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Label Review Manual

Chapter 2: What is a Pesticide?



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What's changed in this version?

- Updated cover page.
- Added *Table of Contents*.
- Added *What's changed in this version?* section.
- Editorial changes to improve readability and remove redundancies.
- Updated hyperlinks and removed outdated references.
- Revised the section header "*What makes a product a pesticide?*" to "*What is a pesticide?*" and moved to Section II.
- *Products that are not pesticides* section moved to Section III.
- Clarified term "plant regulator."
- Added explanatory text and updated Section III.E on determining whether food commodities that have undergone dehydration processing activities are considered "processed food."
- Updated Section V. 'Is the product a device?'

I. Introduction

This chapter discusses the statutory and regulatory criteria used to determine if a product is a pesticide under FIFRA. Section 2 of FIFRA contains the relevant definitions, and the applicable regulations are found in [40 CFR Part 152](#), Subparts A and B. If a product is determined to be a pesticide, then the label reviewer should consider whether the pesticide has been exempted from FIFRA registration requirements. If the product is *not* a pesticide, the label reviewer must then consider whether the product is a “device,” which is discussed in brief in the last section of this chapter and in further detail in [Chapter 13](#) of the Pesticide Registration Manual. Under FIFRA, a determination as to whether a product is considered a pesticide, or a device must be treated confidentially through applicable confidential business information (CBI) protections. Registrants may submit a formal request for a device determination to EPA using PRIA code [M009](#), if they are unsure whether their product qualifies as a pesticide or a device, and whether it would be subject to FIFRA regulation.

II. What is a pesticide?

A “pesticide” is 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. See [FIFRA 2\(u\)](#). A “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; including any accompanying physical apparatus used to deliver or apply the pesticide. See [40 CFR 152.3](#). The criteria for determining whether a product is *intended* as a pesticide that may require EPA registration are described below. See [40 CFR 152.15](#).

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 considered a pesticide [40 CFR 152.15\(a\)](#).

B. Composition

Even in the absence of an expressed claim, if a product is composed of one or more active ingredients and has no other significant commercially valuable use other than (1) for a pesticidal purpose or (2) for use in manufacturing a pesticide, then the product is considered a pesticide. See [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 broadleaf 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

If the person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose, then the substance is a pesticide product under [40 CFR 152.15\(c\)](#).

D. Plant regulators

A plant regulator, through physiological action, is intended to accelerate or retard growth, accelerate or retard maturation, or alter plant behavior or the produce of the plant. See [FIFRA 2\(v\)](#). Although “plant regulator” is the term defined in FIFRA, the term “plant growth regulator” is commonly used interchangeably with it. Examples of plant regulator claims include, but are not limited to:

- increased blossom set
- stimulation of root or shoot growth
- prevention of sucker growth
- delayed onset of sprouting of harvested root crops
- abscission of fruit crops
- stimulates plant growth and fruiting
- promotes fruit and seed development
- increases fruit size

Whether a product is considered a plant 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 is considered when making the determination. See [40 CFR 152.6\(f\)-\(g\)](#).

- Plant hormones and many other growth-promoting and growth-inhibiting substances, such as auxins, cytokinins, and gibberellins have no other uses except as plant regulators. Therefore, the presence of any of these types of compounds generally causes a product to be considered a plant regulator.
- A vitamin-hormone horticulture product is not considered a plant regulator under FIFRA if the product is not intended for use on food crops and is labeled accordingly, and meets the other criteria in [40 CFR 152.6\(f\)](#). Vitamin-hormone horticulture products containing auxins, cytokinins, and gibberellins and any other known plant regulator found naturally in plants are exempt if the [40 CFR 152.6\(f\)](#) criteria are met.

The following types of products are not considered plant regulators:

- Plant nutrient products, consisting of one or more macronutrients or micronutrient trace elements necessary to normal growth in plants and in a form readily usable by plants.
- Plant inoculant products consisting of microorganisms to be applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system.
- Soil amendment products containing a substance or substances intended for the purpose of improving soil characteristics favorable for plant growth.

III. What is *not* a pesticide

Certain 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 [FIFRA 2\(u\)](#) if it meets certain criteria set forth in [40 CFR 152.6\(a\)](#). Instead, they are regulated by the Food and Drug Administration (FDA). See [PR Notice 98-2](#). A product is excluded from FIFRA registration if it meets all the following criteria:

1. Composition

The product must be in liquid form when sold or distributed. Pressurized gases or products in dry or semi-solid form, and ethylene oxide products 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.

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.

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 FIFRA regulation if it is a substance or mixture of substances meeting all of the following criteria (see [40 CFR 152.6\(b\)](#)):

- 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.
- The substance was in “commercial agronomic use” in the United States before January 1, 1992. A substance is considered 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.
- The substance was not registered under FIFRA before January 1, 1992.
- 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 \(5\)](#) for additional criteria.

C. Products labeled only for use in or on living man or animals

A product is excluded from FIFRA registration if it meets any of the following criteria:

- The product is intended and labeled for use for the control of fungi, bacteria,

viruses, or other microorganisms in or on living humans or animals. See [40 CFR 152.6\(c\) and \(d\)](#). Such products include athlete's foot remedies, dandruff medications, aquaculture and aquarium additives for treatment of fish diseases, and dermal disinfectants (including hand sanitizers). However:

- Insects that can be seen without a microscope are not microorganisms, so the living body exemption does not apply to products that target such insects. For example, products such as mosquito repellents, flea and tick remedies for pets, and other insecticides used directly on the living body of humans, pets, or livestock have been considered pesticides and required EPA registration.
 - An animal feed containing an animal drug is not a pesticide under [FIFRA2\(u\)](#). Rather, it is regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA). See [40 CFR 152.6\(e\)](#).
- The product is intended and labeled for use for the control of internal invertebrate parasites or nematodes in living humans or animals. See [40 CFR 152.5\(b\)](#).

D. Products intended only to aid the growth of desirable plants

A product intended only to aid the growth of desirable plants is not a "plant regulator" as defined under [FIFRA 2\(v\)](#) and discussed in Section II.D. above, and is therefore not a pesticide and is exempt from FIFRA registration. See [40 CFR 152.6\(g\)](#). Examples include:

- a) **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\(g\)\(1\)](#). Note that this is different than a *plant regulator* product, which is defined under [FIFRA 2\(v\)](#) as any substance or mixture of substances intended, through physiological action, to speed up or slow down the growth rate or rate of maturation or otherwise alter the behavior of plants or the produce thereof.
- b) **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. Historically, a product is exempt from FIFRA-registration if does not make plant disease or plant regulator claims, and its composition is not such that pesticidal benefits would be delivered.
- c) **Products sold as vase water additives for cut flowers** if they are composed, as

many are, of simple sugars intended to supply nourishment to the cut flowers, are exempt. Historically, however, products are *not* exempt from FIFRA-registration if it claims to prevent bacterial or fungal growth in the vase water, such as “delays flower opening;” claims to control stem rot or decay; or contains chemicals that only have pesticidal uses.

- d) **Food washing products** that do not claim to remove bacteria such as *E. coli* or salmonella.
- e) **Fertilizer products not containing a pesticide**, such as sphagnum moss used as plant growth media to retard damping-off.
- f) **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\(g\)\(2\)](#).
- g) **Soil amendment products** containing a substance or substances (e.g., vermiculite, sand, or lime) intended for the purpose of improving soil characteristics favorable for plant growth. See [40 CFR 152.6\(g\)\(3\)](#). Soil amendment products are intended for use to increase porosity, retain moisture, adjust pH, and other uses to benefit crop production. For example, although sulfur-containing products are normally registered as a fungicide or miticide, historically such products do not require registration when it is applied solely to adjust the pH of the soil. Sulfur may also have other non-pesticidal uses as a foliar plant nutrient at low concentrations.

E. Antimicrobial products used solely in processed foods or feeds, in beverages, or in pharmaceuticals

EPA’s definition of “pest” at [40 CFR 152.5\(d\)](#) makes an exception for fungi, bacteria, viruses, prions, and other microorganisms on or in processed food or processed animal feed, beverages, drugs and cosmetics. So, products intended to control microorganisms in or on processed food, processed animal feed, beverages, drugs and cosmetics are not pesticides.

As defined in [FFDCA 201\(gg\)](#) ([21 U.S.C. 321\(gg\)](#)) and FDA’s guidance document, the following activities constitute food processing and any food subjected to these activities becomes a “processed food” within the meaning of that term in [40 CFR 152.5\(d\)](#): canning, freezing, cooking, homogenization, pasteurization, irradiation, milling, grinding, chopping, skinning, cutting, or peeling.

Food processing also includes post-slaughter activities to carcasses such as skinning, eviscerating, and quartering. These post-slaughter activities result in “processed food”

within the meaning of [40 CFR 152.5\(d\)](#).

Similarly, seafood that is harvested is processed. 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 FFDCa.

The following post-harvest activities are not food processing, therefore, commodities that have been treated by these processes alone remain raw agricultural commodities: washing, coloring, waxing, hydro-cooling, refrigeration, shelling of nuts, ginning of cotton, and removal of leaves, stems, and husks. Pesticides applied to raw agricultural commodities regulated by EPA would require FIFRA registration.

Although products intended to control microorganisms in or on processed food, processed animal feed, beverages, drugs and cosmetics are not pesticides, some antimicrobial products used in the processing or production of these articles are pesticides. For example, antimicrobials used to disinfect equipment but not intended to be applied to the processed food, processed animal feed, beverages, drugs and cosmetics are pesticides subject to FIFRA. Products used to reduce bacterial loading in water used to process food, animal feed, beverages, drugs and cosmetics can be pesticides if the water is not being used to apply the antimicrobials to the processed food, processed animal feed, beverages, drugs and cosmetics.

FIFRA's definition of pest and pesticide do not exactly match the FFDCa definition of "pesticide residue", so some antimicrobial products that require registration may require an FDA food additive clearance instead of a section 408 tolerance/exemption. The Antimicrobial Regulation Technical Correction Act of 1998 (ARTCA) amended the Food Quality Protection Act (FQPA) to clarify the jurisdictions of EPA and FDA regarding residues of antimicrobials in or on food. Post-ARTCA, an antimicrobial pesticide applied on food, or applied to water that comes into contact with food, in the preparing, packing, or holding of the food for commercial purposes requires an FDA food additive clearance, except if:

- It is ethylene oxide or propylene oxide; or
- It is applied on a raw agricultural commodity, or applied in water that comes into contact with the commodity:
 - in the field;
 - at a treatment facility where raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner); or

- during the transportation of such commodity between the field and such a treatment facility.

In addition, an antimicrobial pesticide requires an FDA food additive clearance if it is incorporated in food packaging, or if it is incorporated in food contact objects not but intended to have an ongoing pesticidal effect on the food contact surface.

For further details, see FDA's July 1999 [Guidance for Industry: Antimicrobial Food Additives](#) document.

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 the labeling or in connection with its sale and distribution*. See [40 CFR 152.10](#). Examples of these types of products include:

1. Deodorizers, bleaches, and cleaning agents

Products bearing sanitizing or disinfecting claims generally require FIFRA registration. For example, a bleach product containing 5.25% sodium hypochlorite would require registration if the label states that bacteria will be killed at certain doses. In contrast, a bleach product with the same composition would not need to be registered if the label only claims to whiten, bleach, or clean laundry, and does not contain an explicit or implicit antimicrobial claim. For more information on cleaning-product claims, see EPA's guidance document [Determining If a Cleaning Product Is a Pesticide Under FIFRA](#).

2. Attractants

Products that contain no toxicants, are intended only to attract pests for survey or detection purposes and are labeled accordingly.

3. Physical barrier

Products that contain no toxicants and are intended to exclude pests only by providing a physical barrier against pest access. For example:

- pruning paints to trees
- latex or asphalt tree wound dressings used to prevent insects or fungi from entering freshly cut surfaces
- cocoa bark or pine bark mulches used to suppress weed growth
- black plastic or tar paper used to suppress weeds or prevent insects from entering

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 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 Section 25(b):

A. Pesticides regulated by another federal agency

FIFRA section 25(b) gives EPA the authority to exempt products from regulation if they are adequately regulated by another federal agency, but EPA must exercise this authority through rulemaking. At the present time, only two types of products are exempted:

1. Biological control agents

These are generally exempt from FIFRA regulation with the exception of the following which are *not exempt* and are subject to FIFRA (see [40 CFR 152.20\(a\)](#)):

- Eucaryotic microorganisms, including but not limited to: protozoa, algae, and fungi
- Procaryotic microorganisms, including some bacteria
- Certain viruses

2. Non-liquid chemical sterilants

A non-liquid chemical sterilant, except ethylene oxide, that meets the criteria of [40 CFR 152.6\(a\)\(2\)](#) with respect to its claims and [40 CFR 152.6\(a\)\(3\)](#) with respect to its use sites is exempted from regulation under FIFRA. See [40 CFR 152.20\(b\)](#).

B. Pesticides not requiring FIFRA regulation

1. Treated articles or substances

An article or substance containing a pesticide to protect the article or substance itself from pests 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 an exempt treated 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 of treated articles/substances that could be exempt treated articles:

- Paints that have been treated with antimicrobial pesticides and bear claims that the dried paint film will be resistant to mold or mildew, and paints containing antimicrobial pesticides to protect the paint in the can.

However, paints with expressed or implied claims made for protection of the surface beneath the paint film or destroying mold or mildew on the surface of the paint or beneath the paint are *not* within the treated articles exemption and require FIFRA registration.

Paints manufactured with public health pesticidal claims especially paints that are intended to be used in canneries, breweries, hospitals, or other similar areas generally are *not* within the treated articles exemption and require FIFRA registration.

- Shower curtains treated with a fungicide to retard mildew growth.
- Lumber treated with a wood preservative.
- Bathroom caulks impregnated with a mildewcide.
- Fabrics and leather goods treated with preservative compounds.

Treated articles that are not eligible for the exemption are pesticides and require registration. Shirts and other articles of clothing treated with an insecticide to repel mosquitoes and other insect pests are examples of products that require registration. Because the pesticidal effect is intended to 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 FIFRA 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. See [40 CFR 152.25\(b\)](#). Refer to [40 CFR 152.25\(b\)\(4\)](#) to determine whether the pheromone trap falls within the exemption. Refer to [40 CFR 152.25\(b\)\(1\)-\(3\)](#) to determine whether a substance is a pheromone for purposes of this exemption. Pheromones are chemicals used in intra-species communication. A chemical used in inter-species communication (e.g., using fox urine to repel rabbits) is an “allomone” and would be subject to FIFRA.

3. Preservatives for biological specimens

- **Embalming fluids.** Mortuary supplies intended to prevent or mitigate mold

and bacteria on or in human cadavers are exempt from FIFRA regulation, since its use is limited to embalmers and morticians, who are specially trained to handle such products and do not require the protection afforded by registration, and the general public would not be exposed to such products. See [40 CFR 152.25\(c\)\(3\)](#).

- **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. See [40 CFR 152.25\(c\)\(2\)](#).
- **Preservatives for laboratory analysis.** Products used to preserve the integrity of milk, urine, blood, or other bodily fluids for laboratory analysis are exempt. See [40 CFR 152.25\(3\)](#).

4. Foods

Products consisting of foods which are used to attract pests but do not contain any active ingredients (e.g., food bait on a mouse trap) are exempt. See [40 CFR 152.25\(d\)](#).

5. Natural cedar

Natural cedar blocks, chips, shavings, balls, chests, drawer liners, paneling, and needles that meet all the following criteria are exempt:

- The product consists totally of cedar wood or natural cedar;
- The product is not treated, combined or impregnated with any additional substance(s); and
- The product bears claims or contains 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. See [40 CFR 152.25\(e\)](#).

6. Minimum risk pesticides

Certain “minimum risk pesticides” are exempt from the requirements of FIFRA if they satisfy all the conditions described in [40 CFR 152.25\(f\)\(1\)-\(3\)](#). Products containing the specific active ingredients listed in Table 1 of 40 CFR 152.25(f)(1), either alone or in combination with other substances within the same table, are designated minimum risk pesticides. Additionally, a pesticide product

designated as minimum risk may only include inert ingredients listed in Table 2 of [40 CFR 152.25\(f\)\(2\)](#). Lastly, [152.25\(f\)\(3\)](#) lists other conditions of exemption, including specific labeling requirements. For more information, see EPA's webpage on [Minimum Risk Pesticides](#).

V. Is the product a device?

Pesticidal devices do not require registration, but are subject to certain FIFRA requirements, including some concerning labeling. [FIFRA 2\(h\)](#) 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.” Pesticidal devices regulated under FIFRA include:

- Certain ultraviolet light systems, ozone generators, water filters and air filters (except those containing substances or mixtures of substances which are pesticides), and ultrasonic devices, for which claims are made to kill, inactivate, entrap, or suppress the growth of fungi, bacteria, or viruses in various sites;
- Certain high frequency sound generators, carbide cannons, foils, and rotating devices, for which claims are made to repel birds;
- Black light traps, fly traps, electronic and heat screens, fly ribbons, and fly paper, for which claims are made to kill or entrap certain insects; and
- Mole thumpers, sound repellents, foils and rotating devices, for which claims are made to repel certain mammals.

Traps for vertebrate animals (e.g. fish traps, rodent traps) and products that “depend for their effectiveness more upon the performance of the person using the device than on the performance of the device itself” (e.g., fly swatters, tillage equipment for weed control) are devices, but they are “of a character unnecessary to be subject to this Act in order to carry out the purposes of the Act” and not regulated under FIFRA per [41 Fed. Reg. 51065 \(1976\)](#).

If a device “incorporates a substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, it is considered to be a pesticide.” [41 Fed. Reg. 51065 \(1976\)](#). [T]he key distinction between pesticides and devices is whether the pesticidal activity of the article is due to physical or mechanical actions or due to a substance or mixture of substances. ... Because [articles such as ion generators] incorporate a substance or substances that accomplish their pesticidal function, such items are considered pesticides for purposes of FIFRA, and must be registered prior to sale or distribution.” [72 Fed.Reg. 54039 \(2007\)](#).

Although FIFRA does not require the registration of pesticidal devices, they are subject to several FIFRA provisions as specified in [40 CFR 152.500](#). The following labeling requirements

apply to pesticidal devices:

- The producing establishment number appear on the product in its retail presentation, and
- The product must not be misbranded, as defined in FIFRA section 2(q) and including the 40 CFR 156(a)(5) prohibitions against false or misleading statements. Note: FIFRA section 2(q)(1)(F)&(G) require that the labeling accompanying a product must contain directions for use and warning or caution statements which are necessary for effecting the product's intended purpose and which if complied with are adequate to protect health and the environment.

See [Chapter 13](#) of the Pesticide Registration Manual for more information on devices and additional FIFRA requirements. Persons who are uncertain about whether their product is a pesticidal device or a pesticide may submit a formal request for a device determination to EPA using PRIA code [M009](#), if they are unsure whether their product qualifies as a pesticide or a device, and whether it would be subject to FIFRA regulation.

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Label Review Manual Chapter 2: What is a Pesticide?

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Summary: This chapter discusses the statutory and regulatory criteria used to determine if a product is a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Non-Binding Disclaimer: This guidance was prepared pursuant to Executive Order 13891 and “EPA Guidance; Administrative Procedures for Issuance and Public Petitions” (85 FR 66230, October 19, 2020). The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.