

Environmental Protection Agency

§ 152.97

(iii) Whether the new use would substantially increase the risk of unreasonable adverse effects on the environment, usually required when the application involves a new use of a product which is identical or substantially similar to a currently registered product.

(b) *Data gap listed in a Registration Standard.* The applicant may rely on a data gap that is documented by a Registration Standard without submitting the certification required by paragraph (c) of this section. If the data gap listed in the Registration Standard has been filled since the issuance of the Standard, the Agency will notify the applicant and require him to choose another method of demonstrating compliance.

(c) *Certification of a data gap.* Except as provided by paragraph (b) of this section, an applicant who wishes to claim that a data gap exists must certify to the Agency that:

(1) The applicant has furnished, by certified mail, to each original data submitter on the current Data Submitters List for the active ingredient in question, a notice containing the following information:

(i) The name and address of the applicant;

(ii) The name of the product, and a statement that the applicant intends to apply for registration of that product;

(iii) The name(s) of the active ingredient(s) in the product;

(iv) A list of the data requirements for which the applicant intends to claim under this section that a data gap exists; and

(v) A request that the data submitter identify, within 60 days of receipt of the notice, any valid study which he has submitted to the Agency that would fulfill any of the data requirement(s) listed.

(2) The applicant has, within that 60-day period, received no response, or has received a negative response, from each person notified; and

(3) The applicant has no basis to believe that any data have been submitted to the Agency that would fulfill the data requirement, and is entitled to claim that a data gap exists.

(d) *Requirement to obtain permission or make offer to pay.* In responding to a

data gap letter, the original data submitter is not deemed to have given his authorization for the applicant to cite any study which the data submitter identifies in his response. The applicant must seek and obtain specific written authorization from, or make an offer to pay to, the original data submitter to cite the identified study in order to demonstrate compliance for the data requirement. Nothing, however, precludes the applicant from requesting written authorization or making an offer to pay at the same time that he requests confirmation of a data gap.

§ 152.97 Rights and obligations of data submitters.

(a) *Right to be listed on Data Submitters List.* (1) Each original data submitter shall have the right to be included on the Agency's Data Submitters List.

(2) Each original data submitter who wishes to have his name added to the current Data Submitters List must submit to the Agency the following information:

(i) Name and current address;

(ii) Chemical name and common name (if any) of the active ingredient(s), with respect to which he is an original data submitter;

(iii) For each such active ingredient, the type(s) of study he has previously submitted (corresponding to Guidelines reference numbers given in tables in 40 CFR part 158, if applicable), the date of submission, and the EPA registration number, file symbol, or other identifying reference for which it was submitted.

(3) Each applicant not already included on the Data Submitters List for a particular active ingredient must inform the Agency at the time of submission of a relevant study whether he wishes to be included on the Data Submitters List for that pesticide.

(b) *Obligation to respond to data gap letters.* An applicant who chooses to defer his obligation by demonstrating the existence of a data gap must write to each original data submitter for confirmation that the data submitter has not submitted a valid study that would satisfy the requirement. The original data submitter is not required to respond to such letters. However, if

he fails to respond, the applicant is entitled to assume (and the Agency will act on the assumption) that the original data submitter has not submitted a study to satisfy the requirement. The data submitter may thereby limit his right to later challenge the applicant's claim if he fails respond in writing delivered to the applicant within 60 days of receipt of the applicant's data gap letter.

§ 152.98 Procedures for transfer of exclusive use or compensation rights to another person.

A person who possesses rights to exclusive use or compensation under FIFRA section 3(c)(1)(D) may transfer such rights to another person in accordance with this section.

(a) The original data submitter must submit to the Agency a transfer document that contains the following information:

(1) The name, address and state of incorporation (if any) of the original data submitter (the transferor);

(2) The name, address and state of incorporation (if any) of the person to whom the data rights are being transferred (the transferee);

(3) Identification of each item of data transferred including:

(i) The name of the study or item of data;

(ii) Whether the study is an exclusive use study, and, if so, when the period of exclusive use protection expires;

(iii) The name of the person or laboratory that conducted the study;

(iv) The date the study was submitted to the Agency;

(v) The EPA document number assigned to the item of data (the Master Record Identification Number or Accession Number), if known. If not known, the EPA administrative number (such as the EPA Registration Number, petition number, file symbol, or permit number) with which the item of data was submitted, such that the Agency can identify the item of data.

(vi) A statement that the transferor transfers irrevocably to the transferee all rights, titles, and interest in the items of data named;

(vii) A statement that the transferor and transferee understand that any

false statement may be punishable under 18 U.S.C. 1001; and

(viii) The names, signatures and titles of the transferor and transferee, and the date signed.

(b) In addition, the original data submitter must submit to the Agency a notarized statement affirming that:

(1) The person signing the transfer agreement is authorized by the original data submitter to bind the data submitter;

(2) No court order prohibits the transfer, and any required court approvals have been obtained; and

(3) The transfer is authorized under Federal, State, and local law and relevant corporate charters, bylaws or partnership agreements.

(c) The Agency will acknowledge the transfer of the data by notifying both transferor and transferee, and will state the effective date of the transfer. Thereafter the transferee will be considered to be the original data submitter of the items of data transferred for all purposes under FIFRA section 3(c)(1)(D), unless a new transfer agreement is submitted to the Agency.

§ 152.99 Petitions to cancel registration.

An original data submitter may petition the Agency to deny or cancel the registration of a product in accordance with this section if he has submitted to the Agency a valid study which, he claims, satisfies a data requirement that an applicant purportedly has failed to satisfy.

(a) *Grounds for petition.* (1) If an applicant has offered to pay compensation to an original data submitter of a study (either specifically or by filing a general offer to pay statement), the original data submitter may petition the Agency to deny or cancel the registration to which the offer related on any of the following grounds:

(i) The applicant has failed to participate in an agreed-upon procedure for reaching an agreement on the amount and terms of compensation. The petitioner shall submit a copy of the agreed-upon procedure and describe the applicant's failure to participate in the procedure.

(ii) The applicant has failed to comply with the terms of an agreement on