

## Environmental Protection Agency

## § 152.86

safety of any ingredient (or mixture of ingredients) contained in his product that is derived solely from one or more EPA-registered products which the applicant purchases from another producer.

(b) 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 requirements pertaining to the safety of any 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):

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

(2) 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;

(3) A statement that the listed ingredients meet the requirements for the formulators' exemption;

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

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

(c) 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.

[49 FR 30903, Aug. 1, 1984, as amended at 58 FR 34203, June 23, 1993; 60 FR 32096, June 19, 1995]

### § 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 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 author-

ization 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)(D) 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)(D) 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)(D) the application relies on the following data:

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(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.

### § 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.

(1) If a Registration Standard has been issued for any active ingredient, the applicant must list the applicable data requirements enumerated in that Standard for the active ingredient and, if end use products are covered by the Registration Standard, for such products containing that active ingredient.

(2) If a Registration Standard has not been issued, or if an issued Registra-

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tion Standard does not cover all data requirements for products containing the active ingredient in question, the applicant must list the applicable requirements as prescribed by 40 CFR part 158. All required (R) studies, and any studies that could be conditionally required (CR) based upon composition, use pattern, or the results of required studies, are to be listed. The applicant may demonstrate via the data gap procedures in § 152.96 that a conditional requirement need not be satisfied by the submission or citation of data at the time of application.

(b) *Methods of demonstrating compliance.* The applicant must state for each data requirement on the list required by paragraph (a) of this section which of the following methods of compliance with the requirement he is using, and shall provide the supporting documentation specified in the referenced section.

(1) Existence of or granting of a data waiver. Refer to § 152.91.

(2) Submission of a new valid study. Refer to § 152.92.

(3) Citation of a specific valid study previously submitted to the Agency by the applicant or another person, with any necessary written authorizations or offers to pay. Refer to § 152.93.

(4) Citation of a public literature study. Refer to § 152.94.

(5) Citation of all pertinent studies previously submitted to the Agency, with any necessary written authorizations or offers to pay. Refer to § 152.95.

(6) Documentation of a data gap. Refer to § 152.96.

### § 152.91 Waiver of a data requirement.

The applicant may demonstrate compliance for a data requirement by documenting the existence of a waiver in accordance with paragraph (a) of this section, or by being granted a new waiver requested in accordance with paragraph (b) of this section.

(a) *Request for extension of an existing waiver.* An applicant may claim that a waiver previously granted by the Agency also applies to a data requirement for his product. To document this claim, the applicant must provide a reference to the Agency record that describes the previously granted waiver, such as an Agency list of waivers or an