

Environmental Protection Agency

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disease transmitting bacteria or viruses, or claims to control insects or rodents carrying specific diseases, including, but not limited to ticks that carry Lyme disease.

(iii) The product must not include any false and misleading labeling statements, including those listed in 40 CFR 156.10(a)(5)(i) through (viii).

[53 FR 15977, May 4, 1988, as amended at 59 FR 2751, Jan. 19, 1994; 61 FR 8878, Mar. 6, 1996]

§ 152.30 Pesticides that may be transferred, sold, or distributed without registration.

An unregistered pesticide, or a pesticide whose registration has been cancelled or suspended, may be distributed or sold, or otherwise transferred, to the extent described by this section.

(a) *A pesticide transferred between registered establishments operated by the same producer.* An unregistered pesticide may be transferred between registered establishments operated by the same producer. The pesticide as transferred must be labeled in accordance with part 156 of this chapter.

(b) *A pesticide transferred between registered establishments not operated by the same producer.* An unregistered pesticide may be transferred between registered establishments not operated by the same producer if:

(1) The transfer is solely for the purpose of further formulation, packaging, or labeling into a product that is registered;

(2) Each active ingredient in the pesticide, at the time of transfer, is present as a result of incorporation into the pesticide of either:

(i) A registered product; or

(ii) A pesticide that is produced by the registrant of the final product; and

(3) The product as transferred is labeled in accordance with part 156 of this chapter.

(c) *A pesticide distributed or sold under an experimental use permit.* (1) An unregistered pesticide may be distributed or sold in accordance with the terms of an experimental use permit issued under FIFRA sec. 5, if the product is labeled in accordance with §172.6 of this chapter.

(2) An unregistered pesticide may be distributed or sold in accordance with

the provisions of §172.3 of this chapter, pertaining to use of a pesticide for which an experimental use permit is not required, provided the product is labeled in accordance with part 156 of this chapter.

(d) *A pesticide transferred solely for export.* An unregistered pesticide may be transferred within the United States solely for export if it meets the following conditions:

(1) The product is prepared and packaged according to the specifications of the foreign purchaser; and

(2) The product is labeled in accordance with part 156 of this chapter.

(e) *A pesticide distributed or sold under an emergency exemption.* An unregistered pesticide may be distributed or sold in accordance with the terms of an emergency exemption under FIFRA sec. 18, if the product is labeled in accordance with part 156 of this chapter.

(f) *A pesticide transferred for purposes of disposal.* An unregistered, suspended, or cancelled pesticide may be transferred solely for disposal in accordance with FIFRA sec. 19 or an applicable Administrator's order. The product must be labeled in accordance with part 156 of this chapter.

(g) *Existing stocks of a formerly registered product.* A cancelled or suspended pesticide may be distributed or sold to the extent and in the manner specified in an order issued by the Administrator concerning existing stocks of the pesticide.

Subpart C—Registration Procedures

SOURCE: 53 FR 15978, May 4, 1988, unless otherwise noted.

§ 152.40 Who may apply.

Any person may apply for new registration of a pesticide product. Any registrant may apply for amendment of the registration of his product.

§ 152.42 Application for new registration.

Any person seeking to obtain a registration for a new pesticide product must submit an application for registration, containing the information specified in §152.50. An application for new registration must be approved by

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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