

§ 152.85 Formulators' exemption.

(a) *Statutory provision.* FIFRA section 3(c)(2)(D) excuses an applicant from the requirement to submit or cite data pertaining to any pesticide contained in his product that is derived solely from one or more EPA-registered products which the applicant purchases from another person. This provision is commonly referred to as the formulators' exemption.

(b) *Applicability of the formulators' exemption.* (1) The formulators' exemption applies only to data concerning the purchased product or its ingredients. These data may include, but are not limited to, product chemistry, toxicology, residue chemistry, exposure, environmental fate, and ecological effects.

(2) The data to which the formulators' exemption applies usually will concern the safety of one or more of the product's active ingredients, specifically, those active ingredients which are contained in the purchased product. In general, data for which the required test substance is the technical grade of the active ingredient, the pure active ingredient, the radiolabeled pure active ingredient, or a typical end-use product are eligible for the formulators' exemption.

(3) The formulators' exemption generally does not apply to data on the applicant's product itself, including the safety or efficacy of the product, unless the composition of the product is identical to the purchased product. In general, data for which the required test substance is the product proposed for registration are not eligible for the formulators' exemption.

(c) *Limitation of the formulators' exemption.* EPA interprets FIFRA section 3(c)(2)(D) as allowing an applicant to use the formulators' exemption with respect to data concerning an ingredient of his product only if:

(1) The application indicates that the ingredient's presence in the product is attributable solely to the purchase from another person of an identified, registered product containing that ingredient and the use of the purchased product in formulating the 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 labeled for any use for which the applicant's product will be labeled; or

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

(d) *Claiming eligibility for the exemption.* (1) If the product contains one or more ingredients eligible for the formulators' exemption, the applicant need not comply with the requirements of §§152.90 through 152.96 with respect to any data requirement pertaining to such ingredient, provided that he submits to the Agency a certification statement containing the following information (a form for this purpose is available from the Agency):

(i) Identification of the applicant, and of the product by EPA registration number or file symbol.

(ii) Identification of each ingredient in the pesticide that is eligible for the formulators' exemption, and the EPA registration number of the product that is the source of that ingredient.

(iii) A statement that the listed ingredients meet the requirements for the formulators' exemption.

(iv) A statement that the applicant has submitted (either previously or with the current application) a complete, accurate and current Confidential Statement of Formula.

(v) The name, title and signature of the applicant or his authorized representative and the date of signature.

(2) An applicant for amended registration is not required to submit a new formulators' exemption statement, if the current statement in Agency files is complete and accurate.

(e) *Approval of registration.* Notwithstanding FIFRA section 3(c)(2)(D), EPA will not approve an application unless there are available to EPA for its review all data that are necessary to make the required risk/benefit finding under FIFRA section 3(c)(5) or section 3(c)(7).

[72 FR 61027, Oct. 26, 2007]

§ 152.86 The cite-all method.

An applicant may comply with this subpart by citing all data in Agency files that are pertinent to its consideration of the requested registration

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under FIFRA section 3(c)(5), in accordance with the procedures in this section, as applicable.

(a) *Exclusive use studies.* The applicant must certify to the Agency that he has obtained, from each person listed on the Data Submitters List as an exclusive use data submitter for the chemical in question, a written authorization that contains at least the following information:

- (1) Identification of the applicant to whom the authorization is granted;
- (2) Authorization to the applicant to use all pertinent studies in satisfaction of data requirements for the application in question; and
- (3) The signature and title of the original data submitter or his authorized representative and date of the authorization.

If the Agency identifies any exclusive use data submitter not on the Data Submitters List, the applicant will be required prior to registration to obtain the necessary written authorization from such person.

(b) *Other studies.* The applicant must certify to the Agency that, with respect to each other person on the Data Submitters List for the chemical in question:

- (1) He has obtained from that person a written authorization that contains the information required by paragraphs (a) (1) through (3) of this section; or
- (2) He has furnished to that person:
 - (i) A notification of his intent to apply for registration, including the name of the proposed product, and a list of the product's active ingredients;
 - (ii) An offer to pay the person compensation to the extent required by FIFRA section 3(c)(1)(F) for any data on which the application relies;
 - (iii) An offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of any study; and
 - (iv) His name, address and telephone number.

(c) *General offer to pay statement.* The applicant must submit to the Agency the following general offer to pay statement:

[Name of applicant] hereby offers and agrees to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA section

3(c)(1)(F) of the Federal Insecticide, Fungicide and Rodenticide Act.

(d) *Acknowledgement of reliance on data.* Each application filed under this section shall include an acknowledgement that for purposes of FIFRA section 3(c)(1)(F) the application relies on the following data:

- (1) All data submitted with or specifically cited in the application; and
- (2) Each other item of data in the Agency's files which:
 - (i) Concerns the properties or effects of the applicant's product, of any product which is identical or substantially similar to the applicant's product, or of one or more of the active ingredients in the applicant's product; and
 - (ii) Is one of the types of data that EPA would require to be submitted if the application sought the initial registration under FIFRA section 3(c)(5) of a product with composition and intended uses identical or substantially similar to the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

§ 152.90 The selective method.

An applicant may comply with this subpart by listing the specific data requirements that apply to his product, its active ingredients, and use patterns, and demonstrating his compliance for each data requirement by submitting or citing individual studies, or by demonstrating that no study has previously been submitted to the Agency. This section summarizes the procedures that an applicant must follow if he chooses the selective method of demonstrating compliance. Sections 152.91 through 152.96 contain specific procedures for citing or submitting a study or demonstrating a data gap.

(a) *List of data requirements.* Each applicant must submit a list of the data requirements that would apply to his pesticide, its active ingredients, and its use patterns, if the product were being proposed for registration under FIFRA section 3(c)(5) for the first time. The applicant need not list data requirements pertaining to any ingredient which qualifies for the formulator's exemption.