter minimize the amount of data and other information claimed as Confidential Business Information (CBI), a submitter may assert a claim of confidentiality for all or part of the information submitted to EPA in a submission for a plant-incorporated protectant (40 CFR 174.9). To assert such a claim, the submitter must comply with all of the following procedures:

- Any claim of confidentiality must accompany the information at the time the information is submitted to EPA. Failure to assert a claim at that time constitutes a waiver of confidentiality for the information submitted, and the information may be made available to the public, subject to section 10(g) of FIFRA, with no further notice to the submitter.
- Any claim of confidentiality must be accompanied, at the time the claim is made, by comments substantiating the claim and explaining why the submitter believes that the information should not be disclosed. The submitter must address each of the points listed in 40 CFR 2.204(e)(4) in the substantiation. EPA will consider incomplete all plant-incorporated protectant submissions containing information claimed as CBI that are not accompanied by substantiation, and will suspend any applicable review of such submissions until the required substantiation is provided.

Good Laboratory Practice Statement

A statement of compliance or non-compliance with the Good Laboratory Practice Standards contained in 40 CFR Part 160 is required for all studies as defined in 40 CFR 160.3 that support or are intended to support pesticide applications.

- This statement should appear on page 3 of each study, and must be signed and dated by the study sponsor, the study submitter, and the study director.
- If the submitter neither conducted nor sponsored the study and therefore does not know whether or not the study complies with 40 CFR Part 160, then a statement to that effect, signed and dated by the submitter, is acceptable.

Flagging Statement

Flagging statements are required for certain types of subchronic and chronic toxicology data to alert EPA to potential adverse effects. Based on the results of the data, submitters must include one of two statements that indicate that the study either does or does not meet or exceed the triggers listed in 40 CFR 158.34 or 40 CFR 161.34.

- This statement, when required, should appear on page 4 of the study, and must be signed and dated by an authorized representative of the submitting company.

Adverse Effects Submitted Under FIFRA 6(a)(2)

Whenever an applicant becomes aware of any potential unreasonable adverse effects data meeting the statutory requirements of FIFRA section 6(a)(2), such data must be submitted to the Agency. The exact procedures concerning when data must be submitted are outlined in the following pesticide registration notices:

- 98-3,
- 98-4, and
- 2000-8, as well as 40 CFR Part 159, Subpart D.

These studies are subject to the same data-formatting requirements as all other data submissions. They must be sent in triplicate to the Document Processing Desk, using distribution code 6(a)(2). FIFRA 6(a)(2) incidents are submitted in single copy. More information is found on the Web page: Incident Reporting by Pesticide Manufacturers.

Common Errors

In an analysis conducted by the Office of Pesticide Programs in 2006, EPA identified common formatting errors of submitted data. These common errors included:

- incorrectly formatted Confidential Business Information Statement,
- missing or incomplete Good Laboratory Practice (GLP) Standards Compliance Statement,
- incorrect pagination,
- legibility problems, and
- unsigned documents.

Important Notes: Following the instructions in PR Notice 86-5 is critical. Taking time to ensure that data submissions are in accordance with these formatting requirements will help avoid delays due to incorrectly formatted submissions and avoid rejection under FIFRA section 33(f)(4)(B) (see Chapter 5).

Contacts for Additional Information

If you have any questions concerning confidential business information as it may concern your application or how to format and submit supporting data, please contact the Information Technology & Resources Management Division, Information Services Branch. Refer to Chapter 21 of this manual for contact names, telephone numbers, and addresses.

References Cited in Chapter 15

Refer to Chapter 19 for information on the sources of these documents.

Code of Federal Regulation, Title 40

- Part 2 – Public Information
- Part 158 - Data Requirements for Registration
- Part 159 – Statements of Policies and Interpretations

- Part 160 – Good Laboratory Practice Standards
- Part 161 – Data Requirements for Registration of Antimicrobial Pesticides
- Part 174 – Procedures and Requirements for Plant-Incorporated Protectants

Federal Insecticide, Fungicide, and Rodenticide Act, as amended by the Food Quality Protection Act of August 3, 1996

- Section 7(d)
- Section 10
- Section 12

PR Notices

- PR Notice 2011-3 - Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)
- PR Notice 98-1 - Self-Certification of Product Chemistry Data with Attachments
- PR Notice 98-3 - Guidance on Final FIFRA 6(a)(2) Regulations for Pesticide Product Registrants
- PR Notice 98-4 - Additional Guidance on Final FIFRA Section 6(a)(2) Regulations for Pesticide Product Registrants w/Attachment
- PR Notice 2000-8 - Reportability of Attorneys' Opinions and Conclusions Under 40 CFR Part 159 and FIFRA section 6(a)(2)