

EPA Regulation of Pest Control Devices

Overview

The U.S. Environmental Protection Agency (EPA) has a role in regulating pest control devices. How a device is regulated by EPA depends on the device's design and function and whether it incorporates or is used with a pesticide substance. This report is intended to address EPA requirements for the ozone-generating device that is marketed by Tersano Inc.

Pest Control Device Definition

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), a pest control device is defined as "...any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant life or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom."¹ Ozone-generating devices qualify as pest control devices under this definition.

Regulated vs. Unregulated Devices

Unlike chemical, biochemical, and microbial pesticide substances, EPA does not require the *registration* of pest control devices. EPA does, however, *regulate* certain, but not all, devices. Devices subject to regulation include, but are not limited to:

- Ultraviolet light systems, certain water and air filters, or ultrasonic devices that make claims that the device kills, inactivates, entraps, or suppresses growth of fungi, bacteria, or viruses in various sites;
- High frequency sound generators, carbide cannons, foils, and rotating devices that make claims about repelling birds;
- Black-light traps, fly traps (without an attractant substance other than food), electronic and heat screens, fly ribbons, and fly paper that make claims about killing or entrapping insects; and
- Mole thumpers, sound repellants, foils, and rotating devices that make claims about repelling certain mammals.

¹ Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Section 2(h).

Examples of unregulated pest control devices include, but are not limited to:

- Those which depend for their effectiveness more upon the performance of the person using the device than on the performance of the device itself (*e.g.*, fly swatter); and
- Those which operate to entrap vertebrate animals.

EPA Requirements for Regulated Pest Control Devices

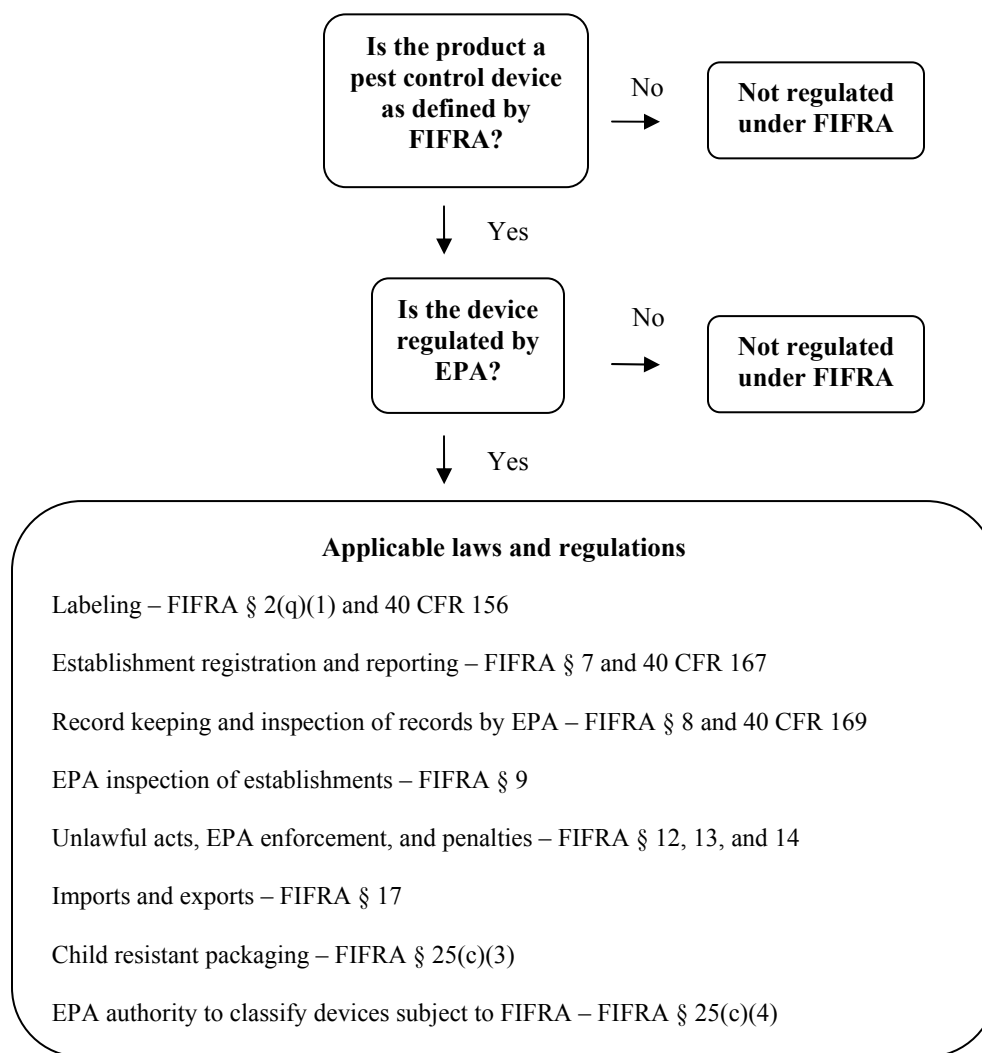
If a pest control device falls within the category of devices that are regulated, the device does not need to be registered by EPA, but it is subject to certain labeling, production, record keeping, packaging, and import/export requirements. Specifically, a regulated device must comply with the requirements set forth in:²

- FIFRA Section 2(q)(1): The product cannot be misbranded. See Attachment 1 for the definition of “misbranded.”
- Title 40, Code of Federal Regulations, Part 156 (40 CFR 156): These regulations specify labeling requirements. See Attachment 2.
- FIFRA Section 7: The device must be produced in an EPA-registered establishment. See Attachment 3.
- Title 40, Code of Federal Regulations, Part 167 (40 CFR 167): These regulations specify the requirements for EPA-registered production establishments, including the requirement to make annual reports to EPA on the production of regulated devices. These reports are due to EPA no later than March 1 of each year. See Attachment 4.
- FIFRA Section 8: The producer of a pest control device must maintain certain records and allow EPA to inspect those records. See Attachment 5.
- Title 40, Code of Federal Regulations, Part 169 (40 CFR 169): These regulations outline the types of records on device production and distribution that must be maintained, the duration of maintenance, and the availability of the records for inspection by EPA. See Attachment 6.
- FIFRA Section 9: EPA is authorized to inspect establishments in which devices are held for distribution or sale. See Attachment 7.
- FIFRA Sections 12, 13, and 14: These sections of FIFRA outline unlawful acts (Section 12), enforcement activities including stop sales and seizures (Section 13), and penalties for FIFRA violations (Section 14). See Attachment 8.

² Title 40, Code of Federal Regulations, Part 152.500 (40 CFR 152.500).

- FIFRA Section 17: Imports and exports of pest control devices must be in compliance with this section of FIFRA (see Attachment 9). All imports of devices must be accompanied by a Notice of Arrival (NOA) form (EPA Form 3540-1; see Attachment 10).
- FIFRA Section 25(c)(3): Certain pest control devices may need to comply with the child-resistant packaging provisions. See Attachment 11.
- FIFRA Section 25(c)(4): This section of FIFRA indicates EPA has the authority to specify the classes of devices that are subject to certain provisions of FIFRA. See Attachment 11.

Pest Control Device Regulatory Flowchart



Tersano's Ozone-Generating Device

Tersano has developed an ozone-generating device. Based on previous correspondence with EPA's Antimicrobial Division regarding this device (Attachment 12), it has been confirmed that the device is regulated under FIFRA, but is not required to be registered under FIFRA. As such, the product needs to adhere to the applicable elements of the U.S. pesticide law (i.e., FIFRA).

Attachment 1

FIFRA Section 2(q)(1) Definition of “Misbranded”

(1) LABEL.—The term “label” means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) LABELING.—The term “labeling” means all labels and all other written, printed, or graphic matter—

(A) accompanying the pesticide or device at any time;

or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

(q) MISBRANDED.—

(1) A pesticide is misbranded if—

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 25(c)(3);

(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

(D) its label does not bear the registration number assigned under section 7 to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 3(d) of this Act, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 3(d) of this Act, is adequate to protect health and the environment; or

(H) in the case of a pesticide not registered in accordance with section 3 of this Act and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the

following: "Not Registered for Use in the United States of America".

(2) A pesticide is misbranded if—

(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph if—

(i) the size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

(ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;

(B) the labeling does not contain a statement of the use classification under which the product is registered;

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing—

(i) the name and address of the producer, registrant, or person for whom produced;

(ii) the name, brand, or trademark under which the pesticide is sold;

(iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and

(iv) when required by regulation of the Administrator to effectuate the purposes of this Act, the registration number assigned to the pesticide under this Act, and the use classification; and

(D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this Act—

(i) the skull and crossbones;

(ii) the word "poison" prominently in red on a background of distinctly contrasting color; and

(iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide.

(r) NEMATODE.—The term "nematode" means invertebrate animals of the phylum nemathelminthes and class nematoda, that is, unsegmented round worms with elongated, fusiform, or saclike bodies covered with cuticle, and inhabiting soil, water, plants, or plant parts; may also be called nemas or eelworms.

(s) PERSON.—The term "person" means any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.

(t) PEST.—The term "pest" means (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man

Attachment 2

40 CFR 156

Labeling Requirements for Pesticides and Devices

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comment when it issues a proposed decision on the registration review case.

(2) If the Agency finds that it is not necessary to conduct a new risk assessment, it will issue a proposed decision on the registration review case as described in §155.58.

§ 155.56 Interim registration review decision.

The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. A FIFRA 3(c)(2)(B) notice requiring the needed data or information may precede, accompany, or follow issuance of the interim registration review decision. The Agency will follow procedures in §155.58 when issuing an interim registration review decision.

§ 155.57 Registration review decision.

A registration review decision is the Agency’s determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA.

§ 155.58 Procedures for issuing a decision on a registration review case.

(a) The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a proposed registration review decision or a proposed interim registration review decision. At that time, the Agency will place in the pesticide’s registration review docket the Agency’s proposed decision and the bases for the decision. There will be a comment period of at least 60 calendar days on the proposed decision.

(b) In its proposed decision, the Agency will, among other things:

(1) State its proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings.

(2) Identify proposed risk mitigation measures or other remedies as needed

and describe the basis for such proposed requirements.

(3) State whether it believes that additional data are needed and, if so, describe what is needed. A FIFRA 3(c)(2)(B) notice requiring such data may be issued in conjunction with a proposed or final decision on the registration review case or a proposed or final interim decision on a registration review case.

(4) Specify proposed labeling changes; and

(5) Identify deadlines that it intends to set for completing any required actions.

(c) After considering any comments on the proposed decision, the Agency will issue a registration review decision or interim registration review decision. This decision will include an explanation of any changes to the proposed decision and the Agency’s response to significant comments. The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a registration review decision or interim registration review decision. The registration review case docket will remain open until all actions required in the final decision on the registration review case have been completed.

(d) If the registrant fails to take the action required in a registration review decision or interim registration review decision, the Agency may take appropriate action under FIFRA.

PART 156—LABELING REQUIREMENTS FOR PESTICIDES AND DEVICES

Subpart A—General Provisions

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156.10 Labeling requirements.

Subparts B–C [Reserved]

Subpart D—Human Hazard and Precautionary Statements

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Subpart H—Container Labeling

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156.203 Definitions.

156.204 Modification and waiver of requirements.

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156.208 Restricted-entry statements.

156.210 Notification-to-workers statements.

156.212 Personal protective equipment statements.

AUTHORITY: 7 U.S.C. 136–136y.

Subpart A—General Provisions

§ 156.10 Labeling requirements.

(a) *General*—(1) *Contents of the label*. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Hazard and precautionary statements as prescribed in subpart D of this part for human and domestic animal hazards and subpart E of this part for environmental hazards.

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility*. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used*. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General*. The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this section, and the misbranding provisions of the Act, “securely attached” shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of

the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation*. While a pesticide product is in transit, the appropriate provisions of 49 CFR parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage*. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements*. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to §152.500, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active

ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as “safe,” “nonpoisonous,” “noninjurious,” “harmless” or “nontoxic to humans and pets” with or without such a qualifying phrase as “when used as directed”; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) “Contains all natural ingredients”;

(B) “Among the least toxic chemicals known”

(C) “Pollution approved”

(6) *Final printed labeling*. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark*. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to §152.132.

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is

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not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as “Packed for * * *,” “Distributed by * * *,” or “Sold by * * *” to show that the name is not that of the producer.

(d) *Net weight or measure of contents.*

(1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68 F (20 C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semi-solid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, *i.e.*, “1 pound 10 ounces” rather than “26 ounces.”

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(7) For a pesticide product packaged in a refillable container, an appropriately sized area on the label may be left blank to allow the net weight or measure of content to be marked in by the refiller according to 40 CFR 165.65(h) or 165.70(i) prior to distribution or sale of the pesticide. As required in paragraph (a)(1)(iii) of this section, the net contents must be shown clearly and prominently on the label.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase “EPA Registration No.,” or the phrase “EPA Reg. No.”

The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishment's registration number.* The producing establishment registration number preceded by the phrase “EPA Est.,” of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. For a pesticide product packaged in a refillable container, an appropriately sized area on the label may be left blank after the phrase “EPA Est.” to allow the EPA establishment registration number to be marked in by the refiller according to 40 CFR 165.65(h) or 165.70(i) prior to distribution or sale of the pesticide.

(g) *Ingredient statement—(1) General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term “active ingredients” and the inert ingredients by the term “inert ingredients,” or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement “Inert Ingredients, none” is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term “analysis” shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or

wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following

statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) [Reserved]

(i) *Directions for Use—(1) General requirements—(i) Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular;" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use.* (A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is

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available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in paragraph (j) of this section immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Worker protection statements meeting the requirements of subpart K of this part.

(ix) Specific directions concerning the storage, residue removal and disposal of the pesticide and its container, in accordance with subpart H of this part and part 165 of this chapter. These instructions must be grouped and appear under the heading, "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See table in §156.60(b))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) For total release foggers as defined in paragraph (h)(2)(iii)(B) of this section, the following statements must be included in the "Directions for Use":

DO NOT use more than one fogger per room. DO NOT use in small, enclosed spaces such as closets, cabinets, or under counters or tables. Do not use in a room 5 ft. x 5 ft. or smaller; instead, allow fog to enter from other rooms. Turn off ALL ignition sources such as pilot lights (shut off gas valves), other open flames, or running electrical appliances that cycle off and on (*i.e.*, refrigerators, thermostats, etc.). Call your gas

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utility or management company if you need assistance with your pilot lights.”

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of paragraph (j)(2) of this section.

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words “General Classification” immediately below the heading “Directions for Use.” And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

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(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in paragraph (h)(1)(iv) of this section), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement “Restricted Use Pesticide” shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: “For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator’s certification.” If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978. Redesignated and amended at 53 FR 15991, 15999, May 4, 1988; 57 FR 38146, Aug. 21, 1992; 60 FR 32096, June 19, 1995; 63 FR 9082, Feb. 23, 1998; 66 FR 64764, Dec. 14, 2001; 71 FR 47420, Aug. 16, 2006]

Subparts B–C [Reserved]

Subpart D—Human Hazard and Precautionary Statements

SOURCE: 66 FR 64764, Dec. 14, 2001, unless otherwise noted.

§ 156.60 General.

Each product label is required to bear hazard and precautionary statements for humans and domestic animals (if applicable) as prescribed in this subpart. Hazard statements describe the type of hazard that may occur, while precautionary statements will either direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(a) *Location of statements—(1) Front panel statements.* The signal word, child hazard warning, and, in certain cases, the first aid statement are required to

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appear on the front panel of the label, and also in any supplemental labeling intended to accompany the product in distribution or sale.

(2) *Statements elsewhere on label.* Hazard and precautionary statements not required on the front panel may appear on other panels of the label, and may be required also in supplemental labeling. These include, but are not limited to, the human hazard and precautionary statements, domestic animal statements if applicable, a Note to Physician, and physical or chemical hazard statements.

(b) *Placement and prominence—(1) Front panel statements.* All required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The table below shows the minimum type size requirements for the front panel warning statements for various front panel sizes.

TYPE SIZES FOR FRONT PANEL WARNING STATEMENTS

Size of Label Front Panel (Square Inches)	Point Size	
	Signal Word (All Capital Letters)	Child Hazard Warning
5 and under	6	6

TYPE SIZES FOR FRONT PANEL WARNING STATEMENTS—Continued

Size of Label Front Panel (Square Inches)	Point Size	
	Signal Word (All Capital Letters)	Child Hazard Warning
Over 5 to 10	10	6
Over 10 to 15	12	8
Over 15 to 30	14	10
Over 30	18	12

(2) *Other required statements.* All other hazard and precautionary statements must be at least 6 point type.

§ 156.62 Toxicity Category.

This section establishes four Toxicity Categories for acute hazards of pesticide products, Category I being the highest toxicity category. Most human hazard, precautionary statements, and human personal protective equipment statements are based upon the Toxicity Category of the pesticide product as sold or distributed. In addition, toxicity categories may be used for regulatory purposes other than labeling, such as classification for restricted use and requirements for child-resistant packaging. In certain cases, statements based upon the Toxicity Category of the product as diluted for use are also permitted. A Toxicity Category is assigned for each of five types of acute exposure, as specified in the table in this paragraph.

ACUTE TOXICITY CATEGORIES FOR PESTICIDE PRODUCTS

Hazard Indicators	I	II	III	IV
Oral LD ₅₀	Up to and including 50 mg/kg	>50 thru 500 mg/kg	>500 thru 5,000 mg/kg	>5,000 mg/kg
Dermal LD ₅₀	Up to and including 200 mg/kg	>200 thru 2000 mg/kg	>2000 thru 20,000 mg/kg	>20,000 mg/kg
Inhalation LC ₅₀	Up to and including 0.2 mg/liter	>0.2 thru 2 mg/liter	>2 thru 20 mg/liter	>20 mg/liter
Eye irritation	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin irritation	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

§ 156.64 Signal word.

(a) *Requirement.* Except as provided in paragraph (a)(4), each pesticide product must bear on the front panel a signal word, reflecting the highest Toxicity

Category (Category I is the highest toxicity category) to which the product is assigned by any of the five routes of exposure in §156.62. The signal word must also appear together with the heading for the human precautionary

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statement section of the labeling (see § 156.70).

(1) *Toxicity Category I.* Any pesticide product meeting the criteria of Toxicity Category I for any route of exposure must bear on the front panel the signal word "DANGER." In addition, if the product is assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye irritation), the word "Poison" must appear in red on a background of distinctly contrasting color, and the skull and crossbones symbol must appear in immediate proximity to the word "Poison."

(2) *Toxicity Category II.* Any pesticide product meeting the criteria of Toxicity Category II as the highest category by any route of exposure must bear on the front panel the signal word "WARNING."

(3) *Toxicity Category III.* Any pesticide product meeting the criteria of Toxicity Category III as the highest category by any route of exposure must bear on the front panel the signal word "CAUTION."

(4) *Toxicity Category IV.* A pesticide product meeting the criteria of Toxicity Category IV by all routes of exposure is not required to bear a signal word. If a signal word is used, it must be "CAUTION."

(b) *Use of signal words.* In no case may a product:

(1) Bear a signal word reflecting a higher Toxicity Category than indicated by the route of exposure of highest toxicity, unless the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment;

(2) Bear a signal word reflecting a lesser Toxicity Category associated with a diluted product. Although precautionary statements for use dilutions may be included on label, the signal word must reflect the toxicity of the product as distributed or sold; or

(3) Bear different signal words on different parts of the label.

§ 156.66 Child hazard warning.

(a) Each pesticide product must bear on the front panel of the label the statement "Keep Out of Reach of Children." That statement, or any alternative statement approved by EPA,

must appear on a separate line in close proximity to the signal word, if required. The statement is required on Toxicity Category IV products that do not otherwise require a signal word.

(b) In its discretion, EPA may waive the requirement, or require or permit an alternative child hazard warning, if:

(1) The applicant can demonstrate that the likelihood of exposure of children to the pesticide during distribution, marketing, storage or use is remote (for example, an industrial use product); or

(2) The pesticide is approved for use on children (for example, an insect repellent).

(c) EPA may approve an alternative child hazard warning that more appropriately reflects the nature of the pesticide product to which children may be exposed (for example, an impregnated pet collar). In this case, EPA may also approve placement on other than the front panel.

§ 156.68 First aid statement.

(a) *Product as sold and distributed.* Each product must bear a first aid statement if the product has systemic effects in Category I, II, or III, or skin or eye irritation effects in Category I or II.

(b) *Product as diluted for use.* If the product labeling bears directions for dilution with water prior to use, the label may also include a statement describing how the first aid measures may be modified for the diluted product. Such a statement must reflect the Toxicity Category(ies) of the diluted product, based upon data for the route of exposure (or calculations if appropriate). If the labeling provides for a range of use dilutions, only that use dilution representing the highest concentration allowed by labeling may be used as the basis for a statement pertaining to the diluted product. The statement for a diluted product may not substitute for the statement for the concentrate, but augments the information provided for the concentrate.

(c) *Heading.* The heading of the statement may be "First Aid" or "Statement of Practical Treatment."

(d) *Location of first aid statement.* The first aid statement must appear on the

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front panel of the label of all products assigned to Toxicity Category I by any route of exposure. Upon review, the Agency may permit reasonable variations in the placement of the first aid statement if a reference such as “See first aid statement on back panel” appears on the front panel. The first aid statement for products assigned to Toxicity Categories II or III may appear on any panel of the label.

§ 156.70 Precautionary statements for human hazards.

(a) *Requirement.* Human hazard and precautionary statements as required must appear together on the label or labeling under the general heading “Precautionary Statements” and under appropriate subheadings similar to “Humans and Domestic Animals,” “Environmental Hazards” (see subpart E of this part) and “Physical or Chemical Hazards.” The phrase “and Domestic Animals” may be omitted from the

heading if domestic animals will not be exposed to the product.

(b) *Content of statements.* When data or other information show that an acute hazard may exist to humans or domestic animals, the label must bear precautionary statements describing the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or toxic effect or to mitigate the effect. The precautionary paragraph must be immediately preceded by the appropriate signal word.

(c) *Typical precautionary statements.* The table below presents typical hazard and precautionary statements. Specific statements pertaining to the hazards of the product and its uses must be approved by the Agency. With Agency approval, statements may be augmented to reflect the hazards and precautions associated with the product as diluted for use. Refer to §156.68(b) for requirements for use dilution statements.

TYPICAL HUMAN HAZARD AND PRECAUTIONARY STATEMENTS

Toxicity Category	Systemic effects (oral, dermal, inhalation toxicity)	Irritation effects (skin and eye)	Sensitizer (There are no categories of sensitization.)
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel first aid statement required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Front panel first aid statement required.]	If product is a sensitizer: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
II	May be fatal if swallowed, [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statement required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]	
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes or clothing.	
IV	No precautionary statements required	No precautionary statements required.	

§ 156.78 Precautionary statements for physical or chemical hazards.

(a) *Requirement.* Warning statements on the flammability or explosive char-

acteristics of the pesticide product are required if a product meets the criteria in this section. Warning statements pertaining to other physical/chemical

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hazards (e.g., oxidizing potential, conductivity, chemical reactions leading to production of toxic substances) may be required on a case-by-case basis.

(b) *Pressurized products.* The table below sets out the required flammability label statements for pressurized products.

FLAMMABILITY STATEMENTS FOR PRESSURIZED PRODUCTS	
Flash point/flame extension of product	Required labeling statement
—Flash point at or below 20 °F	<i>Extremely flammable.</i> Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130 °F may cause bursting.
OR	
—Flashback at any valve opening	<i>Flammable.</i> Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 °F may cause bursting.
OR	
—Flash point >20 °F to 80 °F	
OR	<i>Contents under pressure.</i> Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 °F may cause bursting.
—Flame extension more than 18 in. long at a distance of 6 in from the flame	
All other pressurized products	

(c) *Non-pressurized products.* The table below sets out the required flammability label statements for non-pressurized products.

FLAMMABILITY STATEMENTS FOR NON-PRESSURIZED PRODUCTS	
Flash point	Required labeling statement
At or below 20 °F	<i>Extremely flammable.</i> Keep away from fire, sparks and heated surfaces.
Greater than 20 °F to 80 °F	<i>Flammable.</i> Keep away from heat and open flame.
Greater than 80 °F to 150 °F	<i>Combustible.</i> Do not use or store near heat or open flame.

(d) *Total release fogger products.* (1) A *total release fogger* is defined as a pesticide product in a pressurized container designed to automatically re-

lease the total contents in one operation, for the purpose of creating a permeating fog within a confined space to deliver the pesticide throughout the space.

(2) If a pesticide product is a total release fogger containing a propellant with a flash point at or below 20 °F, then the following special instructions must be added to the “Physical and Chemical Hazards” warning statement, in addition to any flammability statement required by paragraph (b) of this section:

This product contains a highly flammable ingredient. It may cause a fire or explosion if not used properly. Follow the Directions for Use on this label very carefully.

(3) A graphic symbol depicting fire, such as illustrated in this paragraph, or an equivalent symbol, must be displayed along with the required language adjoining the “Physical and Chemical Hazards” warning statement. The graphic symbol must be no smaller than twice the size of the first character of the human hazard signal word.



Highly Flammable Ingredient
 Ingrediente Altamente Inflamable

Subpart E—Environmental Hazard and Precautionary Statements

SOURCE: 66 FR 64767, Dec. 14, 2001, unless otherwise noted.

§ 156.80 General.

(a) *Requirement.* Each product is required to bear hazard and precautionary statements for environmental hazards, including hazards to non-target organisms, as prescribed in this subpart. Hazard statements describe the type of hazard that may be present, while precautionary statements direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(b) *Location of statements.* Environmental hazard and precautionary

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statements may appear on any panel of the label and may be required also in supplemental labeling. The environmental hazard statements must appear together under the heading "Environmental Hazards." Typically the statements are grouped as a sub-category within the "Precautionary Statements" section of the labeling.

(c) *Type size.* All environmental hazard and precautionary statements must be at least 6 point type.

§ 156.85 Non-target organisms.

(a) *Requirement.* Where a hazard exists to non-target organisms, EPA may require precautionary statements of the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage.

(b) *Examples.* The statements in this paragraph illustrate the types of hazard statements that EPA may require and the circumstances under which they are typically required. These statements are not comprehensive; other statements may be required if more appropriate to the formulation or use.

(1) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD₅₀ of 100 mg/kg or less, the statement, "This pesticide is toxic to wildlife" is required.

(2) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC₅₀ of 1 ppm or less, the statement, "This pesticide is toxic to fish" is required.

(3) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD₅₀ of 100 mg/kg or less, or a subacute dietary LC₅₀ of 500 ppm or less, the statement, "This pesticide is toxic to wildlife" is required.

(4) If either accident history or field studies demonstrate that the use of the pesticide may result in fatality to birds, fish or mammals, the statement, "This pesticide is extremely toxic to wildlife (fish)" is required.

(5) If a product is intended for or involves foliar application to agricultural crops, forests or shade trees, or mosquito abatement treatments, and contains a pesticide toxic to polli-

nating insects, the label must bear appropriate label cautions.

(6) If a product is intended for outdoor use other than aquatic applications, the label must bear the caution, "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

Subparts F–G [Reserved]

Subpart H—Container Labeling

SOURCE: 71 FR 47420, Aug. 16, 2006, unless otherwise noted.

§ 156.140 Identification of container types.

For products other than plant-incorporated protectants, the following statements, as applicable, must be placed on the label or container. The information may be located on any part of the container except the closure. If the statements are placed on the container, they must be durably marked on the container. Durable marking includes, but is not limited to etching, embossing, ink jetting, stamping, heat stamping, mechanically attaching a plate, molding, or marking with durable ink.

(a) *Nonrefillable container.* For non-refillable containers, the statements in paragraphs (a)(1) through (a)(4) of this section are required. If placed on the label, the statements in paragraphs (a)(1) through (a)(3) of this section must be under an appropriate heading under the heading "Storage and Disposal." If any of the statements in paragraphs (a)(1) through (a)(3) of this section are placed on the container, an appropriate referral statement such as "See container for recycling [or other descriptive word] information." must be placed on the label under the heading "Storage and Disposal."

(1) *Statement identifying a nonrefillable container.* The following phrase is required: "Nonrefillable container."

(2) *Reuse statement.* One of the following statements is required. Products with labels that allow household/residential use must use the statement in paragraph (a)(2)(i) or (a)(2)(iii) of this section. All other products must use the statement in paragraph

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(a)(2)(i), (a)(2)(ii), or (a)(2)(iii) of this section.

(i) “Do not reuse or refill this container.”

(ii) “Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state.”

(iii) The following statement may be used if a product is “ready-to-use” and its directions for use allow a different product (that is a similar, but concentrated formulation) to be poured into the container and diluted by the end user: “Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container.”

(3) *Recycling or reconditioning statement.* One of the following statements is required:

(i) “Offer for recycling if available.”

(ii) “Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact [a pesticide container recycling organization] at [phone number] or [web site]. For example, this statement could be “Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact the Ag Container Recycling Council (ACRC) at 1-877-952-2272 (toll-free) or www.acrecycle.org.”

(iii) A recycling statement approved by EPA and published in an EPA document, such as a Pesticide Registration Notice.

(iv) An alternative recycling statement that has been reviewed and approved by EPA.

(v) “Offer for reconditioning if appropriate.”

(4) *Batch code.* A lot number, or other code used by the registrant or producer to identify the batch of the pesticide product which is distributed and sold is required.

(b) *Refillable container.* For refillable containers, one of the following statements is required. If placed on the label, it must be under the heading “Storage and Disposal.” If the statement is placed on the container, an appropriate referral statement, such as “Refilling limitations are on the container.” must be placed under the heading “Storage and Disposal.”

(1) “Refillable Container. Refill this container with pesticide only. Do not reuse this container for any other purpose.”

(2) “Refillable Container. Refill this container with [common chemical name] only. Do not reuse this container for any other purpose.”

§ 156.144 Residue removal instructions—general.

(a) *General.* Except as provided by paragraphs (c) and (d) of this section, the label of each pesticide product must include the applicable instructions for removing pesticide residues from the container prior to container disposal that are specified in §§156.146 and 156.156. The residue removal instructions are required for both non-refillable and refillable containers.

(b) *Placement of residue removal statements.* All residue removal instructions must be placed under the heading “Storage and Disposal.”

(c) *Exemption for residential/household use products.* Residential/household use pesticide products are exempt from the residue removal instruction requirements in this section through §156.156.

(d) *Modification.* EPA may, on its own initiative or based on data submitted by any person, modify or waive the requirements of this section through §156.156, or permit or require alternative labeling statements.

§ 156.146 Residue removal instructions for nonrefillable containers—rigid containers with dilutable pesticides.

The label of each dilutable (liquid or solid) pesticide product packaged in a rigid nonrefillable container must include the following residue removal instructions as appropriate.

(a) *Timing of the residue removal procedure.* One of the following statements

must immediately precede the instructions required in paragraph (b) of this section and must be consistent with the instructions in paragraphs (b) and (c) of this section:

(1) "Clean container promptly after emptying."

(2) "Triple rinse or pressure rinse container (or equivalent) promptly after emptying."

(3) "Triple rinse container (or equivalent) promptly after emptying."

(b) *Triple rinse instructions.* The label of each dilutable pesticide product packaged in rigid nonrefillable containers must include one of the following sets of instructions.

(1) For liquid dilutable pesticide products in containers small enough to shake, use the following instructions: "Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."

(2) For solid dilutable pesticide products in containers small enough to shake, use the following instructions: "Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."

(3) For containers that are too large to shake, use the following instructions: "Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix

tank or store rinsate for later use or disposal. Repeat this procedure two more times."

(c) *Pressure rinse instructions.* The label of each dilutable pesticide product packaged in rigid nonrefillable containers may include one of the following sets of instructions, and one of them must be used if the statement in paragraph (a)(2) of this section is used. If one of these statements is included on the label, it must immediately follow the triple rinse instructions specified in paragraph (b) of this section.

(1) For liquid dilutable pesticide products, use the following label instruction: "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."

(2) For solid dilutable pesticide products, use the following label instruction: "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."

(d) *Non-water diluent.* (1) A registrant who wishes to require users to clean a container with a diluent other than water (e.g., solvents) must submit to EPA a written request to modify the residue removal instructions of this section. The registrant may not distribute or sell the pesticide with the modified residue removal instructions until EPA approves the request in writing.

(2) The registrant must indicate why a non-water diluent is necessary for efficient residue removal, and must propose residue removal instructions and disposal instructions that are appropriate for the characteristics and formulation of the pesticide product and

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non-water diluent. The proposed residue removal instructions must identify the diluent. If the Directions for Use permit the application of a mixture of the pesticide and the non-water diluent, the instructions may allow the rinsate to be added to the application equipment or mix tank. If the Directions for Use do not identify the non-water diluent as an allowable addition to the pesticide, the instructions must require collection and storage of the rinsate in a rinsate collection system.

(3) EPA may approve the request if EPA finds that the proposed instructions are necessary and appropriate.

§ 156.156 Residue removal instructions for refillable containers.

The label of each pesticide product packaged in a refillable container must include the residue removal instructions in this section. Instructions must be given for all pesticide products that are distributed or sold in refillable containers, including those that do not require dilution prior to application.

(a) *Timing of the residue removal procedure.* One of the following statements must immediately precede the instructions required in paragraph (b) of this section and must be consistent with the instructions in paragraph (b) of this section:

(1) "Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller."

(2) "Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller."

(b) *Residue removal instructions prior to container disposal.* (1) Instructions for cleaning each refillable container prior to disposal are required. The residue removal instructions must be appropriate for the characteristics and formulation of the pesticide product and must be adequate to protect human health and the environment.

(2) Subject to meeting the standard in paragraph (b)(1) of this section, the statement on residue removal instructions could include any one of the following:

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(i) The refilling residue removal procedure developed by the registrant for the pesticide product.

(ii) Standard industry practices for cleaning refillable containers.

(iii) For pesticides that require dilution prior to application, the following statement: "To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times."

(iv) Any other statement the registrant considers appropriate.

§ 156.159 Compliance date.

As of August 17, 2009, all pesticide products distributed or sold by a registrant must have labels that comply with §§ 156.10(d)(7), 156.10(f), 156.10(i)(2)(ix), 156.140, 156.144, 156.146, and 156.156.

Subparts I-J [Reserved]

Subpart K—Worker Protection Statements

SOURCE: 57 FR 38146, Aug. 21, 1992, unless otherwise noted.

§ 156.200 Scope and applicability.

(a) *Scope.* (1) This subpart prescribes statements that must be placed on the pesticide label and in pesticide labeling. These statements incorporate by reference the Worker Protection Standard, part 170 of this chapter. The requirements addressed in these statements are designed to reduce the risk of illness or injury resulting from workers' and pesticide handlers' occupational exposures to pesticides used in the production of agricultural plants on agricultural establishments as defined in §170.3 of this chapter. These statements refer to specific workplace practices designed to reduce or eliminate exposure and to respond to emergencies that may arise from the exposures that may occur.

(2) This subpart prescribes interim requirements that must be placed on the pesticide label and in pesticide labeling. These interim requirements pertain to restricted-entry intervals, personal protective equipment, and notification. On a case-by-case basis, these interim requirements will be reviewed and may be revised during re-registration or other agency review processes.

(b) *Applicability.* (1) The requirements of this subpart apply to each pesticide product that bears directions for use in the production of any agricultural plant on any agricultural establishment as defined in §170.3 of this chapter, or whose labeling reasonably permits such use.

(2) The requirements of this subpart do not apply to a product that bears directions solely for uses excepted by §170.202(b) of this chapter.

(c) *Effective dates.* (1) The effective date of this subpart is October 20, 1992.

(2) No pesticide product bearing labeling amended and revised as required by this subpart shall be distributed or sold by a registrant prior to April 21, 1993.

(3) No product to which this subpart applies shall be distributed or sold without amended labeling by any registrant after April 21, 1994.

(4) No product to which this subpart applies shall be distributed or sold without amended labeling by any person after October 23, 1995.

§ 156.203 Definitions.

Terms in this subpart have the same meanings as they do in the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. In addition, the following terms, as used in this subpart, shall have the meanings stated below:

Fumigant means any pesticide product that is a vapor or gas or forms a vapor or gas on application and whose method of pesticidal action is through the gaseous state.

Restricted-entry interval means the time after the end of a pesticide application during which entry to the treated area is restricted.

§ 156.204 Modification and waiver of requirements.

(a) *Modification on Special Review.* If the Agency concludes in accordance with §154.25(c) of this chapter that a pesticide should be placed in Special Review because the pesticide meets or exceeds the criteria for human health effects of §154.7(a)(1)(2) or (6) of this chapter, the Agency may modify the personal protective equipment required for handlers or early-entry workers or both, the restricted-entry intervals, or the notification to workers requirements.

(b) *Other modifications.* The Agency, pursuant to this subpart and authorities granted in FIFRA sections 3, 6, and 12, may, on its initiative or based on data submitted by any person, modify or waive the requirements of this subpart, or permit or require alternative labeling statements. Supporting data may be either data required by Subdivisions U or K of the Pesticide Assessment Guidelines or data from medical, epidemiological, or health effects studies. The Pesticide Assessment Guidelines contain the standards for conducting acceptable tests, guidance on evaluation and reporting of data, definition of terms, further guidance on when data are required, and examples of acceptable protocols. They are available through the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161. A registrant who wishes to modify any of the statements required in §§156.206, 156.208, 156.210, or 156.212 must submit an application for amended registration unless specifically directed otherwise by the Agency.

§ 156.206 General statements.

(a) *Application restrictions.* Each product shall bear the statement: "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." This statement shall be near the beginning of the DIRECTIONS FOR USE section of the labeling under the heading AGRICULTURAL USE REQUIREMENTS.

(b) *40 CFR part 170 reference statement.* (1) Each product shall bear the reference statement: "Use this product

only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170." This statement shall be placed on the product label under the heading AGRICULTURAL USE REQUIREMENTS.

(2) Each product shall bear the statement: "This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label [in this labeling] about [use any of the following that are applicable] personal protective equipment, restricted-entry interval, and notification to workers." These statements shall be placed immediately following the reference statement required by paragraph (b)(1) of this section, or they shall be placed in the supplemental product labeling under the heading AGRICULTURAL USE REQUIREMENTS.

(3) If the statements in paragraph (b)(2) of this section are included in supplemental labeling rather than on the label of the pesticide container, the container label must contain this statement immediately following the statement required in paragraph (b)(1) of this section: "Refer to supplemental labeling entitled AGRICULTURAL USE REQUIREMENTS in the DIRECTIONS FOR USE section of the labeling for information about this standard."

(4) If the statements in paragraph (b)(2) of this section are included in supplemental labeling, they must be preceded immediately by the statement in paragraph (b)(1) of this section under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(c) *Product-type identification.* (1) If the product contains an organophosphate (*i.e.*, an organophosphorus ester that inhibits cholinesterase) or an *N*-methyl carbamate (*i.e.*, an *N*-methyl carbamic acid ester that inhibits cholinesterase), the label shall so state. The statement shall be associated with the product name or product-type identification or shall be in the STATEMENT OF PRAC-

TICAL TREATMENT or FIRST AID section of the label.

(2) If the product is a fumigant, the label shall so state. The identification shall appear:

(i) As part of the product name; or

(ii) Close to the product name, as part of the product-type identification or as a separate phrase or sentence.

(d) *State restrictions.* Each product shall bear the statement: "For any requirements specific to your State, consult the agency in your State responsible for pesticide regulation." This statement shall be under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(e) *Spanish warning statements.* If the product is classified as toxicity category I or toxicity category II according to the criteria in §156.10(h)(1), the signal word shall appear in Spanish in addition to English followed by the statement, "Si Usted no entiende la etiqueta, busque a alguien para que se la explique a Usted en detalle. (If you do not understand the label, find some one to explain it to you in detail.)" The Spanish signal word "PELIGRO" shall be used for products in toxicity category I, and the Spanish signal word "AVISO" shall be used for products in toxicity category II. These statements shall appear on the label close to the English signal word.

[57 FR 38146, Aug. 21, 1992, as amended at 58 FR 34203, June 23, 1993]

§ 156.208 Restricted-entry statements.

(a) *Requirement.* Each product with a restricted-entry interval shall bear the following statement: "Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI)." This statement shall be under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(b) *Location of specific restricted-entry interval statements.* (1) If a product has one specific restricted-entry interval applicable to all registered uses of the product on agricultural plants, the restricted-entry interval for the product shall appear as a continuation of the statement required in paragraph (a) of this section and shall appear as follows: "of X hours" or "of X days" or "until the acceptable exposure level of X ppm or mg/m³ is reached."

(2) If different restricted-entry intervals have been established for some crops or some uses of a product, the restricted-entry statement in paragraph (b)(1) of this section shall be associated on the labeling of the product with the directions for use for each crop each use to which it applies, immediately preceded or immediately followed by the words "Restricted-entry interval" (or the letters "REI").

(c) *Restricted-entry interval based on toxicity of active ingredient*—(1) *Determination of toxicity category.* A restricted-entry interval shall be established based on the acute toxicity of the active ingredients in the product. For the purpose of setting the restricted-entry interval, the toxicity category of each active ingredient in the product shall be determined by comparing the obtainable data on the acute dermal toxicity, eye irritation effects, and skin irritation effects of the ingredient to the criteria of §156.10(h)(1). The most toxic of the applicable toxicity categories that are obtainable for each active ingredient shall be used to determine the restricted-entry interval for that product. If no acute dermal toxicity data are obtainable, data on acute oral toxicity also shall be considered in this comparison. If no applicable acute toxicity data are obtainable on the active ingredient, the toxicity category corresponding to the signal word of any registered manufacturing-use product that is the source of the active ingredient in the end-use product shall be used. If no acute toxicity data are obtainable on the active ingredients and no toxicity category of a registered manufacturing-use product is obtainable, the toxicity category of the end-use product (corresponding to the signal word on its labeling) shall be used.

(2) *Restricted-entry interval for sole active ingredient products.* (i) If the product contains only one active ingredient and it is in toxicity category I by the criteria in paragraph (c)(1) of this section, the restricted-entry interval shall be 48 hours. If, in addition, the active ingredient is an organophosphorus ester that inhibits cholinesterase and that may be applied outdoors in an area where the average annual rainfall for the application site is less than 25

inches per year, the following statement shall be added to the restricted-entry interval statement: "(72 hours in outdoor areas where average annual rainfall is less than 25 inches a year)."

(ii) If the product contains only one active ingredient and it is in toxicity category II by the criteria in paragraph (c)(1) of this section, the restricted-entry interval shall be 24 hours.

(iii) If the product contains only active ingredients that are in toxicity category III or IV by the criteria in paragraph (c)(1) of this section, the restricted-entry interval shall be 12 hours.

(3) *Restricted-entry interval for multiple active ingredient products.* If the product contains more than one active ingredient, the restricted-entry interval (including any associated statement concerning use in arid areas under paragraph (c)(2)(i) of this section) shall be based on the active ingredient that requires the longest restricted-entry interval as determined by the criteria in this section.

(d) *Exception for fumigants.* The criteria for determining restricted-entry intervals in paragraph (c) of this section shall not apply to any product that is a fumigant. For fumigants, any existing restricted-entry interval (hours, days, or acceptable exposure level) shall be retained. Entry restrictions for fumigants have been or shall be established on a case-by-case basis at the time of registration, reregistration, or other Agency review process.

(e) *Existing product-specific restricted-entry intervals.* (1) A product-specific restricted-entry interval, based on data collected in accordance with §158.390 of this chapter and Subdivision K of the Pesticide Assessment Guidelines, shall supersede any restricted-entry interval applicable to the product under paragraph (c) of this section.

(2) Product-specific restricted-entry intervals established for pesticide products or pesticide uses that are not covered by part 170 of this chapter shall remain in effect and shall not be placed under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(f) *Existing interim restricted-entry intervals.* (1) An interim restricted-entry interval established by the Agency before the effective date of this subpart

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will continue to apply unless a longer restricted-entry interval is required by paragraph (c) of this section.

(2) Existing interim restricted-entry intervals established by the Agency for pesticide products or pesticide uses not covered by part 170 of this chapter shall remain in effect and shall not be placed under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

[57 FR 38146, Aug. 21, 1992, as amended at 58 FR 34203, June 23, 1993]

§ 156.210 Notification-to-workers statements.

(a) *Requirement.* Each product that meets the requirements of paragraph (b) of this section shall bear the posting and oral notification statements prescribed below. The statements shall be in the DIRECTIONS FOR USE section of the labeling under the heading AGRICULTURAL USE REQUIREMENTS.

(b) *Notification to workers of pesticide application.* (1) Each product that contains any active ingredient classified as toxicity category I for either acute dermal toxicity or skin irritation potential under the criteria in §156.10(h)(1) shall bear the statement: "Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas." If no acute dermal toxicity data are obtainable, data on acute oral toxicity of the active ingredient shall be considered instead. If no data on acute dermal toxicity, skin irritation potential, or acute oral toxicity are obtainable on the active ingredient, the toxicity category corresponding to the signal word of any registered manufacturing-use product that is the source of the active ingredient in the end-use product shall be used. If none of the applicable acute toxicity data are obtainable on the active ingredient and no toxicity category of the registered manufacturing-use product is obtainable, the toxicity category of the end-use product corresponding to the product's signal word shall be used.

(2) Each product that is a fumigant and is registered for use in a greenhouse (or whose labeling allows use in a greenhouse) shall bear the statement: "For greenhouse applications, notify

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workers of the application by warning them orally and by posting warning signs outside all entrances to the greenhouse."

[57 FR 38146, Aug. 21, 1992, as amended at 58 FR 34203, June 23, 1993]

§ 156.212 Personal protective equipment statements.

(a) *Requirement.* Each product shall bear the personal protective equipment statements prescribed in paragraphs (d) through (j) of this section.

(b) *Exceptions.* (1) If personal protective equipment were required for a product before the effective date of this subpart, the existing requirements shall be retained on the labeling wherever they are more specific or more protective (as specified in EPA guidance materials) than the requirements in the table in paragraph (e) of this section.

(2) Any existing labeling statement that prohibits the use of gloves or boots overrides the corresponding requirement in paragraph (e) of this section and must be retained on the labeling.

(3) If the product labeling contains uses that are not covered by part 170 of this chapter, the registrant may adopt the personal protective equipment required in this section for those uses. However, if the personal protective equipment required in this section would not be sufficiently protective or would be onerously overprotective for uses not covered by part 170 of this chapter, the registrant must continue to apply the existing personal protective equipment requirements to those uses. The labeling must indicate which personal protective equipment requirements apply to uses covered by part 170 of this chapter and which personal protective equipment requirements apply to other uses.

(c) *Location of personal protective equipment statements—*(1) *Personal protective equipment statements for pesticide handlers.* Personal protective equipment statements for pesticide handlers shall be in the HAZARDS TO HUMANS (AND DOMESTIC ANIMALS) section of the labeling. The required statements may be combined to avoid redundancy

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as long as the requirements and conditions under which they apply are identified.

(2) Personal protective equipment statements for early-entry workers. Personal protective equipment statements for early-entry workers shall be placed in the DIRECTIONS FOR USE section of the labeling under the heading AGRICULTURAL USE REQUIREMENTS and immediately after the restricted-entry statement required in § 156.208(a).

(d) *Personal protective equipment statements for pesticide handlers.* (1) The table in paragraph (e) of this section specifies minimum requirements for personal protective equipment (as defined in § 170.240 of this chapter) and work clothing for pesticide handlers. This personal protective equipment requirement applies to any product that presents a hazard through any route of exposure identified in the table (acute dermal toxicity, skin irritation potential, acute inhalation toxicity, and eye irritation potential).

(2) The requirement for personal protective equipment is based on the acute toxicity category of the end-use product for each route of exposure as defined by § 156.10(h)(1). If data to determine the acute dermal toxicity or the acute inhalation toxicity are not obtainable, the acute oral toxicity shall

be used as a surrogate to determine the personal protective equipment requirements for that route of exposure. If data to determine the acute toxicity of the product by a specific route of exposure (including acute oral toxicity in lieu of acute dermal or acute inhalation toxicity) are not obtainable, the toxicity category corresponding to the signal word of the end-use product shall be used to determine personal protective equipment requirements for that route of exposure. If the signal word is "CAUTION," toxicity category III will be used.

(3) The minimum personal protective equipment and work clothing requirements specified in this section shall be included in a statement such as the following: "Applicators and other handlers must wear: (body protection statement); (glove statement, if applicable); (footwear statement, if applicable); (protective eyewear statement, if applicable); (respirator statement, if applicable)." The format of statements given in this paragraph is optional, but it is recommended for clarity.

(e) *Summary of personal protective equipment requirements.* The following table 1 summarizes the personal protective equipment requirements by route of exposure and toxicity category:

TABLE 1—MINIMUM PERSONAL PROTECTIVE EQUIPMENT (PPE) AND WORK CLOTHING FOR HANDLING ACTIVITIES

Route of Exposure	Toxicity Category of End-Use Product			
	I	II	III	IV
Dermal Toxicity or Skin Irritation Potential ¹	Coveralls worn over long-sleeved shirt and long pants Socks Chemical-resistant footwear Chemical-resistant gloves ²	Coveralls worn over short-sleeved shirt and short pants Socks Chemical-resistant footwear Chemical-resistant gloves ²	Long-sleeved shirt and long pants Socks Shoes Chemical-resistant gloves ²	Long-sleeved shirt and long pants Socks Shoes No minimum ⁴
Inhalation Toxicity	Respiratory protection device ³	Respiratory protection device ³	No minimum ⁴	No minimum ⁴
Eye Irritation Potential	Protective eyewear	Protective eyewear	No minimum ⁴	No minimum ⁴

¹ If dermal toxicity and skin irritation potential are in different toxicity categories, protection shall be based on the more toxic (lower numbered) category.

² For labeling language for chemical-resistant gloves, see paragraph (f) of this section.

³ For labeling language for respiratory protection device, see paragraphs (g) and (h) of this section.

⁴ Although no minimum PPE is required by this section for this toxicity category and route of exposure, the Agency may require PPE on a product-specific basis.

(f) *Chemical-resistant gloves labeling statements for pesticide handlers.* If the table in paragraph (e) of this section indicates that chemical-resistant gloves are required, the glove statement shall be as specified in paragraph (f)(2), (3), (4), or (5) of this section.

(1) *Exception.* The registrant shall specify a glove type other than that selected through the criteria in paragraphs (f)(2) through (5) of this section if information available to the registrant indicates that such a glove type is more appropriate or more protective than the glove type specified in this section. The statement must specify the particular types of chemical-resistant glove (such as nitrile, butyl, neoprene, and/or barrier-laminate).

(2) *Solid formulations.* For products formulated and applied as solids or formulated as solids and diluted solely with water for application, the glove statement shall specify: “waterproof gloves.”

(3) *Aqueous-based formulations.* For products formulated and applied as a water-based liquid or formulated as a water-based liquid and diluted solely with water for application, the glove statement may specify: “waterproof gloves” instead of the statement in paragraph (f)(4) of this section.

(4) *Other liquid formulations.* For products formulated or diluted with liquids other than water, the glove statement shall specify: “chemical-resistant (such as nitrile or butyl) gloves.”

(5) *Gaseous formulations and applications.* For products formulated or applied as gases, any existing glove statement established before the effective date of this subpart, including any glove prohibition statement, will continue to apply. If no glove statement or glove prohibition now exists, the glove statement shall specify “chemical-resistant (such as nitrile or butyl) gloves.”

(g) *Existing respirator requirement for pesticide handlers on product labeling—*

(1) *General requirement.* If a statement placed on a product’s labeling before the effective date of this subpart indicates that respiratory protection is required, that requirement for protection shall be retained. The statement must specify, or be amended to specify, one of the following respirator types and

the appropriate MSHA/NIOSH approval number prefix:

(i) Dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C; or

(ii) Respirator with an organic-vapor-removing cartridge and a prefilter approved for pesticides with MSHA/NIOSH approval number prefix TC-23C or with a canister approved for pesticides with MSHA/NIOSH approval number prefix TC-14G; or

(iii) Supplied-air respirator with MSHA/NIOSH approval number prefix TC-19C or self-contained breathing apparatus (SCBA) with MSHA/NIOSH approval number TC-13F.

(2) *Respirator type already specified on labeling.* If the existing respiratory protection requirement specifies a respirator type, it shall be retained. The respirator statement must be revised, if necessary, to conform to the wording in paragraph (g)(1) of this section.

(3) *Respirator type not already specified on labeling.* If the existing respiratory protection requirement on product labeling does not specify a respirator type as listed in paragraph (g)(1) of this section, the specific respirator type shall be that required in the criteria in paragraphs (g)(3)(i) through (vi) of this section.

(i) *Exception.* The registrant shall specify a different type of respiratory protection device if information, such as vapor pressure value, is available to the registrant to indicate that the type of respiratory protection device selected through the criteria in paragraphs (g)(3)(ii) through (vi) of this section would not be adequately protective, or might increase risks to the user unnecessarily.

(ii) *Gases applied outdoors.* For products that are formulated or applied as a gas (space and soil fumigants) and that may be used outdoors, the respiratory protection statement shall be: “For handling activities outdoors, use either a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G).”

(iii) *Gases used in enclosed areas.* For products that are formulated or applied

as a gas (space and soil fumigants) and that may be used in greenhouses or other enclosed areas, the respiratory protection statement shall specify: "For handling activities in enclosed areas, use either a supplied-air respirator with MSHA/NIOSH approval number prefix TC-19C, or a self-contained breathing apparatus (SCBA) with MSHA/NIOSH approval number TC-13F."

(iv) *Solids*. For products that are formulated and applied as solids, the respiratory protection statement shall specify: "dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

(v) *Liquids in toxicity category I*. For products that are formulated or applied as liquids, and, as formulated, have an acute inhalation toxicity (or its surrogate as specified in paragraph (d)(2) of this section) in category I, the respiratory protection statement shall specify: "either a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix 14G)."

(vi) *Liquids in toxicity category II*. For products that are formulated or applied as liquids, and, as formulated, have an acute inhalation toxicity (or its surrogate as specified in paragraph (d)(2) of this section) in category II, the respiratory protection statement shall specify: "For handling activities during (select uses applicable to the product: airblast, mistblower, pressure greater than 40 p.s.i. with fine droplets, smoke, mist, fog, aerosol or direct overhead) exposures, wear either a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix 14G). For all other exposures, wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

(h) *New respirator requirement established for pesticide handlers in this part—*
(1) *General requirement*. If the table in paragraph (e) of this section indicates a respiratory protection device is required, and existing product labeling

has no respiratory protection requirement, the registrant shall add a respiratory protection statement that specifies a: "dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

(2) *Exception*. The registrant shall specify a different type of respiratory protection device if information, such as vapor pressure value, is available to the registrant to indicate that the type of respiratory protection device required in paragraph (h)(1) of this section would not be adequately protective or might increase risks to the user unnecessarily.

(i) *Additional personal protective equipment requirements for pesticide handlers*. In addition to the minimum personal protective equipment and work clothing requirements given in the table in paragraph (e) of this section, the labeling statement for any product in toxicity category I or II on the basis of dermal toxicity or skin irritation potential (or their surrogate as specified in paragraph (d)(2) of this section), shall include the following personal protective equipment instructions, additions, or substitutions as applicable:

(1) If the product is not ready-to-use and there is no existing requirement for a chemical-resistant suit, the following statement shall be included: "Mixers/Loaders: add a chemical-resistant apron."

(2) If the application of the product may result in overhead exposure to any handler (for example, applicator exposure during airblast spraying of orchards or flagger exposure during aerial application), the following statement shall be included: "Overhead Exposure: wear chemical-resistant headgear."

(3) If any type of equipment other than the product container may be used to mix, load, or apply the product, and there is no requirement for a chemical-resistant protective suit, the following statement shall be included: "For Cleaning Equipment: add a chemical-resistant apron."

(j) *Personal protective equipment for early-entry workers*. This paragraph specifies minimum requirements for personal protective equipment (as defined in §170.240 of this chapter) and work clothing for early-entry workers.

(1) For all pesticide products, add the statement: "For early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, wear: (list the body protection, glove, footwear, protective eyewear, and protective headgear, if applicable, statements specified for applicators and other handlers, but omit any respiratory protection statement)."

(2) If the body protection statement in the personal protective equipment requirement for handlers specifies a long-sleeved shirt and long pants, "coveralls" must be specified in the statement of personal protective equipment for early-entry workers.

(3) If there is no statement requiring gloves and no prohibition against gloves for applicators and other handlers under the heading HAZARDS TO HUMANS (AND DOMESTIC ANIMALS) in the labeling, add a requirement for "waterproof gloves" in the statement of personal protective equipment for early-entry workers.

[57 FR 38146, Aug. 21, 1992, as amended at 58 FR 34203, June 23, 1993]

PART 157—PACKAGING REQUIREMENTS FOR PESTICIDES AND DEVICES

Subpart A [Reserved]

Subpart B—Child-Resistant Packaging

Sec.

- 157.20 General.
- 157.21 Definitions.
- 157.22 When required.
- 157.24 Exemptions.
- 157.27 Unit packaging.
- 157.30 Voluntary use of child-resistant packaging.
- 157.32 Standards.
- 157.34 Certification.
- 157.36 Recordkeeping.

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

SOURCE: 51 FR 21286, June 11, 1986; 51 FR 36692, Oct. 15, 1986, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Child-Resistant Packaging

§ 157.20 General.

This subpart prescribes requirements for child-resistant packaging of pesticide products and devices. The requirements are established under the authority of FIFRA section 25(a)(1), which authorizes the Administrator to issue regulations to carry out the purposes of the Act, and FIFRA section 25(c)(3), which authorizes the Administrator to establish standards with respect to the package, container or wrapping in which a pesticide or device is enclosed in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated under the Act.

§ 157.21 Definitions.

Terms used in this subpart shall have the following meanings:

(a) *Appropriate*, when used with respect to child-resistant packaging, means that the packaging is chemically compatible with the pesticide contained therein.

(b) *Child-resistant packaging* means packaging that is designed and constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time, and that is not difficult for normal adults to use properly.

(c) *Package* or *packaging* means the immediate container or wrapping, including any attached closure(s), in which the pesticide is contained for distribution, sale, consumption, use or storage. The term does not include any shipping or bulk container used for transporting or delivering the pesticide unless it is the only such package.

(d) *Practicable*, when used with respect to child-resistant packaging, means that the packaging can be mass produced and can be used in assembly line production.

(e) *Residential use* means use of a pesticide or device:

(1) Directly on humans or pets;

(2) In, on, or around any structure, vehicle, article, surface or area associated with the household, including but

Attachment 3

FIFRA Section 7 Registration of Establishments

(C) If the Administrator approves the transfer and the registrant transfers the registration of the pesticide, the Administrator shall not cancel or amend the registration to delete the use or rescind the transfer of the registration, during the 180-day period beginning on the date of the approval of the transfer unless the Administrator determines that the continued use of the pesticide would cause an unreasonable adverse effect on the environment.

(D) The new registrant of the pesticide shall assume the outstanding data and other requirements for the pesticide that are pending at the time of the transfer.

(4) UTILIZATION OF DATA FOR VOLUNTARILY CANCELED PESTICIDE.—When an application is filed with the Administrator for the registration of a pesticide for a minor use and another registrant subsequently voluntarily cancels its registration for an identical or substantially similar pesticide for an identical or substantially similar use, the Administrator shall process, review, and evaluate the pending application as if the voluntary cancellation had not yet taken place except that the Administrator shall not take such action if the Administrator determines that such minor use may cause an unreasonable adverse effect on the environment. In order to rely on this subsection, the applicant must certify that it agrees to satisfy any outstanding data requirements necessary to support the reregistration of the pesticide in accordance with the data submission schedule established by the Administrator.

(g) NOTICE FOR STORED PESTICIDES WITH CANCELED OR SUSPENDED REGISTRATIONS.—

(1) IN GENERAL.—Any producer or exporter of pesticides, registrant of a pesticide, applicant for registration of a pesticide, applicant for or holder of an experimental use permit, commercial applicator, or any person who distributes or sells any pesticide, who possesses any pesticide which has had its registration canceled or suspended under this section shall notify the Administrator and appropriate State and local officials of—

- (A) such possession,
- (B) the quantity of such pesticide such person possesses, and
- (C) the place at which such pesticide is stored.

(2) COPIES.—The Administrator shall transmit a copy of each notice submitted under this subsection to the regional office of the Environmental Protection Agency which has jurisdiction over the place of pesticide storage identified in the notice.

(h) JUDICIAL REVIEW.—Final orders of the Administrator under this section shall be subject to judicial review pursuant to section 16.

SEC. 7. [7 U.S.C. 136e] REGISTRATION OF ESTABLISHMENTS.

(a) REQUIREMENT.—No person shall produce any pesticide subject to this Act or active ingredient used in producing a pesticide subject to this Act in any State unless the establishment in which it is produced is registered with the Administrator. The application for registration of any establishment shall include the name and address of the establishment and of the producer who operates such establishment.

(b) **REGISTRATION.**—Whenever the Administrator receives an application under subsection (a), the Administrator shall register the establishment and assign it an establishment number.

(c) **INFORMATION REQUIRED.**—

(1) Any producer operating an establishment registered under this section shall inform the Administrator within 30 days after it is registered of the types and amounts of pesticides and, if applicable, active ingredients used in producing pesticides—

(A) which the producer is currently producing;

(B) which the producer has produced during the past year; and

(C) which the producer has sold or distributed during the past year.

The information required by this paragraph shall be kept current and submitted to the Administrator annually as required under such regulations as the Administrator may prescribe.

(2) Any such producer shall, upon the request of the Administrator for the purpose of issuing a stop sale order pursuant to section 13, inform the Administrator of the name and address of any recipient of any pesticide produced in any registered establishment which the producer operates.

(d) **CONFIDENTIAL RECORDS AND INFORMATION.**—Any information submitted to the Administrator pursuant to subsection (c) other than the names of the pesticides or active ingredients used in producing pesticides produced, sold, or distributed at an establishment shall be considered confidential and shall be subject to the provisions of section 10.

SEC. 8. [7 U.S.C. 136f] BOOKS AND RECORDS.

(a) **REQUIREMENTS.**—The Administrator may prescribe regulations requiring producers, registrants, and applicants for registration to maintain such records with respect to their operations and the pesticides and devices produced as the Administrator determines are necessary for the effective enforcement of this Act and to make the records available for inspection and copying in the same manner as provided in subsection (b). No records required under this subsection shall extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed).

(b) **INSPECTION.**—For the purposes of enforcing the provisions of this Act, any producer, distributor, carrier, dealer, or any other person who sells or offers for sale, delivers or offers for delivery any pesticide or device subject to this Act, shall, upon request of any officer or employee of the Environmental Protection Agency or of any State or political subdivision, duly designated by the Administrator, furnish or permit such person at all reasonable times to have access to, and to copy: (1) all records showing the delivery, movement, or holding of such pesticide or device, including the quantity, the date of shipment and receipt, and the name of the consignor and consignee; or (2) in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device. Any inspection with respect to any records and information referred to in this subsection shall not extend to financial data, sales data other than shipment data, pricing data, personnel data,

Attachment 4

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Registration of Pesticide and Active Ingredient Producing Establishments, Submission of Pesticide Reports

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§ 166.49 Public notice of crisis exemptions.

(a) *Periodic notices.* At least quarterly, the Administrator shall issue a notice in the FEDERAL REGISTER announcing issuance of crisis exemptions. The notice shall contain all of the following:

- (1) The name of the applicant;
- (2) The pesticide authorized for use;
- (3) The crop or site to be treated; and
- (4) The name, address, and telephone number of a person in the Agency who can provide further information.

(b) *Annual reports.* Annually, the Agency shall issue a notice in the FEDERAL REGISTER that shall summarize:

- (1) The number of crisis exemptions declared; and
- (2) The number of crisis exemptions revoked.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4512, Jan. 27, 2006]

§ 166.50 Reporting and recordkeeping requirements for crisis exemption.

(a) *Adverse effects information.* Any adverse effects resulting from the use of a pesticide under a crisis exemption must be immediately reported to the Agency.

(b) *Final reports.* (1) A report summarizing the results of treatment under a crisis exemption will be required to be submitted to the Agency within 3 months following the last date of treatment. If a specific, quarantine, or public health exemption has been approved while the crisis exemption is in effect, however, the crisis exemption report may be incorporated into the specific, quarantine, or public health exemption final report required under §166.32(b) and submitted at the time it is due.

(2) Information to be included in the crisis exemption report includes the same information as required in §166.32(b) and an explanation as to why there was a need to utilize the crisis provisions.

(c) *Records.* Records will be maintained for a minimum of 2 years following the date of expiration of the exemption. On request by the Agency, these records shall be made available to the Administrator. Records will include all of the following:

- (1) Location where the pesticide was applied;

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- (2) Dates of application (range); and
- (3) Total quantity of the pesticide used.

[51 FR 1902, Jan. 15, 1986, as amended at 58 FR 34203, June 23, 1993]

§ 166.53 EPA review of crisis exemption and revocation of authority.

(a) *Review.* When a crisis exemption is about to be or has already been declared by a State or Federal agency, EPA will undertake an expedited review of the pesticide to determine if use of the pesticide may result in such unreasonable health or environmental risks that the crisis authority should not be exercised or the crisis exemption should be revoked.

(b) *Revocation*—(1) *Individual crisis exemptions.* A crisis exemption for the use of a specific pesticide may be revoked if the Administrator determines that:

- (i) There are insufficient data to determine the risks posed from the use;
- (ii) Such action is necessary to protect man or the environment; or
- (iii) The State or Federal agency is not complying with the requirements of this subpart C.

(2) *State or Federal agency authority.* The Administrator may revoke the authority of a State or Federal agency to issue crisis exemptions for any pesticide if he determines that:

- (i) Such action is necessary to protect man or the environment; or
- (ii) The State or Federal agency is not complying with the requirements of this subpart C.

(c) *Reason for revocation.* The Agency shall provide the specific reasons for revoking an agency's authority to issue a crisis exemption and for revoking an issued crisis exemption.

PART 167—REGISTRATION OF PESTICIDE AND ACTIVE INGREDIENT PRODUCING ESTABLISHMENTS, SUBMISSION OF PESTICIDE REPORTS

Subpart A—General Provisions

Sec.
167.3 Definitions.

Subpart B—Registration Requirements

167.20 Establishments requiring registration.

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Subparts C–D [Reserved]

Subpart E—Recordkeeping and Reporting Requirements

167.85 Reporting requirements.

167.90 Where to obtain and submit forms.

AUTHORITY: 7 U.S.C. 136 (e) and (w).

SOURCE: 53 FR 35058, Sept. 8, 1988; 54 FR 32638, Aug. 9, 1989, unless otherwise noted.

Subpart A—General Provisions

§ 167.3 Definitions.

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

Act means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. 136 *et seq.*

Amount of pesticidal product means quantity, expressed in weight or volume of the product, and is to be reported in pounds for solid or semi-solid pesticides and active ingredients or gallons for liquid pesticides and active ingredients, or number of individual retail units for devices.

Current production [sales or distribution] means amount of planned production in the calendar year in which the pesticides report is submitted, including new pesticidal products not previously sold or distributed.

Custom blender means any establishment which provides the service of mixing pesticides to a customer's specifications, usually a pesticide(s)-fertilizer(s), pesticide-pesticide, or a pesticide-animal feed mixture, when: (1) The blend is prepared to the order of the customer and is not held in inventory by the blender; (2) the blend is to be used on the customer's property (including leased or rented property); (3) the pesticide(s) used in the blend bears end-use labeling directions which do not prohibit use of the product in such a blend; (4) the blend is prepared from registered pesticides; (b) the blend is delivered to the end-user along with a copy of the end-use labeling of each pesticide used in the blend and a statement specifying the composition of mixture; and (6) no other pesticide pro-

duction activity is performed at the establishment.

Device means any device or class of devices as defined by the Act and determined by the Administrator pursuant to section 25(c) to be subject to the provisions of section 7 of the Act.

Establishment means any site where a pesticidal product, active ingredient, or device is produced, regardless of whether such site is independently owned or operated, and regardless of whether such site is domestic and producing a pesticidal product for export only, or whether the site is foreign and producing any pesticidal product for import into the United States.

Past year means the calendar year immediately prior to that in which the report is submitted.

Pesticidal product means a pesticide, active ingredient, or device.

Pesticidal product report means information showing the types and amounts of pesticidal products which were: (1) Produced in the past calendar year; (2) produced in the current calendar year; and, (3) sold or distributed in the past calendar year. For active ingredients, the pesticidal product report must include information on the types and amounts of an active ingredient for which there is actual or constructive knowledge of its use or intended use as a pesticide. This pesticidal product report also pertains to those products produced for export only which must also be reported. A positive or a negative annual report is required in order to maintain registration for the establishment.

Produce means to manufacture, prepare, propagate, compound, or process any pesticide, including any pesticide produced pursuant to section 5 of the Act, any active ingredient or device, or to package, repackage, label, relabel, or otherwise change the container of any pesticide or device.

Producer means any person, as defined by the Act, who produces any pesticide, active ingredient, or device (including packaging, repackaging, labeling and relabeling).

Sold or distributed means the aggregate amount of a pesticidal product released for shipment by the establishment in which the pesticidal product was produced.

Type of pesticidal product refers to each individual product as identified by: the product name; EPA Registration Number (or EPA File Symbol, if any, for planned products, or Experimental Permit Number, if the pesticide is produced under an Experimental Use Permit); active ingredients; production type (technical, formulation, repackaging, etc.); and, market for which the product was produced (domestic, foreign, etc.). In cases where a pesticide is not registered, registration is not applied for, or the pesticide is not produced under an Experimental Use Permit, the term shall also include the chemical formulation.

Subpart B—Registration Requirements

§ 167.20 Establishments requiring registration.

(a) *Who must register.* (1) Any establishment where a pesticidal product is produced must be registered with the Agency. This requirement does not apply to custom blenders as defined in this part.

(2) Any establishment where a substance is produced must be registered with the Agency if the producer intends the substance to be used as an active ingredient of a pesticide, or has actual or constructive knowledge that the substance will be used by any person as an active ingredient of a pesticide.

(3) Any domestic establishment producing a pesticidal product for export, or any unregistered pesticide, or any foreign establishment producing a pesticidal product for import into the United States must be registered. Also, any establishment, either foreign or domestic, which produces a pesticidal product for use under an Experimental Use Permit, FIFRA section 18 Emergency Exemption or section 24(c) Special Local Needs registration, must be registered.

(b) *Information required.* An applicant for establishment registration must submit the following information:

- (1) Name and address of the company.
- (2) The type of ownership (individual, partnership, cooperative association, corporation, or any organized group of persons whether incorporated or not).

(3) The name and address of each producing establishment for which registration is sought.

(c) *When to apply.* An application for establishment registration must be submitted, and an establishment registration number must be assigned by the Agency, before any production may occur at an establishment. In the case of an establishment which has not previously been required to be registered and is not currently registered, the producer must apply for establishment registration by submitting an application within 180 days after the effective date of this regulation.

(d) *Assignment of establishment registration number.* The Agency will return incomplete or inaccurately completed applications to the applicant. If the application is complete and accurate, the Agency will register the establishment and assign a registration number to the establishment. The establishment registration number will be entered on the application, and a copy of the application will be returned to the applicant.

(e) *Amendment.* If at any time after the first report there is a change in the information required to be submitted under paragraph (b) of this section, that new information must be reported to EPA, in writing on letterhead stationery or on forms supplied by the Agency, within 30 days after such change occurs.

(f) *Duration of registration.* Establishment registration will remain effective provided pesticide reports are submitted annually pursuant to the requirements of this part. Failure to submit a 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]

§ 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. Applica-

tions 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), Ariel Rios Building, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460, ATTN: FIFRA Foreign Establishment Registration Contact.

[53 FR 35058, Sept. 8, 1988; 54 FR 32638, Aug. 9, 1989, as amended at 62 FR 49620, Sept. 23, 1997; 65 FR 4577, Jan. 31, 2000]

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.

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, unless otherwise noted.

Subpart A—General Provisions [Reserved]

Attachment 5

FIFRA Section 8 Books and Records

(b) REGISTRATION.—Whenever the Administrator receives an application under subsection (a), the Administrator shall register the establishment and assign it an establishment number.

(c) INFORMATION REQUIRED.—

(1) Any producer operating an establishment registered under this section shall inform the Administrator within 30 days after it is registered of the types and amounts of pesticides and, if applicable, active ingredients used in producing pesticides—

(A) which the producer is currently producing;

(B) which the producer has produced during the past year; and

(C) which the producer has sold or distributed during the past year.

The information required by this paragraph shall be kept current and submitted to the Administrator annually as required under such regulations as the Administrator may prescribe.

(2) Any such producer shall, upon the request of the Administrator for the purpose of issuing a stop sale order pursuant to section 13, inform the Administrator of the name and address of any recipient of any pesticide produced in any registered establishment which the producer operates.

(d) CONFIDENTIAL RECORDS AND INFORMATION.—Any information submitted to the Administrator pursuant to subsection (c) other than the names of the pesticides or active ingredients used in producing pesticides produced, sold, or distributed at an establishment shall be considered confidential and shall be subject to the provisions of section 10.

SEC. 8. [7 U.S.C. 136f] BOOKS AND RECORDS.

(a) REQUIREMENTS.—The Administrator may prescribe regulations requiring producers, registrants, and applicants for registration to maintain such records with respect to their operations and the pesticides and devices produced as the Administrator determines are necessary for the effective enforcement of this Act and to make the records available for inspection and copying in the same manner as provided in subsection (b). No records required under this subsection shall extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed).

(b) INSPECTION.—For the purposes of enforcing the provisions of this Act, any producer, distributor, carrier, dealer, or any other person who sells or offers for sale, delivers or offers for delivery any pesticide or device subject to this Act, shall, upon request of any officer or employee of the Environmental Protection Agency or of any State or political subdivision, duly designated by the Administrator, furnish or permit such person at all reasonable times to have access to, and to copy: (1) all records showing the delivery, movement, or holding of such pesticide or device, including the quantity, the date of shipment and receipt, and the name of the consignor and consignee; or (2) in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device. Any inspection with respect to any records and information referred to in this subsection shall not extend to financial data, sales data other than shipment data, pricing data, personnel data,

and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed). Before undertaking an inspection under this subsection, the officer or employee must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness.

SEC. 9. [7 U.S.C. 136g] INSPECTION OF ESTABLISHMENTS, ETC.

(a) **IN GENERAL.**—(1) For purposes of enforcing the provisions of this Act, officers or employees of the Environmental Protection Agency or of any State duly designated by the Administrator are authorized to enter at reasonable times (A) any establishment or other place where pesticides or devices are held for distribution or sale for the purpose of inspecting and obtaining samples of any pesticides or devices, packaged, labeled, and released for shipment, and samples of any containers or labeling for such pesticides or devices, or (B) any place where there is being held any pesticide the registration of which has been suspended or canceled for the purpose of determining compliance with section 19.

(2) Before undertaking such inspection, the officers or employees must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness. If the officer or employee obtains any samples, prior to leaving the premises, the officer or employee shall give to the owner, operator, or agent in charge a receipt describing the samples obtained and, if requested, a portion of each such sample equal in volume or weight to the portion retained. If an analysis is made of such samples, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

(b) **WARRANTS.**—For purposes of enforcing the provisions of this Act and upon a showing to an officer or court of competent jurisdiction that there is reason to believe that the provisions of this Act have been violated, officers or employees duly designated by the Administrator are empowered to obtain and to execute warrants authorizing—

(1) entry, inspection, and copying of records for purposes of this section or section 8;

(2) inspection and reproduction of all records showing the quantity, date of shipment, and the name of consignor and consignee of any pesticide or device found in the establishment which is adulterated, misbranded, not registered (in the case of a pesticide) or otherwise in violation of this Act and in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device; and

Attachment 6

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Books and Records of Pesticide Production and Distribution

**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;
- (2) Name and address of shipper;
- (3) Name of delivering carrier;
- (4) Date received; and
- (5) Quantities received.

These records are not intended to cover receipt of pesticides used for in-plant maintenance, extermination, or sanitation programs, etc. Shipping and receiving documents such as invoices, freight bills, receiving tickets, etc., which provide the required information will be considered satisfactory for the purposes of this section. These records shall be retained for a period of two (2) years.

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(d) Records showing the following information regarding the shipment of all pesticides, devices, and active ingredients used in producing pesticides:

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

(2) Name and address of consignee;

(3) Where the pesticide is produced pursuant to an experimental use permit (FIFRA section 5), a special exemption (section 18), or a special local need (section 24), the information required under these sections and any regulations promulgated thereto regarding the distribution of such pesticides;

(4) Name of originating carrier;

(5) Date shipped or delivered for shipment; and

(6) Quantities shipped or delivered for shipment.

Such records are required regardless of whether any shipment or receipt of shipment is between plants owned or otherwise controlled by the same person. Shipping and receiving documents such as invoices, freight bills, receiving tickets, etc., which provide the required information will be considered satisfactory for purposes of this section. These records shall be retained for a period of two (2) years.

(e) Inventory records with respect to the types and amounts of pesticides or pesticide active ingredients, or quantities of devices in stock which he has produced. These records may be disposed of when a more current inventory record is prepared.

(f) Copies of all domestic advertising of the restricted uses of any pesticide registered for restricted use which the producer caused to have prepared, including any radio or television scripts for all such pesticides. These records shall be retained for a period of two (2) years.

(g) Copies of all guarantees given pursuant to section 12(a)(2)(C) of the Act. These records shall be retained for a period of one (1) year after expiration of the guarantee.

(h) In the case of all pesticides, devices, and active ingredients used in producing pesticides intended solely for export to any foreign country:

(1) Copies of the specification or directions of the foreign purchaser for

the production of such pesticides, devices, or pesticide active ingredients;

(2) Copies of labels or labeling required to comply with section 17(a)(1) of the Act; and

(3) For any pesticide other than a pesticide registered under section 3 or sold under section 6(a)(1) of the Act, copies of a statement signed by the foreign purchaser of the pesticide 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 under this Act.

These records shall be retained for a period of 2 years after expiration of the contract.

(i) Records on the method of disposal (burial, incineration, etc.) date or dates of disposal, location of the disposal sites, and the types and amounts of pesticides or pesticide active ingredients disposed of by the producer or his contractor. With regard to the disposal of containers accumulated during production, the Agency will consider satisfactory a statement, attested to by a responsible firm official, describing in general terms the method and location of disposal, e.g., all containers are taken periodically to a certain site. Records of deviations from normal practice must be maintained. In addition, any records on the disposal of pesticides or pesticide active ingredients and/or containers specified pursuant to section 19 of the Act and any regulations promulgated thereto shall also be maintained. The above requirements apply to those products bearing label instructions for disposal and to any other products specified under any regulations promulgated pursuant to section 19. These records shall be retained for twenty (20) years or may be forwarded after three (3) years to the Environmental Protection Agency Regional Administrator for maintenance. Notwithstanding these record keeping requirements, whenever any producer of pesticides or pesticide active ingredients is complying with a rule promulgated under the authority of the Resource Conservation and Recovery Act of 1976 (RCRA) (Pub. L. 94-580, 90 Stat. 2795, October 21, 1976), for the handling

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or disposal of hazardous wastes, as defined by RCRA or any regulations promulgated thereunder, such producer will no longer be required to maintain records in accordance with this subsection.

(j) Records of any tests conducted on human beings whether performed by the producer himself or authorized and/or paid for by the producer. Such records shall include: The names and addresses of subjects tested, dates of tests, types of tests, written consent of subjects to test, and all information and instructions given to the subjects regarding the nature and purpose of the tests and of any physical and mental health consequences which were reasonably foreseen therefrom, and any adverse effects of the test on the subjects, including any such effects coming to the attention of the producer after completion of the tests. These records shall be retained for twenty (20) years or may be forwarded after three (3) years to the Environmental Protection Agency Regional Administrator for maintenance.

(k) Records containing research data relating to registered pesticides including all test reports submitted to the Agency in support of registration or in support of a tolerance petition, *all* underlying raw data, and interpretations and evaluations thereof, whether in the possession of the producer or in the possession of the independent testing facility or laboratory (if any) which performed such tests on behalf of the producer. These records shall be retained as long as the registration is valid and the producer is in business.

[45 FR 54338, Aug. 15, 1980, as amended at 58 FR 9090, Feb. 18, 1993]

§ 169.3 Inspection.

(a) *Producers.* Any producer of any pesticide, device, or active ingredient used in producing a pesticide which is subject to this Act shall, upon request of any officer or employee of the Agency or of any State or political subdivision, duly designated by the Administrator, furnish or permit such person at all reasonable times to have access to and to copy all records required to be maintained by this part, including records in the possession of an independent testing facility or laboratory

which performed tests on behalf of the producer. Such inspection will be conducted in accordance with procedures detailed in section 8(b) of the Act.

(b) Distributors, carriers, dealers, etc. Any distributor, carrier, dealer, or any other person who sells or offers for sale, delivers or offers for delivery any pesticide, device, or active ingredient used in producing a pesticide which is subject to this Act, shall, upon request of any officer or employee of the Agency or of any State or political subdivision, duly designated by the Administrator, furnish or permit such person at all reasonable times to have access to and copy all records showing the delivery or holding of such pesticide, device, or active ingredient used in producing a pesticide, including the quantity, the date of shipment and receipt, and the name and address of the consignor and consignee, and any guarantee received pursuant to section 12(b)(1) of the Act.

(c) *Confidentiality.* Any record which is subject to the regulations under this part, and which may be confidential, shall be treated in accordance with the provisions of section 10 of the Act. The availability to the public of information provided to, or otherwise obtained by, the Administrator under this part shall be governed by part 2 of this chapter.

(d) *Inability.* (1) In the event of the inability of any person to produce records containing the information required to be maintained, furnished for inspection, or given access to, all other records and information regarding the same shall be provided.

(2) Where no such inability exists and any such person fails to give access to and permit copying of such records as required, such failure shall be deemed a refusal to keep records required or a refusal to allow the inspection of any such records or both.

PART 170—WORKER PROTECTION STANDARD

Subpart A—General Provisions

Sec.	
170.1	Scope and purpose.
170.3	Definitions.
170.5	Effective date and compliance dates.
170.7	General duties and prohibited actions.

Attachment 7

FIFRA Section 9 Inspection of Establishments, etc.

and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed). Before undertaking an inspection under this subsection, the officer or employee must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness.

SEC. 9. [7 U.S.C. 136g] INSPECTION OF ESTABLISHMENTS, ETC.

(a) **IN GENERAL.**—(1) For purposes of enforcing the provisions of this Act, officers or employees of the Environmental Protection Agency or of any State duly designated by the Administrator are authorized to enter at reasonable times (A) any establishment or other place where pesticides or devices are held for distribution or sale for the purpose of inspecting and obtaining samples of any pesticides or devices, packaged, labeled, and released for shipment, and samples of any containers or labeling for such pesticides or devices, or (B) any place where there is being held any pesticide the registration of which has been suspended or canceled for the purpose of determining compliance with section 19.

(2) Before undertaking such inspection, the officers or employees must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness. If the officer or employee obtains any samples, prior to leaving the premises, the officer or employee shall give to the owner, operator, or agent in charge a receipt describing the samples obtained and, if requested, a portion of each such sample equal in volume or weight to the portion retained. If an analysis is made of such samples, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

(b) **WARRANTS.**—For purposes of enforcing the provisions of this Act and upon a showing to an officer or court of competent jurisdiction that there is reason to believe that the provisions of this Act have been violated, officers or employees duly designated by the Administrator are empowered to obtain and to execute warrants authorizing—

(1) entry, inspection, and copying of records for purposes of this section or section 8;

(2) inspection and reproduction of all records showing the quantity, date of shipment, and the name of consignor and consignee of any pesticide or device found in the establishment which is adulterated, misbranded, not registered (in the case of a pesticide) or otherwise in violation of this Act and in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device; and

(3) the seizure of any pesticide or device which is in violation of this Act.

(c) ENFORCEMENT.—

(1) CERTIFICATION OF FACTS TO ATTORNEY GENERAL.—The examination of pesticides or devices shall be made in the Environmental Protection Agency or elsewhere as the Administrator may designate for the purpose of determining from such examinations whether they comply with the requirements of this Act. If it shall appear from any such examination that they fail to comply with the requirements of this Act, the Administrator shall cause notice to be given to the person against whom criminal or civil proceedings are contemplated. Any person so notified shall be given an opportunity to present the person's views, either orally or in writing, with regard to such contemplated proceedings, and if in the opinion of the Administrator it appears that the provisions of this Act have been violated by such person, then the Administrator shall certify the facts to the Attorney General, with a copy of the results of the analysis or the examination of such pesticide for the institution of a criminal proceeding pursuant to section 14(b) or a civil proceeding under section 14(a), when the Administrator determines that such action will be sufficient to effectuate the purposes of this Act.

(2) NOTICE NOT REQUIRED.—The notice of contemplated proceedings and opportunity to present views set forth in this subsection are not prerequisites to the institution of any proceeding by the Attorney General.

(3) WARNING NOTICES.—Nothing in this Act shall be construed as requiring the Administrator to institute proceedings for prosecution of minor violations of this Act whenever the Administrator believes that the public interest will be adequately served by a suitable written notice of warning.

SEC. 10. [7 U.S.C. 136h] PROTECTION OF TRADE SECRETS AND OTHER INFORMATION.

(a) IN GENERAL.—In submitting data required by this Act, the applicant may (1) clearly mark any portions thereof which in the applicant's opinion are trade secrets or commercial or financial information and (2) submit such marked material separately from other material required to be submitted under this Act.

(b) DISCLOSURE.—Notwithstanding any other provision of this Act and subject to the limitations in subsections (d) and (e) of this section, the Administrator shall not make public information which in the Administrator's judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary to carry out the provisions of this Act, information relating to formulas of products acquired by authorization of this Act may be revealed to any Federal agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator.

(c) DISPUTES.—If the Administrator proposes to release for inspection information which the applicant or registrant believes to be protected from disclosure under subsection (b), the Administrator shall notify the applicant or registrant, in writing, by certified mail. The Administrator shall not thereafter make available for inspection such data until thirty days after receipt of the notice by the applicant or registrant. During this period, the applicant or

Attachment 8

**FIFRA Sections 12, 13, and 14
Unlawful Acts
Stop Sale, Use, Removal, and Seizure
Penalties**

(e) SEPARATE STANDARDS.—When establishing or approving standards for licensing or certification, the Administrator shall establish separate standards for commercial and private applicators.

SEC. 12. [7 U.S.C. 136j] UNLAWFUL ACTS.

(a) IN GENERAL.—

(1) Except as provided by subsection (b), it shall be unlawful for any person in any State to distribute or sell to any person—

(A) any pesticide that is not registered under section 3 or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this Act;

(B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 3;

(C) any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration under section 3;

(D) any pesticide which has not been colored or discolored pursuant to the provisions of section 25(c)(5);

(E) any pesticide which is adulterated or misbranded;

or
(F) any device which is misbranded.

(2) It shall be unlawful for any person—

(A) to detach, alter, deface, or destroy, in whole or in part, any labeling required under this Act;

(B) to refuse to—

(i) prepare, maintain, or submit any records required by or under section 5, 7, 8, 11, or 19;

(ii) submit any reports required by or under section 5, 6, 7, 8, 11, or 19; or

(iii) allow any entry, inspection, copying of records, or sampling authorized by this Act;

(C) to give a guaranty or undertaking provided for in subsection (b) which is false in any particular, except that a person who receives and relies upon a guaranty authorized under subsection (b) may give a guaranty to the same effect, which guaranty shall contain, in addition to the person's own name and address, the name and address of the person residing in the United States from whom the person received the guaranty or undertaking;

(D) to use for the person's own advantage or to reveal, other than to the Administrator, or officials or employees of the Environmental Protection Agency or other Federal executive agencies, or to the courts, or to physicians, pharmacists, and other qualified persons, needing such information for the performance of their duties, in accordance with such directions as the Administrator may prescribe, any information acquired by authority of this Act which is confidential under this Act;

(E) who is a registrant, wholesaler, dealer, retailer, or other distributor to advertise a product registered under this Act for restricted use without giving the classification of the product assigned to it under section 3;

(F) to distribute or sell, or to make available for use, or to use, any registered pesticide classified for restricted use for some or all purposes other than in accordance with section 3(d) and any regulations thereunder, except that it shall not be unlawful to sell, under regulations issued by the Administrator, a restricted use pesticide to a person who is not a certified applicator for application by a certified applicator;

(G) to use any registered pesticide in a manner inconsistent with its labeling;

(H) to use any pesticide which is under an experimental use permit contrary to the provisions of such permit;

(I) to violate any order issued under section 13;

(J) to violate any suspension order issued under section 3(c)(2)(B), 4, or 6;

(K) to violate any cancellation order issued under this Act or to fail to submit a notice in accordance with section 6(g);

(L) who is a producer to violate any of the provisions of section 7;

(M) to knowingly falsify all or part of any application for registration, application for experimental use permit, any information submitted to the Administrator pursuant to section 7, any records required to be maintained pursuant to this Act, any report filed under this Act, or any information marked as confidential and submitted to the Administrator under any provision of this Act;

(N) who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by this Act;

(O) to add any substance to, or take any substance from, any pesticide in a manner that may defeat the purpose of this Act;

(P) to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test;

(Q) to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this Act;

(R) to submit to the Administrator data known to be false in support of a registration; or

(S) to violate any regulation issued under section 3(a) or 19.

(b) EXEMPTIONS.—The penalties provided for a violation of paragraph (1) of subsection (a) shall not apply to—

(1) any person who establishes a guaranty signed by, and containing the name and address of, the registrant or person residing in the United States from whom the person purchased

or received in good faith the pesticide in the same unbroken package, to the effect that the pesticide was lawfully registered at the time of sale and delivery to the person, and that it complies with the other requirements of this Act, and in such case the guarantor shall be subject to the penalties which would otherwise attach to the person holding the guaranty under the provisions of this Act;

(2) any carrier while lawfully shipping, transporting, or delivering for shipment any pesticide or device, if such carrier upon request of any officer or employee duly designated by the Administrator shall permit such officer or employee to copy all of its records concerning such pesticide or device;

(3) any public official while engaged in the performance of the official duties of the public official;

(4) any person using or possessing any pesticide as provided by an experimental use permit in effect with respect to such pesticide and such use or possession; or

(5) any person who ships a substance or mixture of substances being put through tests in which the purpose is only to determine its value for pesticide purposes or to determine its toxicity or other properties and from which the user does not expect to receive any benefit in pest control from its use.

SEC. 13. [7 U.S.C. 136k] STOP SALE, USE, REMOVAL, AND SEIZURE.

(a) **STOP SALE, ETC., ORDERS.**—Whenever any pesticide or device is found by the Administrator in any State and there is reason to believe on the basis of inspection or tests that such pesticide or device is in violation of any of the provisions of this Act, or that such pesticide or device has been or is intended to be distributed or sold in violation of any such provisions, or when the registration of the pesticide has been canceled by a final order or has been suspended, the Administrator may issue a written or printed “stop sale, use, or removal” order to any person who owns, controls, or has custody of such pesticide or device, and after receipt of such order no person shall sell, use, or remove the pesticide or device described in the order except in accordance with the provisions of the order.

(b) **SEIZURE.**—Any pesticide or device that is being transported or, having been transported, remains unsold or in original unbroken packages, or that is sold or offered for sale in any State, or that is imported from a foreign country, shall be liable to be proceeded against in any district court in the district where it is found and seized for confiscation by a process in rem for condemnation if—

(1) in the case of a pesticide—

(A) it is adulterated or misbranded;

(B) it is not registered pursuant to the provisions of section 3;

(C) its labeling fails to bear the information required by this Act;

(D) it is not colored or discolored and such coloring or discoloring is required under this Act; or

(E) any of the claims made for it or any of the directions for its use differ in substance from the representations made in connection with its registration;

(2) in the case of a device, it is misbranded; or

(3) in the case of a pesticide or device, when used in accordance with the requirements imposed under this Act and as di-

rected by the labeling, it nevertheless causes unreasonable adverse effects on the environment.

In the case of a plant regulator, defoliant, or desiccant, used in accordance with the label claims and recommendations, physical or physiological effects on plants or parts thereof shall not be deemed to be injury, when such effects are the purpose for which the plant regulator, defoliant, or desiccant was applied.

(c) DISPOSITION AFTER CONDEMNATION.—If the pesticide or device is condemned it shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs, shall be paid into the Treasury of the United States, but the pesticide or device shall not be sold contrary to the provisions of this Act or the laws of the jurisdiction in which it is sold. On payment of the costs of the condemnation proceedings and the execution and delivery of a good and sufficient bond conditioned that the pesticide or device shall not be sold or otherwise disposed of contrary to the provisions of the Act or the laws of any jurisdiction in which sold, the court may direct that such pesticide or device be delivered to the owner thereof. The proceedings of such condemnation cases shall conform, as near as may be to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

(d) COURT COSTS, ETC.—When a decree of condemnation is entered against the pesticide or device, court costs and fees, storage, and other proper expenses shall be awarded against the person, if any, intervening as claimant of the pesticide or device.

SEC. 14. [7 U.S.C. 136I] PENALTIES.

(a) CIVIL PENALTIES.—

(1) IN GENERAL.—Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than \$5,000 for each offense.

(2) PRIVATE APPLICATOR.—Any private applicator or other person not included in paragraph (1) who violates any provision of this Act subsequent to receiving a written warning from the Administrator or following a citation for a prior violation, may be assessed a civil penalty by the Administrator of not more than \$1,000 for each offense, except that any applicator not included under paragraph (1) of this subsection who holds or applies registered pesticides, or uses dilutions of registered pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and who violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than \$500 for the first offense nor more than \$1,000 for each subsequent offense.

(3) HEARING.—No civil penalty shall be assessed unless the person charged shall have been given notice and opportunity for a hearing on such charge in the county, parish, or incorporated city of the residence of the person charged.

(4) DETERMINATION OF PENALTY.—In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. Whenever the Ad-

ministrator finds that the violation occurred despite the exercise of due care or did not cause significant harm to health or the environment, the Administrator may issue a warning in lieu of assessing a penalty.

(5) REFERENCES TO ATTORNEY GENERAL.—In case of inability to collect such civil penalty or failure of any person to pay all, or such portion of such civil penalty as the Administrator may determine, the Administrator shall refer the matter to the Attorney General, who shall recover such amount by action in the appropriate United States district court.

(b) CRIMINAL PENALTIES.—

(1) IN GENERAL.—

(A) Any registrant, applicant for a registration, or producer who knowingly violates any provision of this Act shall be fined not more than \$50,000 or imprisoned for not more than 1 year, or both.

(B) Any commercial applicator of a restricted use pesticide, or any other person not described in subparagraph (A) who distributes or sells pesticides or devices, who knowingly violates any provision of this Act shall be fined not more than \$25,000 or imprisoned for not more than 1 year, or both.

(2) PRIVATE APPLICATOR.—Any private applicator or other person not included in paragraph (1) who knowingly violates any provision of this Act shall be guilty of a misdemeanor and shall on conviction be fined not more than \$1,000, or imprisoned for not more than 30 days, or both.

(3) DISCLOSURE OF INFORMATION.—Any person, who, with intent to defraud, uses or reveals information relative to formulas of products acquired under the authority of section 3, shall be fined not more than \$10,000, or imprisoned for not more than three years, or both.

(4) ACTS OF OFFICERS, AGENTS, ETC.—When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any person shall in every case be also deemed to be the act, omission, or failure of such person as well as that of the person employed.

SEC. 15. [7 U.S.C. 136m] INDEMNITIES.

(a) GENERAL INDEMNIFICATION.—

(1) IN GENERAL.—Except as otherwise provided in this section, if—

(A) the Administrator notifies a registrant under section 6(c)(1) that the Administrator intends to suspend a registration or that an emergency order of suspension of a registration under section 6(c)(3) has been issued;

(B) the registration in question is suspended under section 6(c), and thereafter is canceled under section 6(b), 6(d), or 6(f); and

(C) any person who owned any quantity of the pesticide immediately before the notice to the registrant under subparagraph (A) suffered losses by reason of suspension or cancellation of the registration;

the Administrator shall make an indemnity payment to the person.

Attachment 9

FIFRA Section 17 Imports and Exports

on the basis of the cost of the pesticide owned by the person (other than the cost of transportation, if any) immediately before the issuance of the notice to the registrant referred to in subsection (a)(1)(A), (b)(1)(A), or (b)(2)(B)(i), except that in no event shall an indemnity payment to any person exceed the fair market value of the pesticide owned by the person immediately before the issuance of the notice.

(2) SPECIAL RULE.—Notwithstanding any other provision of this Act, the Administrator may provide a reasonable time for use or other disposal of the pesticide. In determining the quantity of any pesticide for which indemnity shall be paid under this section, proper adjustment shall be made for any pesticide used or otherwise disposed of by the owner.

SEC. 16. [7 U.S.C. 136n] ADMINISTRATIVE PROCEDURE; JUDICIAL REVIEW.

(a) DISTRICT COURT REVIEW.—Except as otherwise provided in this Act, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by the district courts of the United States.

(b) REVIEW BY COURT OF APPEALS.—In the case of actual controversy as to the validity of any order issued by the Administrator following a public hearing, any person who will be adversely affected by such order and who had been a party to the proceedings may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has a place of business, within 60 days after the entry of such order, a petition praying that the order be set aside in whole or in part. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the Administrator's order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The court shall consider all evidence of record. The order of the Administrator shall be sustained if it is supported by substantial evidence when considered on the record as a whole. The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

(c) JURISDICTION OF DISTRICT COURTS.—The district courts of the United States are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this Act.

(d) NOTICE OF JUDGMENTS.—The Administrator shall, by publication in such manner as the Administrator may prescribe, give notice of all judgments entered in actions instituted under the authority of this Act.

SEC. 17. [7 U.S.C. 136o] IMPORTS AND EXPORTS.

(a) PESTICIDES AND DEVICES INTENDED FOR EXPORT.—Notwithstanding any other provision this Act, no pesticide or device or ac-

tive ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this Act—

(1) when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 2(p), 2(q) (1) (A), (C), (D), (E), (G), and (H), 2(q) (2) (A), (B), (C) (i) and (iii), and (D), 7, and 8 of this Act; and

(2) in the case of any pesticide other than a pesticide registered under section 3 or sold under section 6(a) (1) of this Act, if, prior to export, the foreign purchaser has signed a statement 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 under this Act.

A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.

(b) CANCELLATION NOTICES FURNISHED TO FOREIGN GOVERNMENTS.—Whenever a registration, or a cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies. Such notification shall, upon request, include all information related to the cancellation or suspension of the registration of the pesticide and information concerning other pesticides that are registered under section 3 of this Act and that could be used in lieu of such pesticide.

(c) IMPORTATION OF PESTICIDES AND DEVICES.—The Secretary of the Treasury shall notify the Administrator of the arrival of pesticides and devices and shall deliver to the Administrator, upon the Administrator's request, samples of pesticides or devices which are being imported into the United States, giving notice to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. If it appears from the examination of a sample that it is adulterated, or misbranded or otherwise violates the provisions set forth in this Act, or is otherwise injurious to health or the environment, the pesticide or device may be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any pesticide or device refused delivery which shall not be exported by the consignee within 90 days from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe. The Secretary of the Treasury may deliver to the consignee such pesticide or device pending examination and decision in the matter on execution of bond for the amount of the full invoice value of such pesticide or device, together with the duty thereon, and on refusal to return such pesticide or device for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of said bond. All charges for storage, cartage, and labor on pesticides or devices which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

(d) COOPERATION IN INTERNATIONAL EFFORTS.—The Administrator shall, in cooperation with the Department of State and any

other appropriate Federal agency, participate and cooperate in any international efforts to develop improved pesticide research and regulations.

(e) REGULATIONS.—The Secretary of the Treasury, in consultation with the Administrator, shall prescribe regulations for the enforcement of subsection (c) of this section.

SEC. 18. [7 U.S.C. 136p] EXEMPTION OF FEDERAL AND STATE AGENCIES.

The Administrator may, at the Administrator's discretion, exempt any Federal or State agency from any provision of this Act if the Administrator determines that emergency conditions exist which require such exemption. The Administrator, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination.

SEC. 19. [7 U.S.C. 136q] STORAGE, DISPOSAL, TRANSPORTATION, AND RECALL.

(a) STORAGE, DISPOSAL, AND TRANSPORTATION.—

(1) DATA REQUIREMENTS AND REGISTRATION OF PESTICIDES.—The Administrator may require under section 3 or 6 that—

(A) the registrant or applicant for registration of a pesticide submit or cite data or information regarding methods for the safe storage and disposal of excess quantities of the pesticide to support the registration or continued registration of a pesticide;

(B) the labeling of a pesticide contain requirements and procedures for the transportation, storage, and disposal of the pesticide, any container of the pesticide, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the pesticide; and

(C) the registrant of a pesticide provide evidence of sufficient financial and other resources to carry out a recall plan under subsection (b), and provide for the disposition of the pesticide, in the event of suspension and cancellation of the pesticide.

(2) PESTICIDES.—The Administrator may by regulation, or as part of an order issued under section 6 or an amendment to such an order—

(A) issue requirements and procedures to be followed by any person who stores or transports a pesticide the registration of which has been suspended or canceled;

(B) issue requirements and procedures to be followed by any person who disposes of stocks of a pesticide the registration of which has been suspended; and

(C) issue requirements and procedures for the disposal of any pesticide the registration of which has been canceled.

(3) CONTAINERS, RINSATES, AND OTHER MATERIALS.—The Administrator may by regulation, or as part of an order issued under section 6 or an amendment to such an order—

(A) issue requirements and procedures to be followed by any person who stores or transports any container of a pesticide the registration of which has been suspended or canceled, any rinsate containing the pesticide, or any other

Attachment 10

**Notice of Arrival of Pesticides and Devices
EPA Form 3540-1**



United States Environmental Protection Agency
Washington, DC 20460

**Notice of Arrival of
Pesticides and Devices**

Send Completed Form to
Appropriate Regional Office
Listed on the Reverse of this
Form.

Form Approved
OMB No. 2070-0020

Note: Read Instructions on reverse before completing form.

Part I: To Be Completed by Importer or Agent

1. Name and Complete Address of Broker or Agent			2. Name and Complete Address of Importer or Consignee		
<input type="checkbox"/>	Return Form to this Address		<input type="checkbox"/>	Return Form to this Address	
3. Name and Address of Shipper			4. EPA Registration Number	5. EPA Producer Establishment No.	
			6. Brand name of Product		
7. Major Active Ingredients and Percentage of Each					
8. Unit Size	9. Quantity	10. Total Net Weight	11. Country of Origin		
12. Port of Entry			13. Carrier		
14. Entry Number		15. Entry Date	16. I assert that information constituting Confidential Business Information is shown in the above blocks numbered: (Note: Blocks 4, 5, 6, 7 are not entitled to CBI treatment—see Instructions)		
17. Location of Goods for Examination after Importation					
18. Remarks					

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

19. Printed Name of Importer or Agent	Telephone Number	20. Signature of Importer or Agent	Date Signed
---------------------------------------	------------------	------------------------------------	-------------

Part II: To Be Completed by U.S. Environmental Protection Agency

Action to be taken by U.S. Customs Service

Release Shipment
 Detain for Inspection
 Release shipment to consignee under bond. Shipment must

Other (Specify)

Remarks

Signature and Title of EPA Official	Date
-------------------------------------	------

Part III: To Be Completed by U.S. Customs Service

The information shown in Part I was compared with the entry papers for this shipment and no discrepancies were noted. The shipment was handled as instructed by EPA in Part II. Any deviations should be brought to the attention of EPA before releasing shipment and

Remarks

Signature of District Director of Customs	Date
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Instructions

Customs Regulations. 19 CFR 12.112 requires an importer desiring to import pesticides or devices into the United States to submit EPA Form 3540-1, Notice of Arrival of Pesticides and Devices, to the U.S. Environmental Protection Agency prior to the arrival of shipment in the United States. This form will be used by:

Importer or Agent. The Importer or his agent must complete Part 1 of the form. It may be necessary to complete some of the items at the time of entry, e.g., entry data, carrier. To expedite the handling of pesticides shipments, submit this form to the EPA office listed below having jurisdiction over the state/territory in which the Port of Entry is located prior to the arrival of the shipment.

EPA. Part II of this form will be completed by EPA. EPA will retain the EPA Copy for its files and return the other copies to the importer or agent for presentation to Customs at the time of entry.

Customs. Customs will compare the information shown on this form with the entry documents and the shipment. Bring any discrepancies to the attention of EPA before the shipment is released and noted in the remarks section. If the importation is not handled by Customs in the manner instructed in Part II, this should also be noted in remarks. All data left blank by the importer (e.g., entry date) must be completed at this time. After completion of Part III and signing the form, Customs will return the Official File Copy to EPA and retain the Custom's Copy.

The following blocks are self explanatory - 1, 2, 8, 9, 10, 12, 14, 15, 18, 19, and 20.

3. Name and Address of Shipper. The name and address of person exporting the pesticide to the United States.

4. EPA Registration No. The product registration number assigned at the time of registration which identifies the product. If the product is a device, write the word 'device' in the block.

5. EPA Producer Establishment No. The producing establishment registration number which identified where the pesticidal product, active ingredient, or device was produced.

6. Brand Name of Product. Name under which the product is sold or distributed.

7. Major Active Ingredients and Percentage of Each. If block 4 contains registration number, leave blank. If no registration number, list active ingredients (or two major ingredients and percentage of each).

11. Country of Origin. The country in which the pesticide producer is located.

13. Carrier. E.g., ship's name, airline or trucking company.

16. Confidential Business Information (CBI) designation. Please note that the information provided in blocks 4, 5, 6, and 7 is not entitled to confidential treatment under section 7(d) of FIFRA and under labeling requirements for pesticides at 40 CFR 156.10. Information provided in those blocks will be made public with no further notice.

17. Location of Goods for Examination after Importation. Enter the EPA establishment number for importing registered establishment in the case of unregistered product imports between establishments operated by the same producer.

EPA Regional Offices	States Covered	EPA Regional Offices	States Covered
EPA Region I 1 Congress Street (SEA) Boston, MA 02114-2023	CT MA ME NH RI VT	EPA Region VI 1445 Ross Avenue Suite #1200 (6PD-P) Dallas, TX 75202-2733	AR LA NM OK TX
EPA Region II MS-500, Bldg #5 2890 Woodbridge Ave. Edison, NJ 08837-3679	NJ NY PR VI	EPA Region VII 901 N. 5 TH Street (PESTWWPD) Kansas City, KS 66101	IA KS MO NE
EPA Region III 1650 Arch Street (3WC32) Philadelphia, PA 19103-2029	DE DC MD PA VA WV	EPA Region VIII 999 18 th Street Suite #300 (8ENF/TEP) Denver, CO 80202-2466	CO MT ND SD UT WY
EPA Region IV 61 Forsyth Street, SW (APT-PS) Atlanta, GA 30303-8960	AL FL GA KY MS NC SC TN	EPA Region IX 75 Hawthorne Street (CMD-4-3) San Francisco, CA 94105-3901	AZ AS CA GU HI NV PI WK
EPA Region V 77 West Jackson Blvd.(DT-8J) Chicago, IL 60604-3507	IL IN OH MI MN WI	EPA Region X 1200 Sixth Avenue (ECO-084) Seattle, WA 98101-9797	AK ID OR WA

Attachment 11

**FIFRA Sections 25(c)(3) and 25(c)(4)
Authority of Administrator**

garding any such final regulation within 15 days after receiving it, the Administrator shall publish in the Federal Register (with the final regulation) the comments of the Secretary, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 15 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register at any time after such 15-day period notwithstanding the foregoing 30-day time requirement. In taking any final action under this subsection, the Administrator shall include among those factors to be taken into account the effect of the regulation on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such effect.

(C) TIME REQUIREMENTS.—The time requirements imposed by subparagraphs (A) and (B) may be waived or modified to the extent agreed upon by the Administrator and the Secretary.

(D) PUBLICATION IN THE FEDERAL REGISTER.—The Administrator shall, simultaneously with any notification to the Secretary of Agriculture under this paragraph prior to the issuance of any proposed or final regulation, publish such notification in the Federal Register.

(3) CONGRESSIONAL COMMITTEES.—At such time as the Administrator is required under paragraph (2) of this subsection to provide the Secretary of Agriculture with a copy of proposed regulations and a copy of the final form of regulations, the Administrator shall also furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(4) CONGRESSIONAL REVIEW OF REGULATIONS.—Simultaneously with the promulgation of any rule or regulation under this Act, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation shall not become effective until the passage of 60 calendar days after the rule or regulation is so transmitted.

(b) EXEMPTION OF PESTICIDES.—The Administrator may exempt from the requirements of this Act by regulation any pesticide which the Administrator determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this Act in order to carry out the purposes of this Act.

(c) OTHER AUTHORITY.—The Administrator, after notice and opportunity for hearing, is authorized—

(1) to declare a pest any form of plant or animal life (other than man and other than bacteria, virus, and other micro-organisms on or in living man or other living animals) which is injurious to health or the environment;

(2) to determine any pesticide which contains any substance or substances in quantities highly toxic to man;

(3) to establish standards (which shall be consistent with those established under the authority of the Poison Prevention Packaging Act (Public Law 91-601)) with respect to the package, container, or wrapping in which a pesticide or device is enclosed for use or consumption, in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by this Act as well as to accomplish the other purposes of this Act;

(4) to specify those classes of devices which shall be subject to any provision of paragraph 2(q)(1) or section 7 of this Act upon the Administrator's determination that application of such provision is necessary to effectuate the purposes of this Act;

(5) to prescribe regulations requiring any pesticide to be colored or discolored if the Administrator determines that such requirement is feasible and is necessary for the protection of health and the environment; and

(6) to determine and establish suitable names to be used in the ingredient statement.

(d) SCIENTIFIC ADVISORY PANEL.—

(1) IN GENERAL.—The Administrator shall submit to an advisory panel for comment as to the impact on health and the environment of the action proposed in notices of intent issued under section 6(b) and of the proposed and final form of regulations issued under section 25(a) within the same time periods as provided for the comments of the Secretary of Agriculture under such sections. The time requirements for notices of intent and proposed and final forms of regulation may not be modified or waived unless in addition to meeting the requirements of section 6(b) or 25(a), as applicable, the advisory panel has failed to comment on the proposed action within the prescribed time period or has agreed to the modification or waiver. The Administrator shall also solicit from the advisory panel comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of scientific analyses made by personnel of the Environmental Protection Agency that lead to decisions by the Administrator in carrying out the provisions of this Act. The comments, evaluations, and recommendations of the advisory panel submitted under this subsection and the response of the Administrator shall be published in the Federal Register in the same manner as provided for publication of the comments of the Secretary of Agriculture under such sections. The chairman of the advisory panel, after consultation with the Administrator, may create temporary subpanels on specific projects to assist the full advisory panel in expediting and preparing its evaluations, comments, and recommendations. The subpanels may be composed of scientists other than members of the advisory panel, as deemed necessary for the purpose of evaluating scientific studies relied upon by the Administrator with respect to proposed action. Such additional scientists shall be selected by the advisory panel. The panel referred to in this subsection shall consist of 7 members appointed by the Administrator from a list of 12 nominees, 6 nominated by the National Institutes of Health and 6 by the National Science Foundation, utilizing a system of staggered terms of appointment. Members of the panel shall be selected

Attachment 12
EPA Correspondence

Felicia Sellers

From: Hardy.Michael@epamail.epa.gov
ent: Monday, July 17, 2006 8:17 AM
To: Felicia Sellers
Subject: Re: Registration of a water treatment device

Ms. Sellers,

Your product would be considered a pesticide device under 40 CFR Part 152.500. In short, your product would be regulated by the EPA but not registered by the EPA. Please refer to the following link for guidance on pesticide devices:

http://a257.g.akamaitech.net/7/257/2422/08aug20051500/edocket.access.gpo.gov/cfr_2005/julqtr/pdf/40cfr152.500.pdf

Michael Hardy
Ombudsman and Enforcement Team Leader
Antimicrobials Division
703-308-6432

Felicia Sellers
<FSellers@SciReg.com>

07/13/2006 02:48
PM

To
Michael Hardy/DC/USEPA/US@EPA
cc
Subject
Registration of a water treatment
device

Dear Mr. Hardy:

We have a client interested in marketing their product as a water treatment device.

The system uses a 2-stage process. The first stage employs an ozonation process, which is designed to kill and eliminate microorganisms that may be found in drinking water. The second stage uses a carbon-block filter to provide additional removal of microorganisms and other contaminants.

The system must be used with microbiologically safe water from a known source including municipal (tap water), lake, or well water. The system is not intended for the treatment of water that has an obvious contamination source, nor is it intended to convert wastewater into microbiologically safe water. The system is recommended for use with visually clear water (not colored, cloudy, or turbid water).

Our client intends to make the following claims:

1. The water treatment system (the carbon block filter) reduces contaminants and impurities such as (but not limited to) chlorine taste and odor, Cryptosporidium, Giardia, lead, and mercury.
2. The water treatment system (ozone generation) kills and eliminates harmful microorganisms such as (but not limited to) Escherichia

coli and Salmonella typhimurium (surrogates for Bacillus cereus, Listeria monocytogenes, Enterococcus faecalis, Pseudomonas aeruginosa, Yersinia enterocolitica and Staphylococcus aureus).

This system has been tested and certified by NSF International against NSF/ANSI Standards 2 and 53 for the reduction of contaminants. NSF Certification for a microbiological claim is for Cyst reduction only. The system has also been tested and verified by an independent laboratory and validated by the Water Quality Association for the removal of microorganisms including bacteria and protozoa.

Does this system need to be registered with EPA? If you have any questions please feel free to contact us.

Kind Regards,
Felicia

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