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- 152.500 Requirements for devices.
- AUTHORITY: 7 U.S.C. 136-136y; Subpart U is also issued under 31 U.S.C. 9701.

Subpart A—General Provisions

SOURCE: 53 FR 15975, May 4, 1988, unless otherwise noted.

§ 152.1 Scope.

Except as provided in part 174, part 152 sets forth procedures, requirements, and criteria concerning the registration and reregistration of pesticide products under FIFRA sec. 3, and for associated regulatory activities affecting registration. These latter regulatory activities include data compensation and exclusive use (subpart E), and the classification of pesticide uses (subpart I). Part 152 also sets forth procedures, requirements, and criteria applicable to plant-incorporated protectants. Unless specifically superceded by part 174, the regulations in part 152 apply to plant-incorporated protectants.

[66 FR 37814, July 19, 2001]

§ 152.3 Definitions.

Terms used in this part have the same meaning as in the Act. In addition, the following terms have the meanings set forth in this section.

Act or *FIFRA* means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136-136y).

Active ingredient means any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant within the meaning of FIFRA sec. 2(a), except as provided in §174.3 of this chapter.

Acute dermal LD₅₀ means a statistically derived estimate of the single dermal dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

Acute inhalation LC₅₀ means a statistically derived estimate of the concentration of a substance that would cause 50 percent mortality to the test population under specified conditions.

Acute oral LD₅₀ means a statistically derived estimate of the single oral dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

Administrator means the Administrator of the United States Environmental Protection Agency or his delegate.

Agency means the United States Environmental Protection Agency (EPA), unless otherwise specified.

Applicant means a person who applies for a registration, amended registration, or reregistration, under FIFRA sec. 3.

Biological control agent means any living organism applied to or introduced into the environment that is intended to function as a pesticide against another organism declared to be a pest by the Administrator.

Distribute or sell and other grammatical variations of the term such as “distributed or sold” and “distribution or sale,” means the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any State.

End use product means a pesticide product whose labeling

(1) Includes directions for use of the product (as distributed or sold, or after

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combination by the user with other substances) for controlling pests or defoliating, desiccating, or regulating the growth of plants, and

(2) Does not state that the product may be used to manufacture or formulate other pesticide products.

Final printed labeling means the label or labeling of the product when distributed or sold. Final printed labeling does not include the package of the product, unless the labeling is an integral part of the package.

Genetic material necessary for the production means both: Genetic material that encodes a substance or leads to the production of a substance, and regulatory regions. It does not include noncoding, nonexpressed nucleotide sequences.

In a living plant means inside the living plant, on the surface of the living plant, or as an exudate from the living plant.

Inert ingredient means any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product, except as provided by §174.3 of this chapter.

Institutional use means any application of a pesticide in or around any property or facility that functions to provide a service to the general public or to public or private organizations, including but not limited to:

- (1) Hospitals and nursing homes.
- (2) Schools other than preschools and day care facilities.
- (3) Museums and libraries.
- (4) Sports facilities.
- (5) Office buildings.

Living plant means a plant, plant organ, or plant part that is alive, viable, or dormant. Examples of plant parts include, but are not limited to, seeds, fruits, leaves, roots, stems, flowers, and pollen.

Manufacturing use product means any pesticide product that is not an end-use product.

New use, when used with respect to a product containing a particular active ingredient, means:

- (1) Any proposed use pattern that would require the establishment of, the increase in, or the exemption from the requirement of, a tolerance or food ad-

ditive regulation under section 408 or 409 of the Federal Food, Drug and Cosmetic Act;

(2) Any aquatic, terrestrial, outdoor, or forestry use pattern, if no product containing the active ingredient is currently registered for that use pattern; or

(3) Any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms.

Noncoding, nonexpressed nucleotide sequences means the nucleotide sequences are not transcribed and are not involved in gene expression. Examples of noncoding, nonexpressed nucleotide sequences include, but are not limited to, linkers, adapters, homopolymers, and sequences of restriction enzyme recognition sites.

Operated by the same producer, when used with respect to two establishments, means that each such establishment is either owned by, or leased for operation by and under the control of, the same person. The term does not include establishments owned or operated by different persons, regardless of contractual agreement between such persons.

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.

Pesticidal substance, when referring to a plant-incorporated protectant only, means a substance that is intended to be produced and used in a living plant, or in the produce thereof, for a pesticidal purpose during any part of a plant's life cycle (e.g., in the embryo, seed, seedling, mature plant).

Pesticide means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, other than any article that:

- (1) Is a new animal drug under FDCA sec. 201(w), or

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(2) Is an animal drug that has been determined by regulation of the Secretary of Health and Human Services not to be a new animal drug, or

(3) Is an animal feed under FFDCA sec. 201(x) that bears or contains any substances described by paragraph (s) (1) or (2) of this section.

Pesticide product means a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold. The term includes any physical apparatus used to deliver or apply the pesticide if distributed or sold with the pesticide.

Plant-incorporated protectant means a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance. It also includes any inert ingredient contained in the plant, or produce thereof.

Produce thereof, when referring to plant-incorporated protectants only, means a product of a living plant containing a plant-incorporated protectant, where the pesticidal substance is intended to serve a pesticidal purpose after the product has been separated from the living plant. Examples of such products include, but are not limited to, agricultural produce, grains, and lumber. Products such as raw agricultural commodities bearing pesticide chemical residues are not “produce thereof” when the residues are not intended to serve a pesticidal purpose in the produce.

Regulatory region means genetic material that controls the expression of the genetic material that encodes a pesticidal substance or leads to the production of a pesticidal substance. Examples of regulatory regions include, but are not limited to, promoters, enhancers, and terminators.

Residential use means use of a pesticide directly:

(1) On humans or pets,

(2) In, on, or around any structure, vehicle, article, surface, or area associated with the household, including but not limited to areas such as non-agricultural outbuildings, non-commercial greenhouses, pleasure boats and recreational vehicles, or

(3) In any preschool or day care facility.

[53 FR 15975, May 4, 1988, as amended at 66 FR 37814, July 19, 2001]

§ 152.5 Pests.

An organism is declared to be a pest under circumstances that make it deleterious to man or the environment, if it is:

(a) Any vertebrate animal other than man;

(b) Any invertebrate animal, including but not limited to, any insect, other arthropod, nematode, or mollusk such as a slug and snail, but excluding any internal parasite of living man or other living animals;

(c) Any plant growing where not wanted, including any moss, alga, liverwort, or other plant of any higher order, and any plant part such as a root; or

(d) Any fungus, bacterium, virus, or other microorganisms, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs (as defined in FFDCA sec. 201(g)(1)) and cosmetics (as defined in FFDCA sec. 201(i)).

§ 152.6 Substances excluded from regulation by FIFRA.

Products and substances listed in this section are excluded from FIFRA regulation if they meet the specified conditions or criteria.

(a) *Liquid chemical sterilants*. A liquid chemical sterilant product is not a pesticide under section 2(u) of FIFRA if it meets all of the following criteria. Excluded products are regulated by the Food and Drug Administration (FDA). Products excluded are those meeting all of the following criteria:

(1) *Composition*. The product must be in liquid form as sold or distributed. Pressurized gases or products in dry or semi-solid form are not excluded by this provision. Ethylene oxide products are not liquid products and are not excluded by this provision.

(2) *Claims*. The product must bear a sterilant claim, or a sterilant plus subordinate level disinfection claim. Products that bear antimicrobial claims solely at a level less than “sterilant”