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SUBCHAPTER I—INSECTICIDES

§§ 121 to 134. Repealed. June 25, 1947, ch. 125, § 16, 61 Stat. 172

Sections, act Apr. 26, 1910, ch. 191, 36 Stat. 335, formerly known as "The Insecticides Act", are covered by subchapter II of this chapter.

EFFECTIVE DATE OF REPEAL; SAVINGS PROVISION

Act June 25, 1947, ch. 125, § 16, 61 Stat. 172, repealed this subchapter effective one year after June 25, 1947, and further provided that this subchapter should be deemed to remain in full force for the purpose of sustaining any proper suit, action, or other proceeding with respect to any violations, liabilities incurred, or appeals taken prior to such date of repeal or to sales, shipments, or deliveries of insecticides and fungicides exempted by the Secretary.

SUBCHAPTER II—ENVIRONMENTAL PESTICIDE CONTROL

§§ 135 to 135k. Omitted

CODIFICATION

Sections 135 to 135k, acts June 25, 1947, ch. 125, §§ 2-13, 61 Stat. 163-172; Aug. 7, 1959, Pub. L. 86-139, § 2, 73 Stat. 286; May 12, 1964, Pub. L. 88-305, §§ 1-6, 78 Stat. 190-193; Oct. 15, 1970, Pub. L. 91-452, title II, § 204, 84 Stat. 928; Dec. 30, 1970, Pub. L. 91-601, § 6(b), formerly § 7(b), 84 Stat. 1673, renumbered, Aug. 13, 1981, Pub. L. 97-35, title XII, § 1205(c), 95 Stat. 716, which related to economic poison control, were superseded by the amendments made to act June 25, 1947, by Pub. L. 92-516, Oct. 21, 1972, 86 Stat. 975. See section 4 of Pub. L. 92-516, set out as a note under section 136 of this title. The provisions of act June 25, 1947, as amended by Pub. L. 92-516, are set out in section 136 et seq. of this title.

Section 135 provided definitions for the purposes of this subchapter.

Section 135a related to prohibited acts.

Section 135b related to registration of economic poisons.

Section 135c related to access, inspection, and use in criminal prosecutions of books and records.

Section 135d related to rules and regulations, examination of economic poisons or devices, notification to violators, certification to United States attorney, duty of attorney, and publication of judgments.

Section 135e related to exemptions from penalties.

Section 135f provided for penalties.

Section 135g related to seizure, disposal, and award of costs against claimant.

Section 135h related to refusal of admission of imports.

Section 135i related to delegation of duties.

Section 135j related to authorization of appropriations and expenditure of funds.

Section 135k related to cooperation between departments and agencies.

§ 136. Definitions

For purposes of this subchapter—

(a) Active ingredient

The term "active ingredient" means—

(1) in the case of a pesticide other than a plant regulator, defoliant, desiccant, or nitrogen stabilizer, an ingredient which will prevent, destroy, repel, or mitigate any pest;

(2) in the case of a plant regulator, an ingredient which, through physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the product thereof;

(3) in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from a plant;

(4) in the case of a desiccant, an ingredient which will artificially accelerate the drying of plant tissue; and

(5) in the case of a nitrogen stabilizer, an ingredient which will prevent or hinder the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria.

(b) Administrator

The term "Administrator" means the Administrator of the Environmental Protection Agency.

(c) Adulterated

The term "adulterated" applies to any pesticide if—

(1) its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold;

(2) any substance has been substituted wholly or in part for the pesticide; or

(3) any valuable constituent of the pesticide has been wholly or in part abstracted.

(d) Animal

The term "animal" means all vertebrate and invertebrate species, including but not limited to man and other mammals, birds, fish, and shellfish.

(e) Certified applicator, etc.

(1) Certified applicator

The term "certified applicator" means any individual who is certified under section 136i of this title as authorized to use or supervise the use of any pesticide which is classified for restricted use. Any applicator who holds or applies registered pesticides, or uses dilutions of registered pesticides consistent with subsection (ee), only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served is not deemed to be a seller or distributor of pesticides under this subchapter.

(2) Private applicator

The term "private applicator" means a certified applicator who uses or supervises the

use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by the applicator or the applicator's employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

(3) Commercial applicator

The term "commercial applicator" means an applicator (whether or not the applicator is a private applicator with respect to some uses) who uses or supervises the use of any pesticide which is classified for restricted use for any purpose or on any property other than as provided by paragraph (2).

(4) Under the direct supervision of a certified applicator

Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a competent person acting under the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is applied.

(f) Defoliant

The term "defoliant" means any substance or mixture of substances intended for causing the leaves or foliage to drop from a plant, with or without causing abscission.

(g) Desiccant

The term "desiccant" means any substance or mixture of substances intended for artificially accelerating the drying of plant tissue.

(h) Device

The term "device" means 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 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.

(i) District court

The term "district court" means a United States district court, the District Court of Guam, the District Court of the Virgin Islands, and the highest court of American Samoa.

(j) Environment

The term "environment" includes water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these.

(k) Fungus

The term "fungus" means any non-chlorophyll-bearing thallophyte (that is, any non-chlorophyll-bearing plant of a lower order than mosses and liverworts), as for example, rust, smut, mildew, mold, yeast, and bacteria, except those on or in living man or other animals and those on or in processed food, beverages, or pharmaceuticals.

(l) Imminent hazard

The term "imminent hazard" means a situation which exists when the continued use of a

pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary pursuant to the Endangered Species Act of 1973 [16 U.S.C. 1531 et seq.].

(m) Inert ingredient

The term "inert ingredient" means an ingredient which is not active.

(n) Ingredient statement

The term "ingredient statement" means a statement which contains—

(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticide; and

(2) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic.

(o) Insect

The term "insect" means any of the numerous small invertebrate animals generally having the body more or less obviously segmented, for the most part belonging to the class insecta, comprising six-legged, usually winged forms, as for example, beetles, bugs, bees, flies, and to other allied classes of arthropods whose members are wingless and usually have more than six legs, as for example, spiders, mites, ticks, centipedes, and wood lice.

(p) Label and labeling

(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 136w(c)(3) of this title;

(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 136e of this

title to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this subchapter 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 136a(d) of this title, 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 136a(d) of this title, is adequate to protect health and the environment; or

(H) in the case of a pesticide not registered in accordance with section 136a of this title 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 subchapter, the registration number assigned to the pesticide under this subchapter, 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 subchapter—

(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 or other living animals) which the Administrator declares to be a pest under section 136w(c)(1) of this title.

(u) Pesticide

The term "pesticide" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer, except that the term "pesticide" shall not include any article that is a "new animal drug" within the meaning of section 321(w)¹ of title 21, that has been determined by the Secretary of Health and Human Services not to be a new animal drug by a regulation establishing conditions of use for the article, or that is an animal feed within the meaning of section 321(x)¹ of title 21 bearing or containing a new animal drug. The term "pesticide" does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as defined in section 321 of title 21. For purposes of the preceding sentence, the term "criti-

¹ See References in Text note below.

cal device" includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term "semi-critical device" includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

(v) Plant regulator

The term "plant regulator" means any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments. Also, the term "plant regulator" shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration.

(w) Producer and produce

The term "producer" means the person who manufactures, prepares, compounds, propagates, or processes any pesticide or device or active ingredient used in producing a pesticide. The term "produce" means to manufacture, prepare, compound, propagate, or process any pesticide or device or active ingredient used in producing a pesticide. The dilution by individuals of formulated pesticides for their own use and according to the directions on registered labels shall not of itself result in such individuals being included in the definition of "producer" for the purposes of this subchapter.

(x) Protect health and the environment

The terms "protect health and the environment" and "protection of health and the environment" mean protection against any unreasonable adverse effects on the environment.

(y) Registrant

The term "registrant" means a person who has registered any pesticide pursuant to the provisions of this subchapter.

(z) Registration

The term "registration" includes reregistration.

(aa) State

The term "State" means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa.

(bb) Unreasonable adverse effects on the environment

The term "unreasonable adverse effects on the environment" means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a

human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.

(cc) Weed

The term "weed" means any plant which grows where not wanted.

(dd) Establishment

The term "establishment" means any place where a pesticide or device or active ingredient used in producing a pesticide is produced, or held, for distribution or sale.

(ee) To use any registered pesticide in a manner inconsistent with its labeling

The term "to use any registered pesticide in a manner inconsistent with its labeling" means to use any registered pesticide in a manner not permitted by the labeling, except that the term shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency, (2) applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment, (3) employing any method of application not prohibited by the labeling unless the labeling specifically states that the product may be applied only by the methods specified on the labeling, (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling, (5) any use of a pesticide in conformance with section 136c, 136p, or 136v of this title, or (6) any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this subchapter. After March 31, 1979, the term shall not include the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provided for in section 27(b) of the Federal Pesticide Act of 1978, which regulation or advisory opinion specifically requires the use of definite amounts of dilution.

(ff) Outstanding data requirement

(1) In general

The term "outstanding data requirement" means a requirement for any study, information, or data that is necessary to make a determination under section 136a(c)(5) of this title and which study, information, or data—

(A) has not been submitted to the Administrator; or

(B) if submitted to the Administrator, the Administrator has determined must be re-submitted because it is not valid, complete, or adequate to make a determination under section 136a(c)(5) of this title and the regulations and guidelines issued under such section.

(2) Factors

In making a determination under paragraph (1)(B) respecting a study, the Administrator shall examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.

(gg) To distribute or sell

The term “to distribute or sell” means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. The term does not include the holding or application of registered pesticides or use dilutions thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.

(hh) Nitrogen stabilizer

The term “nitrogen stabilizer” means any substance or mixture of substances intended for preventing or hindering the process of nitrification, denitrification, ammonia volatilization, or urease production through action upon soil bacteria. Such term shall not include—

- (1) dicyandiamide;
- (2) ammonium thiosulfate; or
- (3) any substance or mixture of substances.—²

(A) that was not registered pursuant to section 136a of this title prior to January 1, 1992; and

(B) that was in commercial agronomic use prior to January 1, 1992, with respect to which after January 1, 1992, the distributor or seller of the substance or mixture has made no specific claim of prevention or hindering of the process of nitrification, denitrification, ammonia volatilization³ urease production regardless of the actual use or purpose for, or future use or purpose for, the substance or mixture.

Statements made in materials required to be submitted to any State legislative or regulatory authority, or required by such authority to be included in the labeling or other literature accompanying any such substance or mixture shall not be deemed a specific claim within the meaning of this subsection.

(jj) ⁴ Maintenance applicator

The term “maintenance applicator” means any individual who, in the principal course of such individual’s employment, uses, or supervises the use of, a pesticide not classified for restricted use (other than a ready to use consumer

products pesticide); for the purpose of providing structural pest control or lawn pest control including janitors, general maintenance personnel, sanitation personnel, and grounds maintenance personnel. The term “maintenance applicator” does not include private applicators as defined in subsection (e)(2); individuals who use antimicrobial pesticides, sanitizers or disinfectants; individuals employed by Federal, State, and local governments or any political subdivisions thereof, or individuals who use pesticides not classified for restricted use in or around their homes, boats, sod farms, nurseries, greenhouses, or other noncommercial property.

(kk) Service technician

The term “service technician” means any individual who uses or supervises the use of pesticides (other than a ready to use consumer products pesticide) for the purpose of providing structural pest control or lawn pest control on the property of another for a fee. The term “service technician” does not include individuals who use antimicrobial pesticides, sanitizers or disinfectants; or who otherwise apply ready to use consumer products pesticides.

(ll) Minor use

The term “minor use” means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where—

(1) the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or

(2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and—

(A) there are insufficient efficacious alternative registered pesticides available for the use;

(B) the alternatives to the pesticide use pose greater risks to the environment or human health;

(C) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(D) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The status as a minor use under this subsection shall continue as long as the Administrator has not determined that, based on existing data, such use may cause an unreasonable adverse effect on the environment and the use otherwise qualifies for such status.

(mm) Antimicrobial pesticide

(1) In general

The term “antimicrobial pesticide” means a pesticide that—

(A) is intended to—

(i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or

(ii) protect inanimate objects, industrial processes or systems, surfaces, water, or

² So in original. Period probably should not appear.

³ So in original. Probably should be followed by “, or”.

⁴ So in original. No subsec. (ii) was enacted.

other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

(B) in the intended use is exempt from, or otherwise not subject to, a tolerance under section 346a of title 21 or a food additive regulation under section 348 of title 21.

(2) Excluded products

The term “antimicrobial pesticide” does not include—

(A) a wood preservative or antifouling paint product for which a claim of pesticidal activity other than or in addition to an activity described in paragraph (1) is made;

(B) an agricultural fungicide product; or

(C) an aquatic herbicide product.

(3) Included products

The term “antimicrobial pesticide” does include any other chemical sterilant product (other than liquid chemical sterilant products exempt under subsection (u)), any other disinfectant product, any other industrial microbiocide product, and any other preservative product that is not excluded by paragraph (2).

(nn) Public health pesticide

The term “public health pesticide” means any minor use pesticide product registered for use and used predominantly in public health programs for vector control or for other recognized health protection uses, including the prevention or mitigation of viruses, bacteria, or other microorganisms (other than viruses, bacteria, or other microorganisms on or in living man or other living animal) that pose a threat to public health.

(oo) Vector

The term “vector” means any organism capable of transmitting the causative agent of human disease or capable of producing human discomfort or injury, including mosquitoes, flies, fleas, cockroaches, or other insects and ticks, mites, or rats.

(June 25, 1947, ch. 125, §2, as added Pub. L. 92-516, §2, Oct. 21, 1972, 86 Stat. 975; amended Pub. L. 93-205, §13(f), Dec. 28, 1973, 87 Stat. 903; Pub. L. 94-140, §9, Nov. 28, 1975, 89 Stat. 754; Pub. L. 95-396, §1, Sept. 30, 1978, 92 Stat. 819; Pub. L. 100-532, title I, §101, title VI, §601(a), title VIII, §801(a), Oct. 25, 1988, 102 Stat. 2655, 2677, 2679; Pub. L. 102-237, title X, §1006(a)(1), (2), (b)(3)(A), (B), Dec. 13, 1991, 105 Stat. 1894, 1895; Pub. L. 104-170, title I, §§105(a), 120, title II, §§210(a), 221, 230, title III, §304, Aug. 3, 1996, 110 Stat. 1490, 1492, 1493, 1502, 1508, 1512.)

REFERENCES IN TEXT

The Endangered Species Act of 1973, referred to in subsection (l), is Pub. L. 93-205, Dec. 28, 1973, 87 Stat. 884, as amended, which is classified generally to chapter 35 (§1531 et seq.) of Title 16, Conservation. For complete classification of this Act to the Code, see Short Title note set out under section 1531 of Title 16 and Tables.

Section 321 of title 21, referred to in subsection (u), was subsequently amended, and subsections (w) and (x) of section 321 no longer define the terms “new animal drug” and “animal feed”, respectively. However, such terms are defined elsewhere in that section.

Section 27(b) of Federal Pesticide Act of 1978, referred to in subsection (ee), is section 27(b) of Pub. L. 95-396, Sept. 30, 1978, 92 Stat. 841, which was formerly set out as a note under section 136w-4 of this title.

PRIOR PROVISIONS

A prior section 2 of act June 25, 1947, was classified to section 135 of this title prior to amendment of act June 25, 1947, by Pub. L. 92-516.

AMENDMENTS

1996—Subsec. (a)(1). Pub. L. 104-170, §105(a)(1)(A), substituted “defoliant, desiccant, or nitrogen stabilizer” for “defoliant, or desiccant”.

Subsec. (a)(5). Pub. L. 104-170, §105(a)(1)(B)–(D), added par. (5).

Subsec. (u). Pub. L. 104-170, §§105(a)(2), 221(1), struck out “and” before “(2)”, inserted “and (3) any nitrogen stabilizer,” after “desiccant,” and inserted at end “The term ‘pesticide’ does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as defined in section 321 of title 21. For purposes of the preceding sentence, the term ‘critical device’ includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term ‘semi-critical device’ includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.”

Subsec. (bb). Pub. L. 104-170, §304, which directed amendment of section 2(bb) by inserting “(1)” after “means” and adding cl. (2), without specifying the Act being amended, was executed to this subsection, which is section 2(bb) of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress.

Pub. L. 104-170, §230(a), inserted at end “The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.”

Subsec. (hh). Pub. L. 104-170, §105(a)(3), added subsec. (hh).

Subsecs. (jj), (kk). Pub. L. 104-170, §120, added subsecs. (jj) and (kk).

Subsec. (ll). Pub. L. 104-170, §210(a), added subsec. (ll).

Subsec. (mm). Pub. L. 104-170, §221(2), added subsec. (mm).

Subsecs. (nn), (oo). Pub. L. 104-170, §230(b), added subsecs. (nn) and (oo).

1991—Subsec. (e)(1). Pub. L. 102-237, §1006(a)(1), substituted “section 136i” for “section 136b” and “uses dilutions” for “use dilutions” and made technical amendment to reference to subsection (ee) of this section involving corresponding provision of original act.

Subsec. (e)(2). Pub. L. 102-237, §1006(b)(3)(A), substituted “the applicator or the applicator’s” for “him or his”.

Subsec. (e)(3). Pub. L. 102-237, §1006(b)(3)(B), substituted “the applicator” for “he”.

Subsec. (q)(2)(A)(i). Pub. L. 102-237, §1006(a)(2), substituted “size or form” for “size of form”.

1988—Subsec. (c). Pub. L. 100-532, §801(a)(1), substituted “if—” for “if:”.

Subsec. (p)(2)(B). Pub. L. 100-532, §801(a)(2), substituted “Health and Human Services” for “Health, Education, and Welfare”.

Subsec. (q)(2)(A). Pub. L. 100-532, §801(a)(3), substituted “if—” for “if:”.

Subsec. (q)(2)(C)(iii). Pub. L. 100-532, §801(a)(4), substituted “, except that” for “: Provided, That”.

Subsec. (u). Pub. L. 100-532, §801(a)(5), substituted “, except that” for “: Provided, That”, struck out

“(1)(a)” after “include any article” and “or (b)” after “section 321(w) of title 21,” and substituted “Health and Human Services” for “Health, Education, and Welfare”, “or that is” for “or (2) that is”, and “a new animal drug” for “an article covered by clause (1) of this proviso”.

Subsec. (ee). Pub. L. 100-532, §§ 601(a)(1), 801(a)(6), substituted “, except that” for “: *Provided*, That”, inserted “unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency” and “unless the labeling specifically states that the product may be applied only by the methods specified on the labeling”, substituted “labeling, (4) mixing” for “labeling, or (4) mixing”, “, (5)” for “: *Provided further*, That the term also shall not include”, “or (6) any use” for “or any use”, and “. After” for “: *And provided further*, That after”.

Subsec. (ff). Pub. L. 100-532, § 101, added subsec. (ff).

Subsec. (gg). Pub. L. 100-532, § 601(a)(2), added subsec. (gg).

1978—Subsec. (e)(1). Pub. L. 95-396, § 1(1), inserted provision deeming an applicator not a seller or distributor of pesticides when providing a service of controlling pests.

Subsec. (e)(3). Pub. L. 95-396, § 1(2), substituted “an applicator” for “a certified applicator”.

Subsec. (q)(1)(H). Pub. L. 95-396, § 1(3), added subpar. (H).

Subsec. (w). Pub. L. 95-396, § 1(4), (5), amended definition of “producer” and “produce” to include reference to active ingredient used in producing a pesticide and inserted provision that an individual did not become a producer when there was dilution of a pesticide for personal use according to directions on registered labels.

Subsec. (dd). Pub. L. 95-396, § 1(6), inserted “or active ingredient used in producing a pesticide”.

Subsec. (ee). Pub. L. 95-396, § 1(7), added subsec. (ee).

1975—Subsec. (u). Pub. L. 94-140 inserted proviso which excluded from term “pesticide” any article designated as “new animal drug” and any article denominated as animal feed.

1973—Subsec. (l). Pub. L. 93-205 substituted “or threatened by the Secretary pursuant to the Endangered Species Act of 1973” for “by the Secretary of the Interior under Public Law 91-135”.

EFFECTIVE DATE OF 1988 AMENDMENT

Pub. L. 100-532, title IX, § 901, Oct. 25, 1988, 102 Stat. 2688, provided that: “Except as otherwise provided in this Act, the amendments made by this Act [see Short Title of 1988 Amendment note below] shall take effect on the expiration of 60 days after the date of enactment of this Act [Oct. 25, 1988].”

EFFECTIVE DATE OF 1973 AMENDMENT

Amendment by Pub. L. 93-205 effective Dec. 28, 1973, see section 16 of Pub. L. 93-205, set out as an Effective Date note under section 1531 of Title 16, Conservation.

EFFECTIVE DATE

Pub. L. 92-516, § 4, Oct. 21, 1972, 86 Stat. 998, as amended by Pub. L. 94-140, § 4, Nov. 28, 1975, 89 Stat. 752; Pub. L. 95-396, § 28, Sept. 30, 1978, 92 Stat. 842, provided that:

“(a) Except as otherwise provided in the Federal Insecticide, Fungicide, and Rodenticide Act [this subchapter], as amended by this Act and as otherwise provided by this section, the amendments made by this Act [see Short Title note set out below] shall take effect at the close of the date of the enactment of this Act [Oct. 21, 1972], provided if regulations are necessary for the implementation of any provision that becomes effective on the date of enactment, such regulations shall be promulgated and shall become effective within 90 days from the date of enactment of this Act.

“(b) The provisions of the Federal Insecticide, Fungicide, and Rodenticide Act [this subchapter] and the regulations thereunder as such existed prior to the enactment of this Act shall remain in effect until superseded by the amendments made by this Act and regulations thereunder.

“(c)(1) Two years after the enactment of this Act the Administrator shall have promulgated regulations providing for the registration and classification of pesticides under the provisions of this Act and thereafter shall register all new applications under such provisions.

“(2) Any requirements that a pesticide be registered for use only by a certified applicator shall not be effective until five years from the date of enactment of this Act.

“(3) A period of five years from date of enactment shall be provided for certification of applicators.

“(A) One year after the enactment of this Act the Administrator shall have prescribed the standards for the certification of applicators.

“(B) Each State desiring to certify applicators shall submit a State plan to the Administrator for the purpose provided by section 4(b).

“(C) As promptly as possible but in no event more than one year after submission of a State plan, the Administrator shall approve the State plan or disapprove it and indicate the reasons for disapproval. Consideration of plans resubmitted by States shall be expedited.

“(4) One year after the enactment of this Act the Administrator shall have promulgated and shall make effective regulations relating to the registration of establishments, permits for experimental use, and the keeping of books and records under the provisions of this Act.

“(d) No person shall be subject to any criminal or civil penalty imposed by the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by this Act, for any act (or failure to act) occurring before the expiration of 60 days after the Administrator has published effective regulations in the Federal Register and taken such other action as may be necessary to permit compliance with the provisions under which the penalty is to be imposed.

“(e) For purposes of determining any criminal or civil penalty or liability to any third person in respect of any act or omission occurring before the expiration of the periods referred to in this section, the Federal Insecticide, Fungicide, and Rodenticide Act shall be treated as continuing in effect as if this Act had not been enacted.”

SHORT TITLE OF 2012 AMENDMENT

Pub. L. 112-177, § 1, Sept. 28, 2012, 126 Stat. 1327, provided that: “This Act [amending sections 136a-1 and 136w-8 of this title and section 346a of Title 21, Food and Drugs, and enacting provisions set out as notes under section 136a-1 of this title] may be cited as the ‘Pesticide Registration Improvement Extension Act of 2012.’”

SHORT TITLE OF 2007 AMENDMENT

Pub. L. 110-94, § 1, Oct. 9, 2007, 121 Stat. 1000, provided that: “This Act [amending sections 136a, 136a-1, and 136w-8 of this title and section 346a of Title 21, Food and Drugs, and enacting provisions set out as a note under section 136a of this title] may be cited as the ‘Pesticide Registration Improvement Renewal Act.’”

SHORT TITLE OF 2004 AMENDMENT

Pub. L. 108-199, div. G, title V, § 501(a), Jan. 23, 2004, 118 Stat. 419, provided that: “This section [enacting section 136w-8 of this title, amending sections 136a, 136a-1, 136x, and 136y of this title, and enacting provisions set out as notes under section 136a of this title and section 346a of Title 21, Food and Drugs] may be cited as the ‘Pesticide Registration Improvement Act of 2003.’”

SHORT TITLE OF 1996 AMENDMENT

Pub. L. 104-170, § 1, Aug. 3, 1996, 110 Stat. 1489, provided that: “This Act [enacting sections 136i-2, 136r-1, and 136w-5 to 136w-7 of this title, amending this section, sections 136a, 136a-1, 136d, 136q, 136s, 136w, 136w-3,

136x, and 136y of this title, and sections 321, 331, 333, 342, and 346a of Title 21, Food and Drugs, and enacting provisions set out as notes under section 136i-2 of this title and sections 301 and 346a of Title 21] may be cited as the 'Food Quality Protection Act of 1996.'"

[Another Food Quality Protection Act of 1996 was enacted by Pub. L. 104-170, title IV, 110 Stat. 1513, see section 401(a) of Pub. L. 104-170, set out as a note under section 301 of Title 21, Food and Drugs.]

SHORT TITLE OF 1988 AMENDMENT

Pub. L. 100-532, §1(a), Oct. 25, 1988, 102 Stat. 2654, provided that: "This Act [enacting section 136a-1 of this title, amending this section and sections 136a to 136d, 136f to 136g, 136s, 136v to 136w-2, and 136y of this title, and enacting provisions set out as notes under this section and sections 136m and 136y of this title] may be cited as the 'Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988.'"

SHORT TITLE OF 1978 AMENDMENT

Pub. L. 95-396, §29, Sept. 30, 1978, 92 Stat. 842, provided that: "This Act [enacting sections 136w-1 to 136w-4 of this title, amending this section and sections 136a to 136f, 136h, 136j, 136l, 136o, 136q, 136r, 136u to 136w, 136x, and 136y of this title, enacting provisions set out as notes under sections 136a, 136o, and 136w-4 of this title, and amending provisions set out as a note under this section] may be cited as the 'Federal Pesticide Act of 1978.'"

SHORT TITLE

Pub. L. 92-516, §1, Oct. 21, 1972, 86 Stat. 973, provided: "That this Act [amending this subchapter generally, enacting notes set out under this section, and amending sections 1261 and 1471 of Title 15, Commerce and Trade, and sections 321 and 346a of Title 21, Foods and Drugs] may be cited as the 'Federal Environmental Pesticide Control Act of 1972.'"

Act June 25, 1947, ch. 125, §1(a), as added by Pub. L. 92-516, §2, Oct. 21, 1972, 86 Stat. 973, provided that: "This Act [enacting this subchapter] may be cited as the 'Federal Insecticide, Fungicide, and Rodenticide Act.'"

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

FEDERAL COMPLIANCE WITH POLLUTION CONTROL STANDARDS

For provisions relating to the responsibility of the head of each Executive agency for compliance with applicable pollution control standards, see Ex. Ord. No. 12088, Oct. 13, 1978, 43 F.R. 47707, set out as a note under section 4321 of Title 42, The Public Health and Welfare.

§ 136a. Registration of pesticides

(a) Requirement of registration

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

(b) Exemptions

A pesticide which is not registered with the Administrator may be transferred if—

(1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or

(2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

(c) Procedure for registration

(1) Statement required

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

(D) the complete formula of the pesticide;

(E) a request that the pesticide be classified for general use or for restricted use, or for both; and

(F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) With respect to pesticides containing active ingredients that are initially registered under this subchapter after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide, except that such permission shall not be required in the case of defensive data.

(ii) The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after August 3, 1996, and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that—

(I) there are insufficient efficacious alternative registered pesticides available for the use;

(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;