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# Label Review Manual

## Chapter 2: What Is a Pesticide?

National Garden Bureau





## I. Introduction

This chapter discusses the statutory and regulatory criteria used to determine whether or not a product is a pesticide requiring registration under FIFRA. Relevant FIFRA definitions are found in section 2 of the statute and the applicable regulations are at [40 CFR Part 152, Subparts A and B](#). Label reviewers should use the statute and regulations when evaluating the “pesticide” status of products or potential products. It is acceptable to discuss whether hypothetical products are pesticides with anyone, including state enforcement personnel, registrants, applicants or the general public. Whether or not a particular product that is the subject of an application is a pesticide under FIFRA must be treated confidentially through applicable CBI protections. A final decision about the pesticide status of a particular product must be made in writing to the applicant or registrant and should be in response to a written request for an Agency determination, which includes proposed labeling and the composition of the product.

As discussed in detail below, there are a number of types of products that the Agency has determined are not pesticides and others that the Agency has exempted from regulation even though they are pesticides. If a label reviewer determines that a product is a pesticide, the label reviewer should consider whether the pesticide has been exempted from the FIFRA registration requirements.

If the label reviewer determines that the product is not a pesticide, the label reviewer must consider whether the product is a device. The last section of this chapter addresses this topic.

## II. Products that are *not* pesticides

Some substances and products may be excluded from FIFRA registration if they meet certain conditions or criteria. [40 CFR 152.6](#) sets out the following types of products that fall into this category.

### 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. See [40 CFR 152.6\(a\)](#). 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 from regulation under FIFRA. Ethylene oxide products are not liquid products and are therefore 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.



**3. Use site**

- ▶ 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.
- ▶ Liquid chemical sterilants that bear claims solely for use on non-critical medical devices are jointly regulated by EPA and FDA, and must be registered by EPA.
- ▶ 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.
- ▶ Liquid chemical sterilants intended to treat aseptic food packaging systems are also not excluded from FIFRA; these products are subject to registration by EPA as pesticides as well as approval by FDA as food additives.

**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 found in [40 CFR 152.6\(b\)](#):

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 [40 CFR 152.6](#) 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. See [40 CFR 152.6\(b\)\(4\) and \(5\)](#) to learn what EPA considers to be a claim that the product prevents or hinders nitrification, denitrification, ammonia volatilization or urease production and for further information on this topic.

**C. Products Labeled Only for Use in or on Living Man or Animals**

Products excluded are those meeting one of the following criteria:

1. Products intended for use for the control of fungi, bacteria, viruses, or other microorganisms in or on living humans or animals, and labeled accordingly. See [40 CFR 152.6\(c\) and \(d\)](#). Such products include, for example: Athlete’s foot remedies, dandruff medications, aquaculture and aquarium additives for treatment of fish diseases, and dermal disinfectants. Note: These exceptions apply only to antimicrobials (fungicides, disinfectants, viricides, etc.). Insecticides (pesticides that kill insects as opposed to microbes) are not included in the “living body” exception. Thus, products such as mosquito repellents, flea and tick remedies for pets, and other insecticides) used directly on the living body of humans, pets, and livestock have historically been considered to be pesticides and are required to be registered. Note that contact lens solutions that disinfect the lens in the contact lens holder are exempt from federal registration under FIFRA through an agreement with the Food and Drug Administration. An animal feed containing an animal drug is not a pesticide under [section 2\(u\) of FIFRA](#). See also [40 CFR 152.6\(e\)](#). An animal feed containing an animal drug is subject to regulation by the FDA under the FFDCa.
2. Products intended for use for control of internal invertebrate parasites or nematodes in living humans or animals, and labeled accordingly. See [40 CFR 152.5\(b\)](#).

**D. Products Intended Only to Aid in the Growth of Desirable Plants**

As an initial matter, it is important to note that there is an important distinction between *plant nutrients*, which may be exempt from registration, and *plant regulators*, which require registration (and are defined in [FIFRA at 2\(v\)](#)), and in Section III. D. of this chapter. Plant nutrients are described below.

Examples of products that aid in the growth of desirable plants, types of which are found in [40 CFR 152.6\(g\)](#), include:

1. **Plant or leaf coatings** designed to protect against frost or to retard water loss through transpiration. These types of products are usually glycerol-based. Similar products are sometimes sold as cut-flower preservatives. As long as plant disease or plant regulator claims are not made for the product and its composition is not such that pesticide benefits would be delivered, registration has historically not been required.
2. **Products sold as vase water additives for cut flowers**, although such products bear special scrutiny. If they are composed, as many are, of simple sugars intended to supply nourishment to the cut flower, they are likely not under the purview of FIFRA. Historically, however, products with claims to prevent bacterial or fungal growth in the vase water, claims such as “delays flower opening”, claims to control stem rot or decay or products with chemicals that only have pesticidal uses have been subject to FIFRA registration.
3. **Food washing products** that do not claim to remove bacteria such as *e-coli* or salmonella.

4. **Fertilizer products not containing a pesticide**, such as sphagnum moss used as plant growth media to retard damping-off.
5. **Plant inoculant products** consisting of microorganisms applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system. See *40 CFR 152.6(g)(2)*.
6. **Soil amendment (e.g., vermiculite, sand, lime) products** containing a substance or substances added to the soil for the purpose of improving soil characteristics favorable for plant growth. See *40 CFR 152.6(g)(3)*. Soil amendments are intended to increase porosity, retain moisture, adjust pH, and other uses intended to benefit crop production. For example, although normally considered to be a fungicide or miticide, products containing sulfur when applied to soil to solely adjust the pH have historically not been subject to registration. Sulfur may also have non-pesticidal uses as a foliar plant nutrient at low concentrations.
7. **Plant nutrient products** consisting of one or more macronutrients or micronutrient trace elements necessary to normal growth of plants and in a form readily useable by plants. See *40 CFR 152.6(g)(1)*.

**E. Antimicrobial Products Used Solely in Processed Foods or Feeds, in Beverages, or in Pharmaceuticals**

The Antimicrobial Regulation Technical Correction of 1998 (ARTCA) amended the Food Quality Protection Act (FQPA) to clarify the jurisdictions of EPA and FDA regarding food use antimicrobial pesticides. Following is a brief summary of ARTCA's jurisdictional clarifications. For further details, see FDA's July 1999 "Antimicrobial Food Additives Guidance Document" at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm077256.htm>.

The following activities constitute food processing and any food subjected to these activities becomes a "processed food" within the meaning of 40 CFR 152.5 (definition of a pest): canning, freezing, cooking, pasteurization, or homogenization, irradiation, milling, grinding, chopping, skinning, cutting or peeling. Processing also includes carcasses post-slaughter which includes skinning, eviscerating and quartering. These post-slaughter activities result in "processed food" within the meaning of 40 CFR 152.5. In addition, seafood that is harvested is processed food. Activities done post-harvest to seafood include handling, storing, preparing, heating, eviscerating, shucking or holding. Substances used in these processes against microbes in or on the processed food are not pesticides under FIFRA and are regulated solely by the FDA under the FFDCFA.

**The following post-harvest activities do not constitute food processing within the meaning of 40 CFR 152.5: washing, coloring, waxing, hydro-cooling, refrigeration, shelling of nuts, ginning of cotton, and the removal of leaves, stems and husks. These processes do not meet the definition of “processed food” and are not subject to the exclusions of 40 CFR 152.5. Therefore, pesticides used during the processes are FIFRA pesticides and are regulated by EPA under FIFRA.F. Products with No Pesticidal Claims**

Products that are not intended to prevent, destroy, repel, or mitigate a pest, or to defoliate, desiccate, or regulate the growth of plants are not considered to be pesticides. Some of these products may appear to be pesticides, but are not considered as such unless pesticidal claims are made on their labeling or in connection with their sale and distribution. [40 CFR 152.10](#) lists products which fall under this category.

1. **Deodorizers, bleaches, and cleaning agents.** OPP has treated products bearing claims for sanitizing or disinfecting properties as pesticides requiring registration. For example, a bleach which consists of 5.25% sodium hypochlorite would likely require registration if the label states that bacteria will be killed at certain doses. An identical bleach would not likely need to be registered if the labeling only claims to whiten, bleach or clean laundry, and does not contain an explicit or implicit antimicrobial claim.

EPA has also posted guidance on its web page entitled, “Determining If a Cleaning Product is a Pesticide under FIFRA” (<http://www.epa.gov/pesticides/factsheets/pest-habitat-claims.html>). This document provides details on what kinds of cleaning-related claims may be considered pesticidal versus non-pesticidal.

2. **Attractants.** Products that are intended only to attract pests for survey or detection purpose, that are labeled accordingly, and which contain no toxicants.
3. **Physical barrier.** Products that are intended to exclude pests only by providing a physical barrier against pest access, and which contain no toxicants. Examples might include: pruning for trees; latex or asphalt tree wound dressings that make claims of preventing the entrance of insects or fungi into fresh cut surfaces of plants; cocoa bark or pine bark mulches that claim suppression of weed growth; black plastic or tar-paper used to suppress weeds or prevent the entrance of insects.

### III. What makes a product a pesticide?

The term “pesticide” is defined at [FIFRA 2\(u\)](#). One of the most important words in the FIFRA definition of “pesticide” is “intended.” One of the analytical steps to determining whether a product is a pesticide is to consider whether the product is “intended” to be used as a pesticide. Products are generally considered to be pesticides if they are *intended* for preventing, destroying, repelling, or mitigating any pest or *intended* for use as a plant regulator, defoliant, or desiccant. OPP determines **intent** by examining claims on the label, advertising, composition/use, and/or mode of action of the product as distributed or sold. Section [40 CFR 152.15](#) sets forth the criteria

to help establish intent. If the regulatory criteria are met the label reviewer can conclude that the product is a pesticide and must be registered. The regulatory criteria are described below:

**A. Claims**

If a person who distributes or sells the product claims, states or implies by labeling or otherwise (such as, advertising, collateral literature, or verbal statements), that the product can or should be used as a pesticide or that the product contains an active ingredient and that it can be used to manufacture a pesticide, then the product is a pesticide. *40 CFR 152.15(a)*.

**B. Composition**

If a product is composed of one or more active ingredients that have no other significant, commercially valuable use other than for a pesticidal purpose or for use in manufacturing a pesticide then the product historically has been considered to be a pesticide. *40 CFR 152.15(b)*. For example, a company markets a granular product that has labeling identifying the presence of 2,4-D, directions to apply it to lawns at a certain dosage rate, and warns the user about over-application, but does not claim that broad-leaved weeds will be killed, is the product a pesticide? Most likely, the product is a pesticide because 2,4-D is a well-known herbicide and has no other significant commercially valuable use.

**C. Knowledge that the Substances Will Be Used as a Pesticide**

Even if pesticidal claims are not made for the product, if the person who distributes or sells the substance has actual or constructive knowledge that the substances will be used, or is intended to be used, for a pesticidal purpose, the product is a pesticide product required to be registered. *40 CFR 152.15(c)*.

**D. Plant Growth Regulators**

A plant growth regulator, through physiological action, is intended to accelerate or retard growth, or alter plant behavior or the produce of the plant. Examples of claims that can be considered to be plant growth regulator claims include: increased blossom set, stimulation of root or plant growth, prevention of sucker growth, delayed onset of sprouting of harvested root crops, abscission stimulation of fruit crops, stimulates plant growth and fruiting, promotes fruit and seed development, increases stem and stalk strength, and increases fruit size. Whether a product is considered to be a plant growth regulator depends on whether the plant response or mode of action being claimed would go beyond what would be expected from simple nutrition. The composition of the product may aid in making the determination.

1. **Plant hormones and other compounds**, such as auxins, cytokinins, and gibberellins have no other uses except as plant growth regulators. Therefore, the presence of any of these types of compounds generally causes a product to be considered a plant growth regulator.
2. **A vitamin-hormone horticulture product** is not a plant growth regulator if the product is not intended for use on food crops and is labeled accordingly, and meets the other



criteria 40 CFR 152.6(f). Vitamin-hormone horticulture products containing auxins, cytokinins, and gibberellins are exempt from registration if these criteria are met.

## IV. Pesticides exempted from the requirements of FIFRA

The Agency has exempted certain pesticides from regulation under FIFRA under the authority of [FIFRA 25\(b\)](#) because the pesticides have been determined to be (1) adequately regulated by another Federal agency or (2) of a character which is unnecessary to be subject to FIFRA. Just because a pesticide is exempted under FIFRA, however, does not mean that the Federal Food, Drug and Cosmetic Act (FFDCA) or state laws may not apply. For example, even if a pesticide product meets the conditions for exemption from regulation under FIFRA, it might still be subject to FFDCA requirements to have a tolerance or tolerance exemption if there is a pesticide chemical residue on food. The following are examples of products exempted from FIFRA under 25(b):

### A. Pesticides Regulated By Another Federal Agency

1. **Certain Biological Control Agents.** Biological control agents are generally exempt from FIFRA regulation. [40 CFR 152.20\(a\)](#). However, the Agency has determined ([40 CFR 152.20\(a\)\(3\)](#)) that the following biological control agents are *not exempt* and are subject to FIFRA.
  - (a) Eucaryotic microorganisms, including protozoa, algae, and fungi;
  - (b) Procaryotic microorganisms, including bacteria; and
  - (c) Viruses.

### B. Pesticide Not of a Character Requiring FIFRA Regulation

1. **Treated Articles or Substances.** The Agency has determined that an article or substance containing a pesticide to protect the article or substance itself does not require registration and is exempt from all provisions of FIFRA, provided the pesticide is registered for such use and bears appropriate directions for such use. Claims for the preserved article or substance are limited to the protection of the article or substance itself. See [40 CFR 152.25\(a\)](#) and [PR Notice 2000-1](#). Examples include:
  - (a) Paints that have been treated with antimicrobial pesticides and bear claims that the dried paint film will be resistant to mold or mildew. Paints with expressed or implied claims made for protection of the surface beneath the paint film or for preventing or destroying mold or mildew on the surface of the paint or beneath the paint are not within the treated articles exemption and, therefore, will require registration under FIFRA. Paints that are to be used in canneries, breweries, hospitals, or other areas where a crucial consideration is prevention of bacteria or

mold that would pose a health risk are generally not subject to the treated articles exemption and, therefore, are regulated under FIFRA.

- (b) Shower curtains treated with a fungicide to retard mildew growth; lumber treated with a wood preservative; bathroom caulks impregnated with a mildewcide; and fabrics and leather treated with preservative compounds (all of which uses are intended to protect the treated articles themselves) are other examples of products that have been historically exempted from the requirements of FIFRA.
- (c) Shirts and other articles of clothing treated with an insecticide to repel mosquitoes and other insect pests are examples of products treated with insecticides that require registration of the article of clothing. Because the treatment would be for the benefit of the wearer rather than to protect the clothing, the treated article exemption would not apply and the article of clothing would be subject to registration.

## 2. Pheromones and Pheromone Traps

Pheromones and identical or substantially similar compounds labeled for use only in pheromone traps (or labeled for use in a manner which the Administrator determines poses no greater risk of adverse effects on the environment than use in pheromone traps), and pheromone traps in which those compounds are the sole active ingredient are not subject to FIFRA regulation. Refer to [40 CFR 152.25\(b\)\(1\), \(b\)\(2\), and \(b\)\(3\)](#) to determine whether a substance is a pheromone for purposes of this exemption. Refer to [40 CFR 152.25\(b\)\(4\)](#) to determine whether the pheromone trap falls within the exemption. Pheromones are chemicals used in intra-species communication. A chemical used in inter-species communication (i.e., using fox urine to repel rabbits) is an “allomone” and would be subject to FIFRA.

## 3. Preservatives for Biological Specimens

- (a) Embalming Fluids. Mortuary supplies intended to prevent or mitigate mold and bacteria on or in human cadavers are exempt. [40 CFR 152.25 \(c\)\(3\)](#). The rationale for this exemption is that the use is limited to embalmers and morticians who are specially trained to handle such products and do not require the protection afforded by registration. The general public would not be exposed to such products.
- (b) Animal and animal organ preservatives. Products used to preserve animal or animal organ specimens in mortuaries, laboratories, hospitals, museums, and institutions of learning are exempt. [40 CFR 152.25\(c\)\(2\)](#).
- (c) Preservatives for Laboratory Analysis. Products used to preserve the integrity of milk, urine, blood, or other bodily fluids for laboratory analysis are exempt. [40 CFR 152.25\(3\)](#).

- 3. **Foods.** Products consisting of foods and containing no active ingredients, which are used to attract pests, are exempt. [40 CFR 152.25\(d\)](#).

4. **Natural Cedar.** Natural cedar blocks, chips, shavings, balls, chests, drawer liners, paneling, and needles that meet all of the following criteria:
  - (a) The product consists totally of cedarwood or natural cedar;
  - (b) The product is not treated, combined or impregnated with any additional substance(s); and
  - (c) The product bears claims or directions for use solely to repel arthropods other than ticks or to retard mildew, and no additional claims are made in sale or distribution. The labeling must be limited to specific arthropods, or must exclude ticks if any general term such as “arthropods”, “insects,” “bugs,” or any other broad inclusive term, is used. The exemption does not apply to natural cedar products claimed to repel ticks. The exemption does not apply to cedar oil, or formulated products which contain cedar oil, other cedar extracts, or ground cedar wood as part of a mixture. [40 CFR 152.25\(e\)](#).
  
5. **Minimum Risk Pesticides.** 40 CFR Section 152.25(f) (previously 40 CFR 152.25(g)) exempts certain “minimum risk pesticides” from the requirements of FIFRA if they satisfy all the conditions described in that provision (i.e., 152.25(f)(1)-(3)). Some of the conditions of exemption specifically relate to a product’s labeling (see [152.25\(f\)\(3\)](#)). For further information, [PRN 2000-6](#): “Minimum Risk Pesticides Exempted under FIFRA Section 25(b) Clarification of Issues”. See also EPA’s webpage for Minimum Risk Pesticides [http://www.epa.gov/pesticides/biopesticides/regtools/25b\\_list.htm](http://www.epa.gov/pesticides/biopesticides/regtools/25b_list.htm) and the list of permissible inerts <http://www.epa.gov/pesticides/biopesticides/regtools/25b/25b-inerts.htm>

## V. Is the product a device and, therefore, not a pesticide?

FIFRA defines a device 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 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” [FIFRA 2\(h\)](#). FIFRA does not require the registration of pesticidal devices. Devices, however, are subject to a number of FIFRA’s provisions including, labeling requirements and establishment number identifying the location where the device was produced. See [40 CFR 152.500](#) and Chapter 13 of EPA’s Pesticide Registration Manual (<http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>) for more information on devices and additional FIFRA requirements.

Equipment that generates a pesticide (e.g., a CO<sub>2</sub> or ozone generator) may or may not be considered a device. The reviewer should consult with the PM if there is any question about the product's status.