

Environmental Protection Agency

§ 158.30

158.640 Product performance data requirements.

158.690 Biochemical pesticides data requirements.

158.740 Microbial pesticides—Product analysis data requirements.

APPENDIX A TO PART 158—DATA REQUIREMENTS FOR REGISTRATION: USE PATTERN INDEX.

AUTHORITY: 7 U.S.C. 136–136y.

SOURCE: 49 FR 42881, Oct. 24, 1984, unless otherwise noted.

Subpart A—General Provisions

§ 158.20 Overview.

(a) *Legal authority.* These requirements are promulgated under the authority of sections 3, 5, 12, and 25 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA) (7 U.S.C. 136–136y).

(b) *Purposes of this part.* (1) The primary purpose of this part is to specify the types and minimum amounts of data and information the Agency requires in order to make regulatory judgments about the risks and benefits of various kinds of pesticide products under the criteria set forth in FIFRA sections 3(c)(5) (C) and (D) and 3(c)(7).

(2) This part also specifies the types and minimum amounts of data and information the Agency requires to decide whether to approve applications for experimental use permits under FIFRA section 5.

(3) Finally, this part specifies the types and minimum amounts of data and information that an applicant for registration, amended registration, or reregistration must submit or cite in support of an application in order to satisfy the requirements of FIFRA section 3(c)(1)(D) and sections 3(c)(5)(B) or 3(c)(7). Use of the term “registration” in this part will pertain to new registrations and amended registrations as well as reregistration accomplished under section 3(g), unless stated otherwise.

(c) *Availability of related guidelines.* The data requirements for pesticide registration specified in this part pertain to product chemistry, residue chemistry, environmental fate, toxicology, reentry protection, aerial drift evaluation, wildlife and aquatic organisms, plant protection, nontarget in-

sects, product performance, and biochemical and microbial pesticides. The standards for conducting acceptable tests, guidance on evaluation and reporting of data, further guidance on when data are required, definition of most terms, and examples of protocols are not specified in this part. This information is available in advisory documents (collectively referred to as Pesticide Assessment Guidelines) through the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (telephone: 703-487-4650).

§ 158.25 Applicability of data requirements.

(a) Some kinds of data and information are specified in subparts C and D of this part as “required” (“R”) for the evaluation of some or all types of products. Other kinds of data and information are specified in those sections as “conditionally required” (“CR”), that is, they are required if the product’s proposed pattern of use, results of other tests, or other pertinent factors meet the criteria specified in those sections. The terms “required” and “conditionally required” are further discussed in §§ 158.100 and 158.101.

(b) The Agency recognizes that certain data requirements may not be applicable to (or should be waived for) some products, and has made provisions for such cases in this part as specified in § 158.35 *Flexibility of the data requirements*, § 158.40 *Consultation with the Agency*, § 158.45 *Waivers*, and § 158.60 *Minor uses*.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988]

§ 158.30 Timing of the imposition of data requirements.

This part establishes requirements for the types of data which are necessary to support the unconditional registration of a pesticide product under section 3(c)(5) of the Act. While every registered pesticide product must eventually be supported by the data required by part 158, when an applicant or registrant must initially satisfy these data requirements depends on the factors listed below in this section.

(a) *Existing Registrations.* A registrant of a currently registered pesticide

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;