

### 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 (§§ 152.80 through 152.119)<sup>1</sup> describes the information that an applicant must submit with his application for registration, amended registration, or reregistration to comply (and for the Agency to determine compliance) with the provisions of FIFRA section 3(c)(1)(D). 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.

[49 FR 30903, Aug. 1, 1984, as amended at 58 FR 34203, June 23, 1993]

#### § 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;

(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;

<sup>1</sup>EDITORIAL NOTE: Sections 152.116 and 152.119 were transferred to subpart F at 53 FR 15980, May 4, 1988.

## § 152.83

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(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:

(a) *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.

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

(c) *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.

(d) *Original data submitter* means the person who possesses all rights to exclusive use or compensation under FIFRA section 3(c)(1)(D) 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)(D) have been transferred, or the authorized representative of a group of joint data developers.

(e) *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.

### § 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) FIFRA section 3(c)(2)(D) excuses an applicant from the requirement to submit or cite data pertaining to the safety of any ingredient (or mixture of ingredients) contained in his product that is derived solely from one or more EPA-registered products which the applicant purchases from another producer.

(b) 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 requirements pertaining to the safety of any 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):

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