

§ 152.99

40 CFR Ch. I (7-1-04 Edition)

(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 compensation. The petitioner shall submit a copy of the agreement, and shall describe how the applicant has failed to comply with the agreement.

(iii) The applicant has failed to participate in an arbitration proceeding. The petitioner shall submit evidence of such failure.

(iv) The applicant has failed to comply with the terms of an arbitration decision. The petitioner shall submit a copy of the arbitration decision, and describe how the applicant has failed to comply with the decision.

(2) When no offer to pay has been made, the petitioner shall state in his petition the basis for the challenge, and describe how the failure of the applicant to comply with the procedures of this subpart has deprived him of the

rights accorded him under FIFRA section 3(c)(1)(D). Possible grounds for challenge include, but are not limited to, the following:

(i) The applicant has failed to list a data requirement applicable to his product, or has failed to demonstrate compliance with all applicable data requirements.

(ii) The applicant has submitted or cited a study that is not valid.

(iii) The applicant has submitted or cited a study that does not satisfy the data requirement for which it was submitted or cited.

(iv) The applicant has failed to comply with the procedure for showing that a data gap exists.

(v) The applicant has improperly certified that a data gap exists. An original data submitter who has failed without good cause to respond to an applicant's request for confirmation of a data gap may not petition the Agency for review on this basis.

(vi) The applicant has submitted or cited a study originally submitted by the petitioner, without the required authorization or offer to pay.

(b) *Procedure for petition to the Agency—(1) Time for filing.* A petition under paragraph (a)(1) of this section may be filed at any time that the circumstances warrant. A petition under paragraph (a)(2) of this section must be filed within one year after the Agency makes public the issuance of the registration.

(2) *Notice to affected registrant.* At the same time that the petitioner files his petition with the Agency, he shall send a copy by certified mail to the affected applicant or registrant. The applicant or registrant shall have 60 days from the date of his receipt of the petition to submit written comments to the Agency.

(c) *Disposition of petitions.* The Agency will consider the material submitted by the petitioner and the response, if any, by the affected applicant or registrant.

(1) If the Agency determines that the petition is without merit, it will inform the petitioner and the affected applicant or registrant that the petition is denied. Denial of a petition is a final Agency action.

(2) If the Agency determines that an applicant has acted in any way described by paragraph (a)(1) of this section, the Agency will notify the petitioner and the affected applicant or registrant that it intends to deny or cancel the registration of the product in support of which the data were cited. The affected applicant or registrant will have 15 days from the date of delivery of this notice to respond. If the Agency determines, after considering any response, that the affected applicant or registrant has acted in the ways described by paragraph (a)(1) of this section, the Agency will deny or cancel the registration without further hearing. Refer to FIFRA section 3(c)(1)(D)(ii). Denial or cancellation of a registration is a final Agency action.

(3) Except as provided in paragraph (c)(2) of this section, if the Agency determines that an applicant for registration of a product has acted in any way that deprives an original data submitter of rights under FIFRA section 3(c)(1)(D), the Agency will take steps to deny the application or cancel the registration, as appropriate. The procedures in FIFRA section 3(c)(6) or section 6(b) shall be followed. Denial or cancellation is a final Agency action.

(d) *Hearing.* Any hearing will be conducted in accordance with the procedures in 40 CFR part 164. The only matter for resolution at the hearing shall be whether the registrant failed to comply with the requirements and procedures of FIFRA section 3(c)(1)(D) or of this subpart, in the manner described by the petitioner. A decision following a hearing shall be final.

### Subpart F—Agency Review of Applications

SOURCE: 53 FR 15980, May 4, 1988, unless otherwise noted.

#### § 152.100 Scope.

(a) The Agency will follow the procedures in this subpart for all applications for registration, except an application for registration of a pesticide that has been the subject of a previous Agency cancellation or suspension notice under FIFRA sec. 6.

(b) The Agency will follow the procedures of subpart D of part 164 of this