

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 FFDCA sec. 201(w), or
- (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.

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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" are not excluded and are jointly regulated by EPA and FDA. "Sterilant" is defined in §156.441 of this chapter.

(3) *Use site.* (i) The product must be intended and labeled only for use on "critical or semi-critical devices." A "critical device" is 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. A *semi-critical device* is 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.

(ii) Liquid chemical sterilants that bear claims solely for use on non-critical medical devices are jointly regulated by EPA and FDA.

(iii) Liquid chemical sterilants that bear claims solely for use on sites that are not medical devices, such as veterinary equipment, are not excluded and are regulated solely by EPA.

(b) *Nitrogen stabilizers.* A nitrogen stabilizer is excluded from regulation under FIFRA if it is a substance (or mixture of substances), meeting all of the following criteria:

(1) The substance prevents or hinders the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria and is distributed and sold solely for those purposes and no other pesticidal purposes. For purposes of this section, living organisms are not considered to be substances, and the actions of living organisms are not relevant to whether a substance is deemed to be a nitrogen stabilizer.

(2) The substance was in "commercial agronomic use" in the United States before January 1, 1992. EPA considers a substance to be in commercial agronomic use if it is available for sale or distribution to users for direct agronomic benefit, as opposed to limited research, experimental or demonstration use.

(3) The substance was not registered under FIFRA before January 1, 1992.

(4) Since January 1, 1992, the distributor or seller has made no claim that the product prevents or hinders the process of nitrification, denitrification, ammonia volatilization or urease production. EPA considers any of the following claims (or their equivalents) to be a claim that the product prevents or hinders nitrification, denitrification, ammonia volatilization or urease production:

(i) Improves crop utilization of applied nitrogen.

(ii) Reduces leaching of applied nitrogen or reduces groundwater nitrogen contamination.

(iii) Prevents nitrogen loss.

(iv) Prolongs availability of nitrogen.

(v) Increases nitrogen uptake, availability, usage, or efficiency.

(5) A product will be considered to have met the criterion of paragraph (b)(4) of this section that no nitrogen stabilization claim has been made if:

(i) The nitrogen stabilization claim, in whatever terms expressed, is made solely in compliance with a State requirement to include the claim in materials required to be submitted to a State legislative or regulatory authority, or in the labeling or other literature accompanying the product; and

(ii) The State requirement to include the claim was in effect both before the