

Environmental Protection Agency

§ 168.65

pesticides and FIFRA section 24(c) registrations.

Subpart C [Reserved]

Subpart D—Export Policy and Procedures for Exporting Unregistered Pesticides

168.65 Pesticide export label and labeling requirements.

168.75 Procedures for exporting unregistered pesticides—purchaser acknowledgement statements.

168.85 Other export requirements.

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SOURCE: 54 FR 1125, Jan. 11, 1989, unless otherwise noted.

Subpart A—General Provisions [Reserved]

Subpart B—Advertising

§ 168.22 Advertising of unregistered pesticides, unregistered uses of registered pesticides and FIFRA section 24(c) registrations.

(a) FIFRA sections 12(a)(1) (A) and (B) make it unlawful for any person to “offer for sale” any pesticide if it is unregistered, or if claims made for it as part of its distribution or sale differ substantially from any claim made for it as part of the statement required in connection with its registration under FIFRA section 3. EPA interprets these provisions as extending to advertisements in any advertising medium to which pesticide users or the general public have access.

(b) EPA regards it as unlawful for any person who distributes, sells, offers for sale, holds for sale, ships, delivers for shipment, or receives and (having so received) delivers or offers to deliver any pesticide, to place or sponsor advertisements which recommend or suggest the purchase or use of:

(1) Any pesticide for a use authorized under a FIFRA section 5 experimental use permit (EUP).

(2) Any pesticide for a use authorized under a FIFRA section 18 emergency exemption, except for advertisements that:

(i) Are placed in media which address primarily persons in the geographical area to which the exemption applies.

(ii) State the name and address of one or more retail dealers who stock the pesticide.

(iii) Contain a prominent notice of the limitations on use under the section 18 emergency exemption.

(3) Any pesticide for any use authorized only by a FIFRA section 24(c) special local need registration, unless the advertisement contains a prominent notice of the limitations on use under the section 24(c) registrations.

(4) Any unregistered pesticide for any use unless the advertisement is one permitted by paragraph (b) (2) or (3) of this section.

(5) A registered pesticide product for an unregistered use, unless the advertisement is one permitted by paragraph (b) (2) or (3) of this section. However, as a matter of policy, the Agency will not regard as unlawful the advertisement of uses permitted by FIFRA section 2(ee) provided the product is not an antimicrobial pesticide targeted against human pathogens (see 51 FR 19174; May 28, 1986).

(c) For purposes of paragraph (b) of this section, a “prominent notice of the limitations on use” is one which sets forth the limitations on use in a manner reasonably likely to be understood by persons to whom the advertisement is addressed. For printed advertising, this criterion will be met by a legend in 6-point or larger type.

Subpart C [Reserved]

Subpart D—Export Policy and Procedures for Exporting Unregistered Pesticides

SOURCE: 58 FR 9085, Feb. 18, 1993, unless otherwise noted.

§ 168.65 Pesticide export label and labeling requirements.

(a) *General.* This section describes how EPA interprets and will enforce the requirements of FIFRA section 17(a)(1). Every exported pesticide, device, and active ingredient used in producing a pesticide (see §152.3 of this chapter for the definition of “active ingredient” and “pesticide”) must bear a label or labeling which meets the requirements of FIFRA section 17(a)(1).

This requirement applies to all such pesticides, devices, or active ingredients, regardless of whether the export is for commercial or research use. In the case of unregistered pesticides, including research substances which are being exported for testing, the labeling requirements of this section continue to apply independently of whether the exporter must submit a purchaser acknowledgement statement under FIFRA section 17(a)(2) as described at § 168.75 of this chapter. In addition, information which will satisfy FIFRA section 2(q)(1)(E), (G), and (H) and section 2(q)(2)(A) and (D) must appear in English and in the appropriate foreign languages, on the label or labeling as described in paragraph (b)(4) of this section. The required label and labeling statements may be met through either immediate container labels, accompanying supplemental labeling as described in paragraph (c) of this section, or a combination of the two.

(b) *Specific requirements.* The labels and labeling of any exported pesticides, devices, and active ingredients used in producing pesticides must meet the requirements regarding label and labeling content, correct representation, and understandability as stated in this paragraph.

(1) *Label contents.* The term *label* means the written, printed, or graphic matter on or attached to the immediate container of the pesticide, device, or active ingredient used in producing a pesticide. In the case that the immediate container is enclosed in an outer container or wrapper through which the label cannot be read, the label must also be on such outer container or wrapper. Except as provided in paragraph (c) of this section, the immediate container of the pesticide, device, or active ingredient used in producing a pesticide must bear a conspicuous and readable label which includes:

(i) *EPA pesticide producing establishment number.* The producing establishment registration number must be present but may appear anywhere on the label or immediate container in accordance with the establishment registration labeling requirements set forth in § 156.10(f) of this chapter.

(ii) *Warning or caution statements.* Warning or caution statements must

appear on the label and must be adequate for the protection of persons handling the pesticide, device, or active ingredients including warnings regarding general toxicological hazards and environmental, physical, or chemical hazards. Warning and caution statements must appear in English and in the appropriate foreign languages, as described in paragraph (b)(4) of this section. Where the U.S. warning or caution statement, as translated, is obviously inappropriate to protect residents of the importing country, (for example, where a statement calls for a gas mask meeting the specification of the U.S. Bureau of Mines) an equivalent caution must be substituted.

(iii) *The statement "Not Registered for Use in the United States of America."* The labels of all pesticides, devices, and active ingredients which are not registered for use in the United States under FIFRA section 3 must prominently display the following statement: "Not Registered for Use in the United States of America." The statement must appear in English and in appropriate foreign languages, as described in paragraph (b)(4) of this section. It is permissible to append explanatory text which qualifies the statement by pointing out the reasons for the unregistered status. Examples of possible additional statements are "Not Registered for Use on...", "No Longer Registered for Use...", or "Not Registered...because..." Such additions must not be misleading or misrepresent the registration status of the pesticide. The statement "Not Registered For Use in the United States of America" must also be present.

(A) A pesticide is considered registered for the purposes of the section 17(a)(1) requirement only when:

(1) A label and labeling approved under a current FIFRA section 3 registration for the product is either attached to the immediate product container or accompanies the product at all times as supplemental labeling as provided in paragraph (c) of this section.

(2) The formula of the exported product is the same as the formula of the U.S. registered product (within certified limits). In addition, a change in the color or fragrance of the export

product will not affect the product's registration status, as long as the following conditions are met:

(i) The change in color must result only from the addition of a dye included on the list of the chemicals exempted from the requirement of a tolerance at 40 CFR 180.910, 180.920, 180.930, and 180.950, and the dye must not be a List 1 inert. (List 1 inerts are those inerts which the Agency has identified as presenting toxicological concerns. The classification of inerts is explained in EPA's Policy Statement on Inert Ingredients in Pesticide Products, which can be obtained at the OPP Regulatory Public Docket located as set forth in 40 CFR 150.17(c).)

(ii) The change in fragrance must result only from the addition of a chemical included on the list of the chemicals exempted from the requirement of a tolerance at 40 CFR 180.910, 180.920, 180.930, and 180.950, and the chemical must not be a List 1 inert.

(iii) The change in fragrance must not result in a pesticide product containing a food or food-like fragrance. (See "Food Fragrances in Pesticide Formulations," EPA's Office of Pesticide Programs Policy and Criteria Notice number 2155.1, November 20, 1975, which can be obtained at the OPP Regulatory Public Docket located as set forth in 40 CFR 150.17(c).)

(iv) Any differences in color or fragrance of the export product in accordance with this section must be reflected in records which show the complete formula of the export product in accordance with the requirements of § 169.2 and this policy.

(3) No statements which appear on any of the product labels or labeling add new uses or claims or in any way contradict the approved FIFRA section 3 labeling. However, certain minor changes may be made to a product's labeling or packaging without affecting the registration status of the product, as specified in § 152.46(b) of this chapter.

(iv) *The ingredient statement.* The ingredient statement must appear on the label in English and in appropriate foreign languages (as described in paragraph (b)(4) of this section). If the English language description of the ingredients is easily identifiable and

likely to be understood by the ordinary individual, the foreign language ingredient statement need not be included on the label. In the case of pesticide products, devices and active ingredients shipped solely for research and development purposes, it is permissible to use coded identification of ingredients on the label in order to protect confidentiality, in accordance with the requirements of §§ 168.75(c) and 168.85(a).

(v) *Identity of parties.* The name and address of the producer, registrant (if any), or the person for whom the pesticide was produced, must appear on the label.

(vi) *Weight or measure.* The net weight must appear on the label in either English or metric units.

(vii) *Additional warning for highly toxic pesticides.* If the pesticide, device or active ingredient is highly toxic to humans, the skull and crossbones, the word "Poison", and a statement of practical treatment must appear on the label. The word "Poison" and the statement of practical treatment shall be in English and in the appropriate foreign languages, as described in paragraph (b)(4) of this section. The skull and crossbones may be in red or black. For criteria on what pesticides are highly toxic, see § 156.10(h) of this chapter.

(2) *Use classification statement.* In addition to the label contents described in paragraph (b)(1) of this section, the labeling must include a use classification statement, if a use classification has been assigned under a FIFRA section 3 registration. The use classification shall accurately describe the use classification applicable to the U.S. registered use of the pesticide, device or active ingredient (e.g., "Restricted Use Pesticide"). Summary statements describing the use classification, e.g., "For retail sale to and use only by Certified Applicators...", or explaining what such terms mean are not required, but may be included if such statements do not result in false representation of the U.S. regulatory status of the pesticide. The use classification information may appear on the product label or on the labeling accompanying the pesticide product during shipment.

(3) *Misrepresentation.* The labeling shall not make false or misleading representations or represent the product as an imitation of other products.

(4) *Understandability.* The required statements must be expressed in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use. To satisfy this section, certain information described in paragraph (b)(4)(i) of this section, which appears on the labeling of all exported pesticide products, devices and active ingredients must appear in English, in an acceptable language of the country of import as defined in paragraph (b)(4)(ii) of this section, and in an acceptable language of the country of final destination, if known or reasonably ascertainable by the exporter. When there are several official languages or dialects in a country, the language which is predominately spoken or written, or a language in which official government business is conducted, will be acceptable.

(i) *Information required to be multilingual.* The following labeling information must be multilingual:

(A) The warning and caution statements.

(B) Where required, the statement “Not Registered for Use in the United States of America.”

(C) The ingredient statement.

(D) Where required in accordance with paragraph (b)(1)(vii) of this section, the word “Poison” and the statement of practical treatment in case of poisoning.

(ii) *Acceptable languages.* In all cases, English must be one of the languages used on the label or labeling. In addition, either the language which is used to conduct official government business, or the predominantly spoken or written language of the country of import must appear on the labeling. In each case where a country of final destination is known, the language which is used to conduct official government business or which is predominantly spoken in that country, if different from the language of the country of import, shall also appear on the labeling. In any case where English is predominantly spoken or written or is the language used to conduct official gov-

ernment business in a country, no other language need be included to meet the multiple language requirement of this paragraph.

(c) *Supplemental labeling.* A pesticide, device or active ingredient intended for export will not be considered in violation of the labeling requirements of FIFRA when the label and/or labeling requirements stated in paragraph (b) of this section are met by supplemental labeling. Supplemental labeling must be attached to the immediate product container or the shipping container of the pesticide, device or active ingredient at all times when it is shipped or held for shipment to meet export label requirements. Supplemental labeling must meet all of the label requirements in paragraph (b) of this section which are not met by the immediate product labels. Supplemental labeling will satisfy the labeling requirements of FIFRA only if the following conditions are met:

(1) *Applicability.* The use of supplemental labeling applies to any situation where the labeling requirements specified in this section are not met fully on the product label which is attached to the immediate product container. Any required label or labeling statement not met on the immediate container may be met through supplemental labeling.

(2) *Labeling contents and relation to shipment.* If supplemental labeling is used to meet any of the labeling requirements of FIFRA section 17(a)(1), it must meet all of the requirements in paragraph (b) of this section which are not met by the label on the immediate product container. Thus, the supplemental labeling, together with the immediate product container label will meet all of the requirements of paragraph (b) of this section. Where used, supplemental labeling must be attached to or accompany the product shipping container of the pesticide, device, or active ingredient used in producing a pesticide at all times when shipped or held for shipment in the United States.

[58 FR 9085, Feb. 18, 1993, as amended at 69 FR 23117, Apr. 28, 2004; 69 FR 39864, July 1, 2004; 71 FR 35546, June 21, 2006]