

Pesticide Registration Manual:

Chapter 13 – Devices

Devices - Introduction

This chapter describes how EPA regulates pesticidal devices and clarifies which types of devices are subject to regulatory oversight and what requirements apply to them.

In 1976, EPA issued a [Federal Register Notice concerning the regulatory status of devices](#). In that notice, EPA also explained its interpretation of the distinction between a “pesticide” and a “device.” More information can be found on [the EPA’s Pest Control Devices and Device Producers: 1976 Federal Register Notice webpage](#).

FIFRA defines a device as any instrument or contrivance (other than a firearm) that 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. Refer to [FIFRA section 2\(h\)](#).

In general, if an article is an instrument or contrivance that uses physical or mechanical means to trap, destroy, repel, or mitigate any plant or animal life declared to be a pest at 40 CFR 152.5, it is considered to be a device and subject to regulation under FIFRA. However, devices are not subject to the registration requirements that apply to pesticides and pesticide products under FIFRA section 3. Further information can be found on [EPA’s Pest Control Devices Webpage](#).

If a product consists of an object or article that incorporates a substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, the entire product is considered to be a pesticide and is subject to registration under FIFRA section 3. Also, if such a product is sold with any substance that functions as a precursor for creation of a pesticidal substance, the entire product is generally considered to be a pesticide and subject to registration under FIFRA section 3.

If the product is an instrument or contrivance and claims to control pests through physical or mechanical means, the product is considered to be a device, unless it is a firearm.

Distinctions among devices, pesticides, and pesticide application equipment can be illustrated by comparing products that are outwardly similar but are treated differently under FIFRA. For example, a bait station that is sold by itself to be used in conjunction with other products in the control of insects or rodents is considered to be pesticide application equipment and is not directly regulated under FIFRA, although the labels for registered pesticide products may require them to be used in bait stations in some or all applications.

If the same design of bait station is sold with toxic bait in it (or packaged with it for use in it), the entire product is considered a “pesticide product” and is regulated and labeled as such. If the bait station is sold with a sticky trap inside it (or is packaged with sticky traps that are to

be placed inside it), the entire product is a device, and is regulated under FIFRA because it achieves pest control by physical means.

- Pesticidal devices must be produced in an EPA registered pesticide-producing establishment. It is important to note that EPA establishment numbers, which are required for devices, are not the same as EPA pesticide registration numbers required for pesticide products. Obtaining an [establishment number](#) is an administrative process, completed upon request to the EPA. In contrast, obtaining an EPA pesticide registration requires a fee for review of product specific data and is a longer process.
- EPA establishment numbers are composed of a company number, followed by a 2-letter U.S. State or 3-letter Country abbreviation, followed by the unique facility number (e.g., xxxx-PA-xx; xxxxx-CHN-xxxx)
- EPA Registration Numbers are composed of a company number followed by a product number (e.g., xxxxx-xxxx). For registered distributor products, the company number and product number are followed by the distributor company number (e.g., xxxxx-xx-xxxx)
- See [Chapter 14](#) for information on how to register a pesticide-producing establishment. Devices are also subject to certain labeling requirements. Refer to [FIFRA section 2\(q\)\(1\)](#) and [40 CFR Part 156](#).

How to Obtain a Device Determination from EPA

If you are uncertain about whether your product requires EPA registration as a pesticide, you may request a determination from EPA. If you would like a determination from EPA as to whether your product is considered a pesticidal device, please submit a request to the Agency using PRIA code M009. The cost is \$2,482* and the timeframe is 4 months. Please submit the following information with your request:

- Submit 8570-1 application form (select “miscellaneous” and provide an explanation in the space provided);
- Submit a cover letter on company letterhead requesting a device determination and include as much of the following information as possible:
 - Your EPA issued company number;
 - The complete brand names of the product;
 - Complete copy of the label for the product, and a statement of all claims to be made for the product, including all written, printed, or broadcast claims made for the product;
 - Directions for use and warnings or cautionary statements;
 - All material distributed with the product;
 - A detailed written description of how the product works to kill, destroy, repel, or mitigate a pest;

- Starting material inputs or ingredients or specifications used in the operation of the product. Ingredients in the product must be identified by common name and CAS number if applicable;
- Schematic diagram or detailed engineering drawings, diagrams, flow diagrams or patent(s) application information. Note: if a patent(s) has been issued, please include copies;
- Photographs of the product from all sides, including digital copies available upon request; and
- Comparisons to current industry products;
- Provide proof of payment;

Once all of the submitted information is reviewed by the Agency, a determination letter will be issued to the applicant within the 4-month PRIA timeframe.

*There are provisions for waiving up to 75% of the fee if you qualify as a small business ([waiver information is also on the website](#)). The fee waiver application must be submitted with the registration application.

- [Fees may be reduced under some circumstances.](#)

If you have questions, please contact us at OPPDeviceDeterminations@epa.gov.

Devices Subject to Regulation

In a *Federal Register* notice published on November 19, 1976 ([Pest Control Devices and Device Producers](#)), EPA stated that devices subject to FIFRA section 2(q)(1) and section 7 include, but are not limited to:

- certain ultraviolet light systems, ozone generators, water filters and air filters (except those containing substances), 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.

Since that notice was issued, EPA has determined that products of the following types also fall within the definition of device:

- products that are claimed to control pests via **electromagnetic and/or electrical emissions** (e.g., hand held bug zappers, electric flea combs);
- products that are claimed to control burrowing animals via **product-caused subterranean explosions**; and
- products that work via principles indicated in the 1976 *Federal Register Notice* for one category of pest but are claimed to control pests of different types (e.g., sticky traps for rodents (without attractants), light or laser repellents for birds, etc.).

Important Note: In applying the definition of "device" in FIFRA section 2(h), EPA examines each individual product on a case-by-case basis. For instance, the public should be aware that EPA has reviewed a number of individual products that claim to provide pest control through the use of electromagnetic radiation and has found these products to be devices within the meaning of section 2(h). In addition, EPA has found that a silver ion generating washing machine marketed with claims that odor causing bacteria will be killed on laundry must be registered as a pesticide. [Read more about regulation of ion generating equipment.](#)

Devices Not Subject to Regulation

The November 19, 1976, *Federal Register Notice* [Pest Control Devices and Device Producers](#) also provided examples of those types of devices that are not subject to regulation under FIFRA:

- devices that depend for their effectiveness more upon the performance of the person using the device than on the performance of the device itself; and
- devices that operate to entrap vertebrate animals.

Products generally falling within these two categories include rat and mousetraps, fly swatters, tillage equipment for weed control, and fish traps.

Requirements for a Device Subject to Regulation

Registration Not Required

A device is not required to be registered under FIFRA section 3. However, devices are subject to certain requirements of FIFRA as specified in [40 CFR 152.500](#).

Production Requirements

Pesticidal devices must be produced in a registered pesticide-producing establishment. Refer to 40 CFR 152.500(b)(2). See [Chapter 14](#) for information on registering a site.

Labeling Requirements

Devices are subject to the labeling requirements of FIFRA section 2(q)(1) and 40 CFR Part 156. These requirements are summarized below.

Misbranding - Under FIFRA section 2(q)(1) a device is considered to be misbranded and subject to enforcement action if:

- the labeling bears any statements, designs, or graphic representations that are false or misleading (see 40 CFR 156.10(a)(5));
- its packaging or wrapping does not conform to standards established pursuant to FIFRA section 25(c)(3) (as of 2010, such standards have yet to be established for devices);
- it is an imitation of, or is offered for sale under the name of another device;
- the label fails to bear the establishment number of the establishment where it was produced;
- any required information is not prominently displayed on the label;
- it lacks adequate directions for use; or
- it lacks an adequate warning or caution statement.

Device Efficacy

Unlike registrants of pesticide products, FIFRA does not require device producers to submit any data concerning either safety or efficacy of a device prior to distribution or sale. This is particularly important to note for antimicrobial pesticide devices that claim to disinfect, sanitize, and/or sterilize items or ambient air. Because microbial pests are not visible to the

naked eye, users of such devices generally cannot evaluate the actual performance of the device. The device may be “misbranded” if labels, labeling, and/or websites for devices including general or specific efficacy claims include any statement, design, or graphic representation that is “false or misleading in any particular.” Distribution or sale of a misbranded device is prohibited under FIFRA. Therefore, every producer or seller of devices is responsible for ensuring that these products perform as claimed, and that such performance claims are not misleading to the intended user.

Also, please note that some state laws have requirements for devices in addition to those imposed by FIFRA. Some state governments require registration of devices, including submission and review of efficacy data and labeling, before a device can be sold or distributed in that state. Therefore, compliance with FIFRA’s requirements does not ensure that a device can be legally sold in those states. Click the link below for a contact list of state lead agencies.

http://npic.orst.edu/reg/state_agencies.html

Child-Resistant Packaging

Devices are subject to child-resistant packaging (CRP) requirements when they meet certain toxicity and use criteria. For information concerning CRP requirements, see:

- [Child-Resistant Packaging for Pesticides](#)
- EPA regulations on child-resistant packaging --40 CFR 157.20 – 157.36

Child-resistant packaging is defined as packaging designed or constructed to be significantly difficult for children less than five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time, and that is not difficult for normal adults to use properly. 40 CFR 157.21(b).

Import and Export of Devices

Please refer to [FIFRA section 17](#) for information concerning import and export requirements for devices. U.S. Customs regulations at 19 CFR 12.1(b) related to the implementation of FIFRA section 17 require, in part, that devices produced by foreign manufacturers and imported into the U.S. comply with all requirements applicable to domestic producers. In addition, the regulations require an importer to submit to EPA a [Notice of Arrival of](#)

[Pesticides and Devices](#) (EPA Form 3540-1) for review and determination as to whether the shipment should be sampled and/or permitted entry into the U.S.

FIFRA section 17 states that no device produced solely for export to any foreign country shall be deemed in violation of FIFRA when prepared or packaged to the specifications or directions of the foreign producer, except that producers of such devices are subject to labeling requirements and certain misbranding restrictions found in sections 2(p) and 2(q) of FIFRA.

In addition, producers of devices are subject to record keeping and inspection requirements in accordance with [section 8 of FIFRA](#).

Contacts for Additional Information

If you have any questions concerning regulatory requirements for devices that are not subject to registration, please contact:

OPPDevicedeterminations@epa.gov

References Cited in Chapter 13

Refer to [Chapter 19](#) for information on the source of these documents.

[Code of Federal Regulation, Title 40](#)

- Part 152 - Pesticide registration and classification procedures
- Part 153 - Statement of policies and interpretations
- Part 156 - Labeling requirements for pesticides and devices
- Part 157 - Packaging requirements for pesticides and devices
- Part 167 - Registration of pesticide-producing establishments, submission of pesticide reports, and labeling
- Part 169 - Books and records of pesticide production and distribution

[Federal Insecticide, Fungicide, and Rodenticide Act](#), as amended by the Food Quality Protection Act of August 3, 1996

- Section 2 - Definitions
- Section 3 - Registration of pesticides
- Section 7 - Registration of establishments
- Section 8 - Books and records
- Section 9 - Inspection of establishments, etc.
- Section 12 - Unlawful acts
- Section 13 - Stop sale, use, removal, and seizure
- Section 14 - Penalties
- Section 17 - Imports and exports
- Section 25 - Child-resistant packaging

Federal Register Notice, [Pest Control Devices and Device Producers](#), (41 FR 51065), November 19, 1976