

§ 158.40

40 CFR Ch. I (7-1-03 Edition)

(e) The data requirements and guidelines are not static documents. Section 3(c)(2) of FIFRA states that the administrator "shall revise such guidelines from time to time." Therefore, the data requirements and guidelines will be revised periodically to reflect new scientific knowledge, new trends in pesticide development, and new Agency policies under § 158.80.

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

§ 158.40 Consultation with the Agency.

This part establishes data requirements applicable to various general use patterns of pesticide products, but some unique or unanticipated aspect of a proposed product's use pattern or composition may result in the need for conferences between registration applicants and the Agency. Such conferences may be initiated by the Agency or by registration applicants. Applicants are expected to contact their respective Product Managers to arrange discussions. The Agency welcomes suggestions for changes to improve the clarity, accuracy, or some other aspect of the data requirements set forth in this part. Specific suggestions should be forwarded to the Director of the Hazard Evaluation Division.

§ 158.45 Waivers.

(a) *Rationale and policy.* (1) The data requirements specified in this part as applicable to a category of products will not always be appropriate for every product in that category. Some products may have unusual physical, chemical, or biological properties or atypical use patterns which would make particular data requirements inappropriate, either because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks or benefits of the product. The Agency will waive data requirements it finds are inappropriate, but will ensure that sufficient data are available to make the determinations required by the applicable statutory standards.

(2) The Agency will waive data requirements on a case-by-case basis in response to specific written requests by applicants. Because of the wide variety

of types and use patterns of pesticides, it is impossible to spell out all of the circumstances which might serve as a basis for waiving data requirements. The Agency, however, will take into account, as appropriate, the factors enumerated in sections 3(c)(2)(A) and 25(a)(1) of FIFRA.

(b) *Procedure for requesting waiver.* (1) An applicant should discuss his plans to request a waiver with the EPA Product Manager responsible for his product before developing and submitting extensive support information for the request.

(2) To request a waiver, an applicant must submit a written request to the appropriate Product Manager. The request must specifically identify the data requirement for which a waiver is requested, explain why he thinks data requirement(s) should be waived, describe any unsuccessful attempts to generate the required data, furnish any other information which he believes would support the request, and when appropriate, suggest alternative means of obtaining data to address the concern which underlies the data requirement.

(c) *Notification of waiver decision.* The Agency will review each waiver request and inform the applicant in writing of its decision. In addition, for decisions that could apply to more than a specific product, the Agency may choose to send a notice to all registrants or to publish a notice in the FEDERAL REGISTER announcing its decision. An Agency decision denying a written request to waive a data requirement shall constitute final Agency action for purposes of FIFRA section 16(a).

(d) *Availability of waiver decisions.* Agency decisions under this section granting waiver requests will be available to the public at the Office of Pesticide Programs Reading Room, Rm. 236, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202 from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays. Any person may obtain a copy of any waiver decision by written request in the manner set forth in 40 CFR part 2.

§ 158.50 Formulators' exemption.

(a) FIFRA section 3(c)(2)(D) provides that an applicant for registration of an