

## Environmental Protection Agency

## § 152.50

minor modifications to registration having no potential to cause unreasonable adverse effects to the environment may be accomplished without notification to or approval by the Agency. If EPA so determines, it will issue procedures following an opportunity for public comment describing the types of amendments permitted without notification (also known as non-notification). A registrant may distribute or sell a product changed in a manner consistent with such procedures without notification to or approval by the Agency.

(c) *Effect of non-compliance.* Notwithstanding any other provision of this section, if the Agency determines that a product has been modified through notification or without notification in a manner inconsistent with paragraphs (a) or (b) of this section and any procedures issued thereunder, the Agency may initiate regulatory and/or enforcement action without first providing the registrant with an opportunity to submit an application for amended registration.

[61 FR 33041, June 26, 1996]

### § 152.50 Contents of application.

Each application for registration or amended registration must include the following information, as applicable:

(a) *Application form.* An application form must be completed and submitted to the Agency. Application forms are provided by the Agency, with instructions as to the number of copies required and proper completion.

(b) *Identity of the applicant—(1) Name.* The applicant must identify himself. An applicant not residing in the United States must also designate an agent in accordance with paragraph (b)(3) of this section to act on behalf of the applicant on all registration matters.

(2) *Address of record.* The applicant must provide an address in the United States for correspondence purposes. The U.S. address provided will be considered the applicant's address of record, and EPA will send all correspondence concerning the application and any subsequent registration to that address. It is the responsibility of the applicant and any registrant under § 152.122 to ensure that the Agency has a current and accurate address.

(3) *Authorized agent.* An applicant may designate a person residing in the United States to act as his agent. If an applicant wishes to designate an agent, he must send the Agency a letter stating the name and United States address of his agent. The applicant must notify the Agency if he changes his designated agent. This relationship may be terminated at any time by the applicant by notifying the Agency in writing.

(4) *Company number.* If an applicant has been assigned a company number by the Agency, the application must reference that number.

(c) *Summary of the application.* Each application must include a list of the data submitted with the application, together with a brief description of the results of the studies. The list of data submitted may be the same as the list required by § 158.32 of this chapter. The summary must state that it is releasable to the public after registration in accordance with § 152.119.

(d) *Identity of the product.* The product for which application is being submitted must be identified. The following information is required:

- (1) The product name;
- (2) The trade name(s) (if different); and
- (3) The EPA Registration Number, if currently registered.

(e) *Draft labeling.* Each application for new registration must be accompanied by five legible copies of draft labeling (typescript or mock-up). Each application for amended registration that proposes to make any changes in the product labeling must be accompanied by five legible copies of draft labeling incorporating the proposed labeling changes. If the proposed labeling change affects only a portion of the labeling, such as the use directions, the applicant may submit five copies of that portion of the label which is the subject of the amendment. Upon request, an applicant for amended registration must submit a complete label to consolidate amendments.

(f) *Registration data requirements.* (1) An applicant must submit materials to demonstrate that he has complied with the FIFRA sec. 3(c)(1)(D) and subpart E of this part with respect to satisfaction of data requirements, to enable the

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Agency to make the determination required by FIFRA sec. 3(c)(5)(B). Required items are described in subpart E of this part.

(2) An applicant must furnish any data specified in part 158 of this chapter which are required by the Agency to determine that the product meets the registration standards of FIFRA sec. 3(c) (5) or (7). Each study must comply with:

(i) Section 158.30 of this chapter, with respect to times for submission;

(ii) Section 158.32 of this chapter, with respect to format of submission;

(iii) Section 158.33 of this chapter, with respect to studies for which a claim of trade secret or confidential business information is made;

(iv) Section 158.34 of this chapter, with respect to flagging for potential adverse effects; and

(v) Section 160.12 of this chapter, if applicable, with respect to a statement of whether studies were conducted in accordance with the Good Laboratory Practices of part 160.

(3) An applicant shall furnish with his application any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on man or the environment, which would be required to be reported under FIFRA sec. 6(a)(2) if the product were registered.

(g) *Certification relating to child-resistant packaging.* If the product meets the criteria for child-resistant packaging, the applicant must submit a certification that the product will be distributed or sold only in child-resistant packaging. Refer to part 157 of this chapter for the criteria and certification requirements.

(h) *Request for classification.* If an applicant wishes to request a classification different from that established by the Agency, he must submit a request for such classification and information supporting the request.

(i) *Statement concerning tolerances.* If the proposed labeling bears instructions for use of the pesticide on food or feed crops, or if the intended use of the pesticide results or may be expected to result, directly or indirectly, in pesticide residues in or on food or feed (including residues of any active ingredient, inert ingredient, metabolite, or

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degradation product), the applicant must submit a statement indicating whether such residues are authorized by a tolerance, exemption from the requirement of a tolerance, or food additive regulation issued under section 408 or 409 of the Federal Food, Drug and Cosmetic Act (FFDCA). If such residues have not been authorized, the application must be accompanied by a petition for establishment of appropriate tolerances, exemptions from the requirement of a tolerance, or food additive regulations, in accordance with part 180 of this chapter.

[53 FR 15978, May 4, 1988, as amended at 58 FR 34203, June 23, 1993; 60 FR 32096, June 19, 1995]

### § 152.55 Where to send applications and correspondence.

Applications and correspondence relating to registration should be mailed to the Registration Division (TS-767C), U.S. Environmental Protection Agency, Washington, DC 20460. Persons who wish to hand-deliver applications should contact the Registration Division to determine the location for delivery.

### 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 (§§ 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

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