

product is not obligated to satisfy any data requirement in part 158 with respect to that product until he receives a notice under section 3(c)(2)(B) of the Act that additional data are required to support the continued registration of the product, until he applies for an amendment to the registration, or until the product is subject to reregistration.

(b) *Applications.* The amount of data required by the Agency to evaluate an application for initial or amended registration depends on whether the product is being reviewed under section 3(c)(5) of the Act (unconditional registration) or section 3(c)(7) of the Act (conditional registration). Refer to §152.111 of this chapter or consult with the appropriate EPA Product Manager to determine under which section of the Act the application will be reviewed. The following paragraphs identify, for each different type of application, the minimum amount of data that must be available for EPA review to permit EPA to make the statutory risk-benefit determinations required by section 3(c)(5) or 3(c)(7) of the Act. In addition to satisfying these minimum data requirements, applicants may be required to submit or cite additional data, either to permit EPA to assess the safety or efficacy of the product (refer to §158.75) or to comply with the statutory requirements of section 3(c)(1)(D) of the Act, or both.

(1) *Applications for unconditional registration under section 3(c)(5) of the Act.* EPA will not approve an application for unconditional registration unless all data required by this part which have not been waived are available for EPA to review.

(2) *Applications for conditional registration of a new chemical under section 3(c)(7)(C) of the Act.* EPA will not approve an application for conditional registration of a pesticide containing an active ingredient not contained in any currently registered product unless data required by this part are available for EPA to review except for:

(i) Those data for which the requirement has been waived.

(ii) Those data for which the requirement was imposed so recently that the applicant has not had sufficient time to produce the data.

(3) *Applications for conditional registration of products which are identical or substantially similar to currently registered products under section 3(c)(7)(A) of the Act.* EPA will not approve an application for conditional registration of a pesticide product which is identical or substantially similar to a currently registered pesticide unless the following data are available for EPA to review:

(i) Product chemistry data, as required by subpart C of this part.

(ii) Product performance data, to the extent required by §158.160.

(4) *Applications for conditional registration of new uses of currently registered products under section 3(c)(7)(B) of the Act.* EPA will not approve an application for registration of a pesticide for a new use of a currently registered pesticide product unless the following data are available for EPA to review:

(i) Product chemistry data, as required by subpart C of this part.

(ii) Product performance data, to the extent required by §158.160.

(iii) Other data pertaining solely to the new use. The applicant may generally determine which data pertain solely to the new use by comparing the data requirements for all existing uses of all currently registered products containing the same active ingredient(s) with those for all uses including the new use. Any differences are attributable to the new use and must be submitted with the application.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988; 58 FR 34203, June 23, 1993]

§ 158.32 Format of data submission.

(a) *Transmittal document.* All data submitted at the same time and for review in support of a single administrative action (e.g., an application for registration, reregistration, experimental use permit, or in response to a requirement for data under the authority of FIFRA sec. 3(c)(2)(B), must be accompanied by a single transmittal document including the following information:

(1) The identity of the submitter, or the identity of each joint submitter and of the agent for joint submitters;

(2) The date of the submission;

Environmental Protection Agency

§ 158.33

(3) The identification of the Agency action in support of which the data are being submitted, such as the registration number or file symbol, petition number, experimental use permit number, or registration standard review; and

(4) A bibliography of all specific documents included in the submission and covered by the transmittal.

(b) *Individual studies.* (1) All data must be submitted in the form of individual studies. Unless otherwise specified by the Agency, each study should address a single data requirement, and be listed separately in the bibliography.

(2) Each study must include the following elements in addition to the study itself:

(i) A title page, as described in paragraph (c) of this section;

(ii) A Statement of Data Confidentiality Claims and, if desired, a Supplemental Statement of Data Confidentiality Claims, in accordance with § 158.33;

(iii) A certification with respect to Good Laboratory Practice standards, if required by § 160.12 of this chapter;

(iv) If the original study is not in the English language, a complete and accurate English translation under the same cover; and

(v) If the study is of a type listed in § 158.34(b), the statement prescribed by paragraph (c) of that section.

(3) Three identical copies of each study must be submitted. If the study is submitted in conjunction with a pending Special Review or Registration Standard under development, four copies must be submitted. Three copies must be identical and must conform to the requirements of § 158.33 with respect to claims of confidentiality. The fourth copy will be placed in the public docket and must conform to the requirements of § 154.15(c) of this chapter or § 155.30(c) of this chapter with respect to claimed confidential business information.

(4) All copies must be in black ink on uniform pages of white, 8½ × 11 inch paper. Copies must have high contrast and good resolution for microfilming. Frayed or oversize pages and glued bindings are not acceptable.

(c) *Contents of title page.* Each individual study must have a title page bearing the following identifying information:

(1) The title of the study, including identification of the substance(s) tested and the test name or data requirement addressed;

(2) The author(s) of the study;

(3) The date the study was completed;

(4) If the study was performed in a laboratory, the name and address of the laboratory and any laboratory project numbers or other identifying codes;

(5) If the study is a commentary on or supplement to another previously submitted study, full identification of the other study with which it should be associated in review; and

(6) If the study is a reprint of a published document, all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and date of publication.

(d) *EPA identification number.* EPA will assign each study an EPA Master Record Identification (MRID) number, and will promptly notify the submitter of the number assigned. This number should be used in all further communications with the Agency about the study.

(e) *Reference to previously submitted data.* Data which previously have been submitted need not be resubmitted unless resubmission is specifically requested by the Agency. If an applicant or registrant wishes the Agency to consider such data in the review of an Agency action, he should cite the data by providing:

(1) The title or adequate description of the study;

(2) The transmittal information required by paragraph (a) (1), (2), and (3) of this section; and

(3) The MRID number assigned in accordance with paragraph (d) of this section.

[53 FR 15991, May 4, 1988]

§ 158.33 Procedures for claims of confidentiality of data.

(a) *General.* A data submitter must clearly identify any information which he claims is entitled to confidential treatment under FIFRA sec. 10. The