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the Agency before the product may legally be distributed or sold, except as provided by § 152.30.

§ 152.43 Alternate formulations.

(a) A product proposed for registration must have a single, defined composition, except that EPA may approve a basic formulation and one or more alternate formulations for a single product.

(b) An alternate formulation must meet the criteria listed in paragraph (b) (1) through (4) of this section. The Agency may require the submission of data to determine whether the criteria have been met.

(1) The alternate formulation must have the same certified limits for each active ingredient as the basic formulation.

(2) If the alternate formulation contains an inert ingredient or impurity of toxicological significance, the formulation must have the same upper certified limit for that substance as the basic formulation;

(3) The label text of the alternate formulation product must be identical to that of the basic formulation.

(4) The analytical method required under § 158.180 must be suitable for use on both the basic formulation and the alternate formulation.

(c) Notwithstanding the criteria in this section, the Agency may determine that an alternate formulation must be separately registered. If EPA makes this determination, the Agency will notify the applicant of its determination and its reasons. Thereafter the application for an alternate formulation will be treated as an application for new registration, and the alternate formulation will be assigned a new registration number.

§ 152.44 Application for amended registration.

(a) Except as provided by § 152.46, any modification in the composition, labeling, or packaging of a registered product must be submitted with an application for amended registration. The applicant must submit the information required by § 152.50, as applicable to the change requested. If an application for amended registration is required, the application must be approved by the

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Agency before the product, as modified, may legally be distributed or sold.

(b) In its discretion, the Agency may:

(1) Waive the requirement for submission of an application for amended registration;

(2) Require that the applicant certify to the Agency that he has complied with an Agency directive rather than submit an application for amended registration; or

(3) Permit an applicant to consolidate an amendment affecting a number of products into a single application.

(4) Permit an applicant to modify a registration by notification or non-notification in accordance with § 152.46.

[53 FR 15978, May 4, 1988, as amended at 61 FR 33041, June 26, 1996]

§ 152.46 Notification and non-notification changes to registrations.

(a) *Changes permitted by notification.*

(1) EPA may determine that certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment may be accomplished by notification to the Agency, without requiring that the registrant obtain Agency approval. If EPA so determines, it will issue procedures following an opportunity for public comment describing the types of modifications permitted by notification and any conditions and procedures for submitting notifications.

(2) A registrant may modify a registration consistent with paragraph (a)(1) of this section and any procedures issued thereunder and distribute or sell the modified product as soon as the Agency has received the notification. Based upon the notification, the Agency may require that the registrant submit an application for amended registration. If it does so, the Agency will notify the registrant and state its reasons for requiring an application for amended registration. Thereafter, if the registrant fails to submit an application the Agency may determine that the product is not in compliance with the requirements of the Act. Notification under this paragraph is considered a report filed under the Act for the purposes of FIFRA section 12(a)(2)(M).

(b) *Changes permitted without notification.* EPA may determine that certain

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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