

### 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.