

## Environmental Protection Agency

## § 152.90

### § 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 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)(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:

- (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