

Environmental Protection Agency

§ 158.55

(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 OPP Regulatory Public Docket located as set forth in 40 CFR 150.17(c). Any person may obtain a copy of any waiver decision by written request in the manner set forth in 40 CFR part 2.

[49 FR 42881, Oct. 24, 1984, as amended at 69 FR 39864, July 1, 2004; 71 FR 35545, June 21, 2006]

§ 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 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 required 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