

§ 158.45

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

40 CFR Ch. I (7-1-00 Edition)

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 end-use pesticide product need not submit or cite any data that pertain to the safety of another registered pesticide product which is purchased by the applicant and used in the manufacture or formulation of the product for which registration is sought.

(b) This exemption applies only to data concerning safety of a product or its ingredients, not to efficacy data. Data concerning safety includes toxicity, metabolism, environmental fate, product chemistry, and residue chemistry data.

(c) This exemption does not apply to data concerning the safety of the applicant's end-use product itself, unless the composition of the applicant's product and that of the purchased product are

Environmental Protection Agency

§ 158.60

identical, i.e., data which this part indicates must be developed by tests using the end-use product for which registration is sought as the test substance. These requirements can be identified by the notation "EP*" in the "test substance" column of the tables in subparts C and D of this part and these are the minimum data requirements that the applicant described in paragraph (a) of this section (i.e., the "formulator") must satisfy.

(d) The data to which this exemption applies usually will concern the safety of one or more of the end-use product's active ingredients, specifically, those active ingredients which are contained in the purchased product. These data requirements normally can be identified by the notations "TGAI" (technical grade of active ingredient), "PAI" (pure active ingredients), "PAIRA" (pure active ingredient, radiolabeled), or "TEP" (typical end-use product) in the "test substance" column of the tables in subparts C and D of this part.

(e) EPA interprets FIFRA section 3(c)(2)(D) as allowing an applicant to use the formulator's exemption with respect to a data requirement concerning the safety of an ingredient of his product only if:

(1) His application indicates that the ingredient's presence in his product is attributable solely to his purchase from another person of an identified, registered product containing that ingredient and his use of the purchased product in formulating his product; and

(2) The purchased product is a registered manufacturing-use product whose label does not prohibit its use for making an end-use product with any use for which the applicant's product will be labeled; or

(3) The purchased end-use product is a registered end-use product labeled for each use for which the applicant's product will be labeled.

(f) Notwithstanding FIFRA section 3(c)(2)(D), EPA will not approve an application unless there is available to EPA for its review whatever data is necessary in order to make the re-

quired risk/benefit finding under FIFRA section 3(c)(5) or section 3(c)(7).

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

§ 158.55 Agricultural vs. non-agricultural pesticides.

Section 25(a)(1) of FIFRA instructs the Administrator to "take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk and the appropriate data for evaluating such risk between agricultural and non-agricultural pesticides." This part distinguishes the various classes of pesticide use (e.g., crop vs. non-crop) and the corresponding data necessary to support registration under FIFRA. This information is present in each data requirement table. In addition, the Use Pattern Index (appendix A) is a comprehensive list of pesticide use patterns, cross-referenced to the general use patterns appearing in the tables; the index will further assist the reader in distinguishing agricultural versus non-agricultural uses of pesticides.

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

§ 158.60 Minor uses.

(a) *Minor use policy.* A minor use of a pesticide is a use on a "minor crop" (a crop which is planted on a small total amount of acreage) or a use which is otherwise limited such that the potential market volume of the product for that use is inherently small. EPA's policy concerning data requirements for minor uses of pesticides includes the following elements:

(1) Since the market volume for a minor use of a pesticide is intrinsically low, and the risk associated with the use often is also correspondingly low, EPA will adjust the data requirements concerning the minor use appropriately.

(2) A new data requirement pertinent to both an unregistered minor use and a registered major use will not be applied to a minor use applicant until it is applied to the major use registrations.