

## § 167.85

report may result in termination of establishment registration, civil and/or criminal penalty assessments.

[53 FR 35058, Sept. 8, 1988; 54 FR 32638, Aug. 9, 1989, as amended at 58 FR 34203, June 23, 1993]

### Subparts C–D [Reserved]

### Subpart E—Recordkeeping and Reporting Requirements

#### § 167.85 Reporting requirements.

(a) *Who must report.* Each producer operating an establishment must submit the reports required by this section concerning any pesticide, active ingredient, or device produced at each establishment. Custom blenders are not required to report production to the Agency.

(b) *Information required.* The pesticide report shall include the following: (1) Name and address of the establishment; (2) amount of each pesticidal product: (i) Produced during the past year; (ii) sold or distributed during the past year; (iii) estimated to be produced during the current year. The report shall only include those pesticidal products actually produced at the reporting establishment. Reports submitted by foreign-producing establishments shall cover only those pesticidal products exported to the United States.

(c) *How to report.* The reports required by this section must be made on forms supplied by the Agency. It is the ultimate responsibility of companies to obtain, complete, and submit the form each year.

(d) *When to report.* A producer operating an establishment must submit an initial report no later than 30 days after the first registration of each establishment the producer operates. Thereafter, the producer must submit an annual report on or before March 1 of each year, even if the producer has produced no pesticidal product for that reporting year.

[53 FR 35058, Sept. 8, 1988; 54 FR 32638, Aug. 9, 1989, as amended at 58 FR 34203, June 23, 1993]

## 40 CFR Ch. I (7–1–98 Edition)

#### § 167.90 Where to obtain and submit forms.

(a) *Where to obtain forms.* Any person may obtain blank forms for the applications and reports required by this part from any EPA Regional Office, or from the address listed in paragraph (b) of this section.

(b) *Where to submit applications and reports.* Each producer operating an establishment, with the exception of those establishments not found at the same location as their company headquarters, must submit applications and reports required by this part to the EPA Regional Office which serves the area where the establishment is located. The list of Regional Office addresses is found in 40 CFR 1.7. Applications and reports for those establishments not found at the same location as their company headquarters to be submitted by the company headquarters to the Regional Office having jurisdiction over the State in which the company headquarters is located. A foreign producer who exports any pesticide product, device, or active ingredient to the United States must submit all applications and reports to:

U.S. Environmental Protection Agency, Office of Enforcement and Compliance Assurance, Office of Compliance, Agriculture and Ecosystems Division (2225A), 401 M Street, SW, Washington, DC 20460, ATTN: Foreign Registration Clerk.

[53 FR 35058, Sept. 8, 1988; 54 FR 32638, Aug. 9, 1989, as amended at 62 FR 49620, Sept. 23, 1997]

### PART 168—STATEMENTS OF ENFORCEMENT POLICIES AND INTERPRETATIONS

#### Subpart A—General Provisions [Reserved]

#### Subpart B—Advertising

Sec.

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

## Environmental Protection Agency

§ 168.65

### 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.

AUTHORITY: 7 U.S.C. 136–136y.

SOURCE: 54 FR 1125, Jan. 11, 1989.

### 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 ac-

tive 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:

(j) 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 §180.1001, 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 from the Office of Pesticide Programs public docket, Room 1128, Crystal Mall 2, 1921 Jefferson Davis Highway, Arlington, Virginia 22202.)

(ii) The change in fragrance must result only from the addition of a chemical included on the list of chemicals exempted from the requirement of a tolerance (§180.1001) 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 from the Office of Pesticide Programs public docket, Room 1128, Crystal Mall 2, 1921 Jefferson Davis Highway, Arlington, Virginia 22202.)

(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 government 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.

**§ 168.75 Procedures for exporting unregistered pesticides—purchaser acknowledgement statements.**

This section describes how EPA interprets and will enforce requirements of FIFRA section 17(a)(2). Section 17(a)(2) provides that any person exporting a pesticide other than a pesticide registered for use under FIFRA section 3 or sold under FIFRA section 6(a)(1), shall obtain a statement signed by the foreign purchaser prior to export, acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States. Section 17(a)(2) requires that a copy of the statement be transmitted to an appropriate official of the government of the importing country.

(a) *Products subject to the requirement.* EPA will not consider an exporter of an unregistered pesticide to be in violation of FIFRA section 17(a)(2) if, prior to export of the pesticide, the exporter submits to EPA a statement signed by the foreign purchaser which affirms that the purchaser is aware that the pesticide is not registered for use in the United States and cannot be sold for use in the United States. The exporter must also include with the submission of the purchaser acknowledgement statement to EPA, a certification signed by the exporter affirming that the export did not occur until the statement signed by the foreign purchaser was obtained by the exporter. Except as provided in paragraph (b) of this section, all pesticide products produced for export which cannot be sold for use in the United States in the form that they are produced for export, are considered to be unregistered pesticides. This includes pesticides which are of a different formulation, including composition (except for variation within certified limits), or type of formulation, and pesticides which are packaged for use patterns for which they are not registered, which may be evidenced by package type or label use statements. This also includes unregistered products which are under development as pesticidal products and which are being exported for research testing.

(b) *Exceptions.* Under the specific circumstances discussed below, EPA will

not treat a registered product which has been modified slightly for export purposes, as unregistered for the purposes of the purchaser acknowledgement statement requirement. Any changes to the registered product for export purposes must be documented in accordance with the record-keeping requirements at § 169.2 of this chapter and this policy.

(1) *Labeling on Immediate Product.* EPA will not treat as unregistered for the purposes of section 17(a)(2), a registered pesticide product which cannot be sold or distributed for use in the United States because its immediate product container does not bear a label approved under a FIFRA section 3 registration, but which could be sold or distributed in the United States with the approved label attached to the immediate product container, provided that the 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) *Packaging.* (i) Certain 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 and this policy. These changes include any changes in package size and label net contents, provided no change in use directions or requirement for child-resistant packaging would be necessary for the product to be registered for use in the United States. For example, if child-resistant packaging is required for a particular pesticide product in the United States, and the product will be exported without child-resistant packaging, the product would be considered unregistered and therefore subject to all the requirements of FIFRA section 17(a), as described in § 168.75 of this chapter including the requirement for a purchaser acknowledgement statement.

(ii) If an exporter needed to repack a product in a size to meet a foreign purchaser's specifications, that modification would not affect the registration status of the export product. Other modifications to the label used

for export purposes which will not affect the export product's registration status are: the use of metric units for net contents, dosages, and other numeric expressions; the use of a different format for the label, provided that the information does not contradict the U.S. label; revision of non-mandatory U.S. label statements, consistent with 40 CFR part 156, including additions or changes required by other Federal statutes or regulations; a change of the name or address of the registrant, except for a change resulting from transfer of ownership, which requires that a registrant keep his name and address current with the Agency; and any correction of typographical or printing errors that appeared on the U.S. labeling. (See § 152.46(b)).

(3) *Labeling statements.* The following statements which appear on any of the product labels or labeling will not affect the status of the product, provided that they do not contradict the approved FIFRA section 3 labeling:

(i) It is permissible to add explanatory language which accurately explains the meaning of a use classification. For example, the statement "restricted use pesticide" may be expanded to read: "Restricted in the United States of America to use by certified applicators" or "Restricted Use Pesticide. In The United States this product is restricted to use by applicators determined by each state to be competent in pesticide application and the human health and environmental consequences of misuse." If the explanatory language falsely represents or is misleading regarding the U.S. use classification, the product will be considered misbranded. In addition, a use classification can only be listed if one has been assigned pursuant to the U.S. registration.

(ii) An exporter who is also the manufacturer of a U.S. registered pesticide may add new uses to the label of that product for export purposes, without triggering the requirements of section 17(a)(2), as long as the new uses are within the same general use patterns as those for the registered product. (Pesticide use patterns are listed in appendix A to 40 CFR part 158—Data Requirements for Registration: Use Pat-

tern Index. The general pesticide use patterns are: terrestrial food crop and terrestrial nonfood crop; greenhouse food crop and greenhouse nonfood crop; aquatic food crop and aquatic nonfood crop; indoor use; and forestry use.) Adding new uses to the label which change the use pattern, such as changes from non-food to food use, outdoor to indoor use, or terrestrial to aquatic use, render the product unregistered and subject to the requirements of section 17 for unregistered products. If the new use added to the label is a food or feed use, a tolerance must already be established for the use of that pesticide in or on that commodity.

(4) *Composition.* EPA will not treat a registered product as unregistered for the purposes of the purchaser acknowledgement statement requirement under the following specific circumstances:

(i) The formula of the exported product is within certified limits of the formula of the U.S. registered product.

(ii) An exporter, who is also the manufacturer of a U.S. registered pesticide, may decrease the percentage of the active ingredient(s) of that product by adding a List 4 inert ingredient, without causing the product to be treated as "unregistered" and triggering the requirement to obtain a purchaser acknowledgement statement as a condition for export. In EPA's Policy Statement on Inert Ingredients in Pesticide Products, EPA included inert ingredients on List 4—a list of inert ingredients posing minimal hazard or risk—if the inert ingredients were generally regarded as innocuous. The provisions of this paragraph do not apply to those pesticide products intended for public health uses which are required or conditionally required to submit efficacy data pursuant to § 158.640 of this chapter. Any differences in formula or composition caused by adding a List 4 inert 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.

(iii) 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. 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 §180.1001, 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. The change in fragrance must result only from the addition of a chemical included on the list of chemicals exempted from the requirement of a tolerance (§180.1001) and the chemical must not be a List 1 inert. 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.) Any difference 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.

(5) *Research and development products.* An unregistered pesticide product exported only for research and development purposes is subject to the notification requirements of this section, unless its use fits within the criteria described in this paragraph.

(i) An unregistered pesticide product exported solely for research and development purposes will not be considered to be in violation of the notification requirements if the export of the research and development product:

(A) Would not involve land uses of more than 10 acres (4.05 hectares), or be used on or affect food or feed crops which are intended for consumption.

(B) Would not involve aquatic uses of more than 1 acre (0.405 hectares), or any aquatic uses which involve water used for irrigation, drinking or recreation, or be used on or affect plants or animals taken for food or feed from such waters.

(C) Would not involve tests on animals intended for food or feed.

(ii) Shipments to different purchasers, to different countries of final destination, or which occur more than

a calendar year apart will be evaluated separately. When determining whether total shipments exceed the criteria described in this paragraph, EPA will evaluate the total amount of shipments by a single exporter during a calendar year for use in a particular country.

(iii) An exporter bears the burden of demonstrating that the product meets these criteria before the research product is shipped. This may be met by documenting before the product is shipped and maintaining records for the time period required by §169.2(h) of this chapter from the date of the last shipment relevant to such records. The records to be maintained consist of:

(A) The identity of the purchaser and country of intended use of the research product.

(B) The amount shipped.

(C) The intended research use by the purchaser, including the type of application site, rate of application, and measures taken for protection of humans from direct or dietary exposure.

(c) *Procedures.* An exporter of an unregistered pesticide product must submit a purchaser acknowledgement statement to EPA containing the information stated in paragraph (c)(1) of this section, and a statement signed by the exporter certifying that the exportation did not occur until the signed acknowledgement statement had been obtained from the purchaser. If the foreign purchaser signs a purchaser acknowledgement statement in their own language, it must be accompanied by an English translation when it is submitted to EPA by the exporter. These statements shall be submitted in accordance with one of the two options for submission described in paragraph (c)(2) of this section.

(1) *Contents of the purchaser acknowledgement statements.* The purchaser acknowledgement statement must include the following information in a format that is clearly understandable:

(i) Name, address, and EPA identification number, if applicable, of the exporter.

(ii) Name and address of the foreign purchaser.

(iii) Identity of the product and the active ingredient(s), including:



(A) The Chemical Abstract Services (CAS) Registry number for each active ingredient.

(B) The chemical nomenclature for each active ingredient as used by the International Union of Pure and Applied Chemists (IUPAC).

(C) Other known chemical or common names; or if the export involves a research product, a code name or identification number that can be used by EPA to identify the product from the exporter's records. If a code name or identification number is used, additional information must be attached to the certification statement submitted with the purchaser acknowledgement statement which will enable EPA to identify the product. This attached information may be claimed as confidential, and EPA will not forward this information with the purchaser acknowledgement statement to foreign governments.

(iv) If known or reasonably ascertainable, the country or countries of final destination of the export shipment, i.e., where the exported pesticide is intended to be used, if different from the country of the foreign purchaser's address.

(v) A statement that indicates that the foreign purchaser understands that the product is not registered for use in the United States and cannot be sold in the United States.

(vi) The signature of the foreign purchaser.

(vii) The date of the foreign purchaser's signature.

(2) *Reporting options.* At the discretion of the exporter, the requirements of paragraph (c)(1) of this section may be met on a per-shipment or annual basis, as stated in paragraphs (c)(2)(i) and (c)(2)(ii) of this section. If the procedures in paragraph (c)(2)(ii) of this section are not followed, EPA will consider paragraph (c)(2)(i) of this section, requiring pershipment purchaser acknowledgement statements, to be applicable in full. Where paragraph (c)(2)(i) of this section is applicable, each shipment which does not meet the requirements of that paragraph will be considered to be a separate violation of FIFRA.

(i) *Per-shipment purchaser acknowledgement statement.* Unless the exporter

chooses to follow the procedures described in paragraph (c)(2)(ii) of this section for the annual reporting procedures, the exporter must obtain and submit to EPA, a signed purchaser acknowledgement statement prior to each shipment of an unregistered pesticide according to the following procedures:

(A) Prior to each shipment in a calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, the exporter must provide the foreign purchaser with instructions about the required information on a purchaser acknowledgement statement, and inform the foreign purchaser that the pesticide product cannot be exported from the United States until the exporter has received from the foreign purchaser a properly completed, signed, and dated acknowledgement statement.

(B) The exporter must obtain, prior to each shipment in a calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, a signed purchaser acknowledgement statement which contains the information set forth in paragraph (c)(1) of this section.

(C) The exporter must sign a statement certifying that export did not take place until a signed purchaser acknowledgement statement was received. The exporter must also specify the chemical identity of any research product which is referred to by code in the purchaser acknowledgement statement. The information regarding the specific identity of research products, which may be included in the statement or consist of an attachment to the certification, may be claimed as confidential.

(D) The exporter must submit the signed acknowledgement statement from the foreign purchaser, and the accompanying certification by the exporter including attachments, to EPA within 7 working days of the exporter's receipt of the purchaser acknowledgement statement, or by the date of export, whichever occurs first. This information must be transmitted to the following address:

U.S. Environmental Protection Agency,  
Office of Pesticide Programs, (H-7501C),  
401 M Street, SW, Washington, DC 20460,

## Environmental Protection Agency

§ 168.75

Attention: Purchaser Acknowledgement Statement.

(ii) *Annual reporting procedures.* Unless the exporter chooses to follow the per-shipment reporting option described in paragraph (c)(2)(i) of this section, the exporter must follow the procedures for annual summary reporting which include the requirement of a purchaser acknowledgement statement for the first shipment each calendar year of an unregistered pesticide product to a particular purchaser, and an annual summary of shipments to that purchaser. The annual summary reporting procedures are as follows:

(A) Prior to the first shipment each calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, the exporter must provide the foreign purchaser with instructions about the required information on a purchaser acknowledgement statement, and inform the foreign purchaser that the pesticide product cannot be exported from the United States until the exporter has received from the foreign purchaser a properly completed, signed, and dated purchaser acknowledgement statement.

(B) The exporter must obtain, prior to the first shipment each calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, a signed purchaser acknowledgement statement which contains the information set forth in paragraph (c)(1) of this section.

(C) The exporter must sign a statement certifying that export did not take place until a signed purchaser acknowledgement statement was received, indicating that this statement is for the first shipment to a particular purchaser in a specific country for that calendar year, and that the exporter will meet all the purchaser acknowledgement statement requirements as described in this paragraph (c)(2)(ii) of this section. The exporter must also specify the chemical identity of any research product which is referred to by code in the purchaser acknowledgement statement. The information regarding the specific identity of research products, which may be included in the statement or consist of

an attachment to the certification, may be claimed as confidential.

(D) The exporter must submit the signed acknowledgement statement from the foreign purchaser, and the accompanying certification by the exporter including attachments, to EPA within 7 working days of the exporter's receipt of the purchaser acknowledgement statement, or by the date of export, whichever occurs first. This information must be transmitted to the following address:

U.S. Environmental Protection Agency,  
Office of Pesticide Programs, (H-7501C),  
401 M Street, SW, Washington, DC 20460,  
Attention: Purchaser Acknowledgement Statement.

(E) The exporter, who has chosen to comply with the requirements of this paragraph instead of providing per-shipment purchaser acknowledgement statements in accordance with paragraph (c)(2)(i) of this section, must submit an annual summary report to EPA. An annual summary report is required for each unregistered pesticide exported within the preceding calendar year. The report must be in writing, signed by the exporter, and include the following information:

(1) Name, address, and EPA identification number if applicable, of the exporter.

(2) Name and address of the foreign purchaser, and the date the purchaser acknowledgement statement, submitted to EPA during the previous calendar year, was signed by the purchaser.

(3) The identity of the product and the active ingredients, including: the Chemical Abstract Services (CAS) registry number for each active ingredient, the chemical nomenclature for each active ingredient used by the International Union of Pure and Applied Chemists (IUPAC), and other known chemical or common names, or if the export involves a research product, the code name or identification number that can be used by EPA to identify the product from the exporter's records.

(4) The dates of each shipment of the pesticide exported to the foreign purchaser during that calendar year.

(5) If known, or reasonably ascertainable, the country or countries of final

destination of the export shipments, i.e., where the exported pesticide was intended to be used, if different from the foreign purchaser's address.

(F) The exporter shall submit the annual summary no later than March 1st of the following calendar year. The annual summary shall be sent to the following address:

U.S. Environmental Protection Agency,  
Office of Pesticide Programs, H-7501C,  
401 M Street, SW., Washington, DC 20460,  
Attention: Annual Summary of Exports.

(iii) *Confidentiality claims.* Persons submitting the information specified in the purchaser acknowledgement statement may assert a claim of business confidentiality by marking the information claimed confidential as "FIFRA Confidential Business Information." Information so claimed will not be disclosed, with the exception of disclosure to the foreign governments, except in accordance with the procedures set forth in 40 CFR part 2, 7 U.S.C. 136(h), and this policy statement. If such claim is not asserted, EPA may disclose the information to the public without providing further notice prior to disclosure or an opportunity to object. Notwithstanding any claim of confidentiality, the purchaser acknowledgement statement will continue to be forwarded to the appropriate foreign government officials in its entirety, as required by section 17(a)(2).

(3) *Recordkeeping.* Except as specifically stated, the requirement to retain records under part 169 of this chapter applies to all pesticide producers, regardless of whether a particular product is intended for export. All records shall be maintained in accordance with the time period required by § 169.2(h) of this chapter. Producers must also maintain certain records pertaining to pesticide products intended for export. In addition to the requirement that a copy of the purchaser acknowledgement statement be kept, as stated at § 169.2(h)(3) of this chapter, the following records must be maintained:

(i) Copies of the instructions provided to foreign purchasers in accordance with paragraphs (c)(2)(i)(A) and (c)(2)(ii)(A) of this section.

(ii) Copies of signed purchaser acknowledgement statements obtained

according to paragraphs (c)(2)(i)(B) and (c)(2)(ii)(B) of this section.

(iii) Copies of the certification from the exporter; and copies of any accompanying information regarding the identity of coded R&D products.

(d) *Agency transmission of purchaser acknowledgement statements.* EPA will transmit a copy of each purchaser acknowledgement statement to the appropriate government official in each of the intended destination countries. After receipt of the Annual Summary the following calendar year, EPA will also transmit a copy of that document to the appropriate government official in each of the intended destination countries. In the case that no Annual Summary has been received within 30 days of the date at which such summary is required to be submitted, EPA will send written notification to the appropriate government official indicating that no summary was submitted, and may also take enforcement action against the exporter.

#### § 168.85 Other export requirements.

This section describes other requirements found in regulations that apply to exporters of pesticides, devices, and active ingredients used in producing a pesticide.

(a) *Recordkeeping and inspection.* Exporters of pesticides, devices and active ingredients must keep records and permit inspections of those records in accordance with part 169 of this chapter. Exporters must keep records of the product labeling used, including the EPA registered labeling, any foreign labeling on or attached to the product when shipped, and, as applicable, any supplemental labeling used. Producers of pesticides for export shall maintain these records in a manner that shows exactly which labels and labeling accompanied each shipment of a pesticide product to a foreign country. As stated at § 168.75(c), when research product identity information appears on the labeling in an encoded manner, information translating the code shall be maintained in records. These records shall be maintained for the time period required by § 169.2(h) of this chapter following the last export of such pesticides. All records required by part 169 of this chapter shall be made available

## Environmental Protection Agency

## § 169.2

for inspection and copying by EPA or its duly authorized representatives.

(b) *Pesticide production establishment requirements.* Exporters of pesticides, devices, and active ingredients must submit annual reports to EPA in accordance with part 167 of this chapter, concerning those products that are exported. All products required to be labeled "Not Registered for Use in the United States of America" must be reported as unregistered production regardless of whether a purchaser acknowledgement statement is required.

### PART 169—BOOKS AND RECORDS OF PESTICIDE PRODUCTION AND DISTRIBUTION

Sec.

169.1 Definitions.

169.2 Maintenance of records.

169.3 Inspection.

AUTHORITY: 7 U.S.C. 136f and 136w.

SOURCE: 45 FR 54338, Aug. 15, 1980, unless otherwise noted.

#### § 169.1 Definitions.

Terms used in this part shall have the meanings set forth for such terms in the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. In addition, as used in this part, the following terms shall have the meanings set forth below:

(a) *Amount of pesticide or active ingredient.* The term "amount of pesticide or active ingredient" means the weight or volume of the pesticide or active ingredient used in producing a pesticide expressed as weight for solid or semi-solid products and as weight or volume of liquid products.

(b) *Batch.* The term "batch" means a quantity of a pesticide product or active ingredient used in producing a pesticide made in one operation or lot or if made in a continuous or semi-continuous process or cycle, the quantity produced during an interval of time to be specified by the producer.

(c) *Device.* The term "device" means any device or class of device as defined by the Act and determined by the Administrator to be subject to the provisions of the Act.

(d) *Inability.* The term "inability" means the incapacity of any person to

maintain, furnish or permit access to any records under this Act and regulations, where such incapacity arises out of causes beyond the control and without the fault or negligence of such person. Such causes may include, but are not restricted to acts of God or of the public enemy, fires, floods, epidemics, quarantine restrictions, strikes, and unusually severe weather, but in every case, the failure must be beyond the control and without the fault or negligence of said person.

(e) *Producer.* The term "producer" means the person, as defined by the Act, who produces or imports any pesticide or device or active ingredient used in producing a pesticide.

#### § 169.2 Maintenance of records.

All producers of pesticides, devices, or active ingredients used in producing pesticides subject to this Act, including pesticides produced pursuant to an experimental use permit and pesticides, devices, and pesticide active ingredients produced for export, shall maintain the following records:

(a) Records showing the product name, EPA Registration Number, Experimental Permit Number if the pesticide is produced under an Experimental Use Permit, amounts per batch and batch identification (numbers, letters, etc.) of all pesticides produced. In cases where the product is an active ingredient used in producing a pesticide or where the product is a pesticide which is not registered, is not the subject of an application for registration, or is not produced under an Experimental Use Permit, the records shall also show the complete formula. The batch identification shall appear on all production control records. These records shall be retained for a period of two (2) years.

(b) Records showing the brand names and quantities of devices produced. These records shall be retained for a period of two (2) years.

(c) Records showing the following information regarding the receipt, by the producer, of all pesticides, devices, and active ingredients used in producing pesticides:

(1) Brand name of the pesticide or device, or common or chemical name of the pesticide active ingredient;