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and shall submit the fee for that category as prescribed by the latest EPA notice of section 33 fees.

(2) If FIFRA sec. 33 is not in effect, the applicant shall submit any fees required by subpart U of this part, if applicable.

[53 FR 15978, May 4, 1988, as amended at 58 FR 34203, June 23, 1993; 60 FR 32096, June 19, 1995; 72 FR 61027, Oct. 26 2007; 73 FR 75594, Dec. 12, 2008]

§ 152.55 Where to send applications and correspondence.

Applications and correspondence relating to registration should be sent to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b).

[71 FR 35545, June 21, 2006]

Subpart D [Reserved]

Subpart E—Procedures To Ensure Protection of Data Submitters' Rights

SOURCE: 49 FR 30903, Aug. 1, 1984, unless otherwise noted.

§ 152.80 General.

This subpart E describes the information that an applicant must submit with his application for registration or amended registration to comply (and for the Agency to determine compliance) with the provisions of FIFRA sec. 3(c)(1)(F). This subpart also describes the procedures by which data submitters may challenge registration actions which allegedly failed to comply with these procedures. If the Agency determines that an applicant has failed to comply with the requirements and procedures in this subpart, the application may be denied. If the Agency determines, after registration has been issued, that an applicant failed to comply with these procedures and requirements, the Agency may issue a notice of intent to cancel the product's registration.

[73 FR 75594, Dec. 12, 2008]

§ 152.81 Applicability.

(a) Except as provided in paragraph (b) of this section, §§152.83 through 152.119 apply to:

(1) Each application for registration of a new product;

(2) Each application for an amendment of a registration; and

(3) Each application for reregistration under FIFRA section 3(g).

(b) This subpart E does not apply to:

(1) Applications for registration submitted to States under FIFRA section 24(c);

(2) Applications for experimental use permits under FIFRA section 5;

(3) Applications for emergency exemptions under FIFRA section 18;

(4) Applications to make only one or more of the following types of amendments to existing registrations, unless the Administrator or his designee finds that Agency consideration of scientific data would be necessary in order to approve the amendment under FIFRA section 3(c)(5):

(i) An increase or decrease in the percentage in the product of one or more of its active ingredients or deliberately added inert ingredients;

(ii) A revision of the identity or amount of impurities present in the product;

(iii) The addition or deletion of one or more deliberately added inert ingredients;

(iv) The deletion of one or more active ingredients;

(v) A change in the source of supply of one or more of the active ingredients used in the product, if the new source of the active ingredient is a product which is registered under FIFRA section 3;

(vi) Deletion of approved uses of claims;

(vii) Redesign of the label format involving no substantive changes, express or implied, in the directions for use, claims, representations, or precautionary statements;

(viii) Change in the product name or addition of an additional brand name, if no additional claims, representations, or uses are expressed or implied by the changes;

(ix) Clarification of directions for use;

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- (x) Correction of typographical errors;
- (xi) Changes in the registrant's name or address;
- (xii) Adding or deleting supplemental registrants;
- (xiii) Changes in the package or container size;
- (xiv) Changes in warranty, warranty disclaimer, or liability limitation statements, or addition to or deletion of such statements;
- (xv) "Splitting" a label for the sole purpose of facilitating the marketing of a product in different geographic regions with appropriate labels, where each amended label will contain previously approved use instructions (and related label statements) appropriate to a particular geographic region;
- (xvi) Any other type of amendment, if the Administrator or his designee determines, by written finding, that the Agency consideration of scientific data would not be necessary in order to approve the amendment under FIFRA section 3(c)(5); and
- (xvii) Compliance with Agency Regulations, adjudicatory hearing decisions, notices, or other Agency announcements that unless the registration is amended in the manner the Agency proposes, the product's registration will be suspended or cancelled, or that a hearing will be held under FIFRA section 6. (However, this paragraph does not apply to amendments designed to avoid cancellation or suspension threatened under FIFRA section 3(c)(2)(B) or because of failure to submit data.)

§ 152.83 Definitions.

As used in this subpart, the following terms shall have the meanings set forth in this section:

Data gap means the absence of any valid study or studies in the Agency's files which would satisfy a specific data requirement for a particular pesticide product.

Data Submitters List means the current Agency list, entitled "Pesticide Data Submitters by Chemical," of persons who have submitted data to the Agency.

Exclusive use study means a study that meets each of the following requirements:

(1) The study pertains to a new active ingredient (new chemical) or new combination of active ingredients (new combination) first registered after September 30, 1978;

(2) The study was submitted in support of, or as a condition of approval of, the application resulting in the first registration of a product containing such new chemical or new combination (first registration), or an application to amend such registration to add a new use; and

(3) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B);

Provided that, a study is an exclusive use study only during the 10-year period following the date of the first registration.

Original data submitter means the person who possesses all rights to exclusive use or compensation under FIFRA section 3(c)(1)(F) in a study originally submitted in support of an application for registration, amended registration, reregistration, or experimental use permit, or to maintain an existing registration in effect. The term includes the person who originally submitted the study, any person to whom the rights under FIFRA section 3(c)(1)(F) have been transferred, or the authorized representative of a group of joint data developers.

Valid study means a study that has been conducted in accordance with the Good Laboratory Practice standards of 40 CFR part 160 or generally accepted scientific methodology and that EPA has not determined to be invalid.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

§ 152.84 When materials must be submitted to the Agency.

All information required by this subpart should be submitted with the application, but may be submitted at any later time prior to EPA's approval of the application. The Agency will not approve any application until it determines either that the application is not subject to these requirements or that all required materials have been submitted and are acceptable.

§ 152.85 Formulators' exemption.

(a) *Statutory provision.* FIFRA section 3(c)(2)(D) excuses an applicant from the requirement to submit or cite data pertaining to any pesticide contained in his product that is derived solely from one or more EPA-registered products which the applicant purchases from another person. This provision is commonly referred to as the formulators' exemption.

(b) *Applicability of the formulators' exemption.* (1) The formulators' exemption applies only to data concerning the purchased product or its ingredients. These data may include, but are not limited to, product chemistry, toxicology, residue chemistry, exposure, environmental fate, and ecological effects.

(2) The data to which the formulators' exemption applies usually will concern the safety of one or more of the product's active ingredients, specifically, those active ingredients which are contained in the purchased product. In general, data for which the required test substance is the technical grade of the active ingredient, the pure active ingredient, the radiolabeled pure active ingredient, or a typical end-use product are eligible for the formulators' exemption.

(3) The formulators' exemption generally does not apply to data on the applicant's product itself, including the safety or efficacy of the product, unless the composition of the product is identical to the purchased product. In general, data for which the required test substance is the product proposed for registration are not eligible for the formulators' exemption.

(c) *Limitation of the formulators' exemption.* EPA interprets FIFRA section 3(c)(2)(D) as allowing an applicant to use the formulators' exemption with respect to data concerning an ingredient of his product only if:

(1) The application indicates that the ingredient's presence in the product is attributable solely to the purchase from another person of an identified, registered product containing that ingredient and the use of the purchased product in formulating the product; and

(2) The purchased product is a registered manufacturing-use product

whose label does not prohibit its use for making an end-use product labeled for any use for which the applicant's product will be labeled; or

(3) The purchased product is a registered end-use product labeled for each use for which the applicant's product will be labeled.

(d) *Claiming eligibility for the exemption.* (1) 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 requirement pertaining to 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):

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

(ii) 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.

(iii) A statement that the listed ingredients meet the requirements for the formulators' exemption.

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

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

(2) 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.

(e) *Approval of registration.* Notwithstanding FIFRA section 3(c)(2)(D), EPA will not approve an application unless there are available to EPA for its review all data that are necessary to make the required risk/benefit finding under FIFRA section 3(c)(5) or section 3(c)(7).

[72 FR 61027, Oct. 26, 2007]

§ 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

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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)(F) 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)(F) 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)(F) 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.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

§ 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.

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(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 Registration 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 or part 161, as applicable. 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.

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

§ 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 applicable Registration Standard, and must explain why that waiver should apply to his product.

(b) *Request for a new waiver.* An applicant who requests a waiver to satisfy a data requirement must submit the information specified in 40 CFR 158.45 or 40 CFR 161.45.

(c) *Effect of denial of waiver request.* If the request for a new waiver or extension of an existing waiver is denied by the Agency, the applicant must choose another method of satisfying the data requirement.

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

§ 152.92 Submission of a new valid study.

An applicant may demonstrate compliance for a data requirement by submitting a valid study that has not previously been submitted to the Agency. A study previously submitted to the Agency should not be resubmitted but should be cited in accordance with §152.93.

§ 152.93 Citation of a previously submitted valid study.

An applicant may demonstrate compliance for a data requirement by citing a valid study previously submitted to the Agency. The study is not to be submitted to the Agency with the application.

(a) *Study originally submitted by the applicant.* If the applicant certifies that he is the original data submitter, no documentation other than the citation is necessary.

(b) *Study previously submitted by another person.* If the applicant is not the original data submitter, the applicant may cite the study only in accordance

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with paragraphs (b) (1) through (3) of this section.

(1) *Citation with authorization of original data submitter.* The applicant may cite any valid study for which he has obtained the written authorization of the original data submitter. The applicant must obtain written authorization to cite any study that is an exclusive use study. The applicant must certify that he has obtained from the original data submitter a written authorization that contains at least the following information:

- (i) Identification of the applicant to whom the authorization is granted;
- (ii) Identification by title, EPA Accession Number or Master Record Identification Number, and date of submission, of the study or studies for which the authorization is granted;
- (iii) Authorization to the applicant to use the specified study in satisfaction of the data requirement for the application in question; and
- (iv) The signature and title of the original data submitter or his authorized representative, and date of the authorization.

(2) *Citation with offer to pay compensation to the original data submitter.* The applicant may cite any valid study that is not subject to the exclusive use provisions of FIFRA section 3(c)(1)(F)(i) without written authorization from the original data submitter if the applicant certifies to the Agency that he has furnished to the original data submitter:

- (i) A notification of the applicant's intent to apply for registration, including the proposed product name and a list of the product's active ingredients;
- (ii) Identification of the specific data requirement involved and of the study for which the offer to pay is made (by title, EPA Accession Number or Master Record Identification Number, and date of submission, if possible);
- (iii) An offer to pay the person compensation to the extent required by FIFRA section 3(c)(1)(F);
- (iv) An offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study; and
- (v) The applicant's name, address and telephone number.

(3) *Citation without authorization or offer to pay.* The applicant may cite any valid study without written authorization from, or offer to pay to, the original data submitter if the study was originally submitted to the Agency on or before the date that is 15 years before the date of the application for which it is cited, and the study is not an exclusive use study, as defined in §152.83(c).

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

§ 152.94 Citation of a public literature study or study generated at government expense.

(a) An applicant may demonstrate compliance for a data requirement by citing, and submitting to the Agency, one of the following:

- (1) A valid study from the public literature.
- (2) A valid study generated by, or at the expense of, any government (Federal, State, or local) agency.

(b) In no circumstances does submission of a public literature study or government-generated study confer any rights on the data submitter to exclusive use of data or compensation under FIFRA section 3(c)(1)(F).

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

§ 152.95 Citation of all studies in the Agency's files pertinent to a specific data requirement.

An applicant normally may demonstrate compliance for a data requirement by citation of all studies in the Agency's files pertinent to that data requirement. The applicant who selects this cite-all option must submit to the Agency:

- (a) A general offer to pay statement having the same wording as that specified in §152.86(c) except that the offer to pay may be limited to apply only to data pertinent to the specific data requirement(s) for which the cite-all method of support has been selected;
- (b) A certification that:

(1) For each person who is included on the Data Submitters List as an original data submitter of exclusive use data for the active ingredient in question, the applicant has obtained a written authorization containing the

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information required by §152.86(a) for the use of the any exclusive use study that would be pertinent to the applicant's product; and

(2) For each person included on the current Data Submitters List as an original data submitter of data that are not exclusive use for the active ingredient in question, the applicant has furnished:

(i) A notification of the applicant's intent to apply for registration, including the name of the proposed product, and a list of the product's active ingredients;

(ii) Identification of the specific data requirement(s) for which the offer to pay for data is being made;

(iii) An offer to pay the person compensation to the extent required by FIFRA section 3(c)(1)(F);

(iv) An offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for use of any study; and

(v) The applicant's name, address and telephone number; and

(c) An acknowledgment having the same wording as that specified in §152.86(d), except that it may be limited to apply only to data pertinent to the specific data requirement(s) for which the cite-all method of support has been selected.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

§ 152.96 Documentation of a data gap.

Except as provided in paragraph (a) of this section, an applicant may defer his obligation to satisfy an applicable data requirement until the Agency requests the data if he can demonstrate, by the procedure in this section, that no other person has previously submitted to the Agency a study that would satisfy the data requirement in question.

(a) *When data gap procedures may not be used.* (1) An applicant for registration of a product containing a new chemical may not defer his obligation by the procedure in this section, unless he can demonstrate to the Agency's satisfaction that the data requirement was imposed so recently that insufficient time has elapsed for the study to have been completed and that, in the public interest, the product should be

registered during the limited period of time required to complete the study. Refer to FIFRA section 3(c)(7)(C).

(2) An applicant for registration of a product under FIFRA section 3(c)(7) (A) or (B) may not defer his obligation by the procedure in this section if the Agency requires the data to determine:

(i) Whether the product is identical or substantially similar to another currently registered product or differs only in ways that would not substantially increase the risk of unreasonable adverse effects on the environment;

(ii) If efficacy data are required, whether the product is efficacious; or

(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

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(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;

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(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)(F), unless a new transfer agreement is submitted to the Agency.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

§ 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)(F). 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.

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(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)(F)(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)(F), 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)(F) or of this subpart, in the manner described by the petitioner. A decision following a hearing shall be final.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

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 chapter in evaluating any application for registration of a pesticide involving use of the pesticide in a manner that is prohibited by a suspension or cancellation order, to the extent required by subpart D of part 164.

§ 152.102 Publication.

The Agency will issue in the FEDERAL REGISTER a notice of receipt of each application for registration of a product that contains a new active ingredient or that proposes a new use. After registration of the product, the Agency will issue in the FEDERAL REGISTER a