

§ 158.85

to fulfill the data requirements specified in this part are acceptable. This determination will be based on the design and conduct of the experiment from which the data were derived, and an evaluation of whether the data fulfill the purpose(s) of the data requirement. In evaluating experimental design, the Agency will consider whether generally accepted methods were used, sufficient numbers of measurements were made to achieve statistical reliability, and sufficient controls were built into all phases of the experiment. The Agency will evaluate the conduct of each experiment in terms of whether the study was conducted in conformance with the design, good laboratory practices were observed, and results were reproducible. The Agency will not reject data merely because they were derived from studies which, when initiated were in accordance with an Agency-recommended protocol, even if the Agency subsequently recommends a different protocol, as long as the data fulfill the purposes of the requirements as described in this paragraph.

(b) *Previously developed data.* The Agency will consider that data developed prior to the effective date of this part would be satisfactory to support applications provided good laboratory practices were followed, the data meet the purposes of this part, and the data permit sound scientific judgments to be made. Such data will not be rejected merely because they were not developed in accordance with suggested protocols.

(c) *Data developed in foreign countries.* The Agency considers all applicable data developed from laboratory and field studies anywhere to be suitable to support pesticide registrations except for data from tests which involved field test sites or a test material, such as a native soil, plant, or animal, that is not characteristic of the United States. When studies at test sites or with materials of this type are anticipated, applicants should take steps to assure that United States materials are used or be prepared to supply data or information to demonstrate the lack of substantial or relevant differences between the selected material or test site and the United States material or test site. Once comparability has been es-

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tablished, the Agency will assess the acceptability of the data as described in paragraph (a) of this section.

(d) *Data from monitoring studies.* Certain data are developed to meet the monitoring requirements of FIFRA sections 5, 8 or 20. Applicants may wish to determine whether some of these data may meet the requirements of this part. In addition, data developed independently of FIFRA regulations or requirements may also satisfy data requirements in this part. Consultation with appropriate EPA Product Managers would be helpful if applicants are unsure about suitability of such data.

§ 158.85 Revision of data requirements and guidelines.

(a) Data requirements will be revised from time to time to keep up with policy changes and technology. Revisions to this part will be made in accordance with the Administrative Procedure Act (5 U.S.C. 551 *et seq.*). Changes having a significant impact on the registration process, applicants, testers, or other parties, or on the outcome and evaluation of studies, will be made only after public notice and opportunity for comment. Until final rules reflecting a change have been promulgated, the Agency can implement changes in the data requirements on a case-by-case basis.

(b) The Agency invites registration applicants, registrants, and the general public to suggest changes in the data requirements or the Pesticide Assessment Guidelines. Suggestions may be submitted at any time. Those making suggestions are requested to contact, in writing, the Director of the Hazard Evaluation Division. When suggestions consist of new suggested methods, representative test results should accompany the submittals.

Subpart B—How To Use Data Tables

§ 158.100 How to determine registration data requirements.

To determine the specific kinds of data needed to support the registration of each pesticide product, the registration applicant should: