

§ 152.97

40 CFR Ch. I (7–1–12 Edition)

(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 or part 161, as 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.

[49 FR 30903, Aug. 1, 1984, as amended at 72 FR 61028, Oct. 26, 2007]

§ 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)(F) 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;