

# **Pesticide Registration Manual:**

## **Chapter 1 - Overview of Requirements for Pesticide Registration and Registrant Obligations**

**Revised August 3, 2021**

# Introduction

This chapter provides an overview of the federal laws that govern EPA's oversight of pesticide use in the United States. The chapter also introduces concepts further elaborated in later chapters of this manual, such as which products are subject to EPA's review, how EPA evaluates a pesticide chemical's toxicity to humans or other organisms, how EPA evaluates a chemical's environmental risk, how EPA evaluates pesticides intended for use on food crops and nonfood sites, different types of EPA responses, role of state regulations, and obligations of companies and individuals seeking a pesticide registration (referred to as "applicants").

## Laws and Regulations Pertaining to Pesticide Registration

The primary federal law that governs how EPA oversees pesticide use in the United States is the [Federal Insecticide, Fungicide, and Rodenticide Act \(FIFRA\)](#), originally enacted in 1947. This law has been significantly amended several times, notably in the recent past by the [Food Quality Protection Act of 1996 \(FQPA\)](#) and by the Pesticide Registration Improvement Act of 2003 (PRIA), which was reauthorized by the [Pesticide Registration Improvement Extension Act of 2012](#).

- FQPA significantly strengthened the safety criteria in the [Federal Food, Drug, and Cosmetic Act \(FFDCA\)](#), under which EPA evaluates pesticide uses on food crops.
- PRIA established pesticide [registration fees](#) for some registration actions, under which applicants are required to pay a fee and, in exchange, EPA is obligated to perform certain registration functions within defined timeframes.

EPA also derives its authority to regulate pesticide residues on food items from provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA). FIFRA and FFDCA require EPA to carefully evaluate any pesticide intended for use on food or animal feed crops before making a registration decision. If EPA determines that use of the product would result in residues of the chemical(s) in or on food/feed items, the Agency may not register the product under FIFRA unless EPA can determine that the residues are "safe" under the FFDCA. The FFDCA defines "safe" to mean that there is "a reasonable certainty of no harm" from the exposure to the residue in food and from other non-occupational sources.

After making a determination as to safety, the Agency may establish a "[tolerance](#)," i.e., a maximum permissible pesticide residue on a particular food/feed commodity. Alternatively, EPA may establish an exemption from the requirement of a tolerance, which would allow any amount of a pesticide residue to remain in or on food or feed, if EPA determines that

granting the exemption would meet the FFDCA safety standard. There is a more detailed discussion of the FFDCA requirements and pesticide tolerances later in the "Pesticides Intended for Use on Food or Feed" section of this chapter.

Further legal and technical authority regarding how EPA regulates pesticides in the United States is found in FIFRA's implementing regulations at Title 40 of the Code of Federal Regulations (40 CFR) Parts 150-189. These sections of 40 CFR govern the sale, distribution and use of pesticides. Persons or companies subject to the law are responsible for understanding and complying with FIFRA, FFDCA, and the relevant sections of 40 CFR.

## Identifying Which Products Require Registration

For a company to know if EPA must register its pesticide product(s), it is necessary to know what the law defines as a pesticide. Anyone who plans to sell or distribute a product in the United States that is intended to control a pest or regulate plant growth should become familiar with the definition of pesticide in the law and regulations.

The term pesticide, as defined in [FIFRA section 2\(u\)](#) means:

1. any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest;
2. any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant; and
3. any nitrogen stabilizer

EPA has listed in 40 CFR 152.6 substances that are excluded from regulation by FIFRA. Provided they meet the conditions or criteria specified in 40 CFR 152.6, such substances include liquid chemical sterilants, nitrogen stabilizers, human drugs, animal drugs, animal feeds vitamin hormone products, and products intended to aid the growth of desirable plants. Further, EPA has listed, in 40 CFR 152.8, fertilizer products that don't contain pesticide and products intended to force bees from hives for the collection of honey as products that are not pesticides because they are not for use against pests. When other products are not pesticides because they are not intended for a pesticidal purpose is explained in 40 CFR 152.10.

### Substances vs. Devices

The use of the terms substance and mixtures of substances in the definition of pesticide provides the key to separating pesticides from devices (discussed below). If the product contains a substance that is intended to prevent, destroy, repel, or mitigate a pest or constitutes a plant regulator, defoliant, desiccant, or nitrogen stabilizer, then the product is considered to be a pesticide and, in general, will require registration (exceptions to registration also discussed below).

If the pest is controlled by physical or mechanical action (as opposed to a substance), then the product is considered a device and registration by EPA is not required. However, devices are subject to other provisions of the law, which are more thoroughly explained in [Chapter 13](#).

## Definition of Intent

As set forth at 40 CFR section 152.15, a substance is considered to be intended for a pesticidal purpose, thus requiring EPA registration, if:

- The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise):
  - that the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or
  - that the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or
  - the substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose (by itself or in combination with any other substance), (2) use for manufacture of a pesticide; or
  - 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 pesticidal purpose.

## Toxicity to Humans and Nontarget Organisms

Pesticides are substances that prevent, destroy, repel, or mitigate a pest. A product's relative toxicity to humans or other nontarget organisms does not make it a pesticide. However, the product's toxicity to humans and other organisms is carefully evaluated during EPA's registration evaluation process. When EPA determines that a pesticide product can be registered for use, the Agency has concluded that the use of the pesticide product will not cause unreasonable adverse effects to humans or the environment when applied according to the label directions and restrictions.

It is important to become familiar with the other definitions in the law and regulations. The definitions for devices, active and inert ingredients, and pests are terms that will be vital for fully understanding the definition of a pesticide.

- **Active ingredient (A.I.)** – "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 [40 CFR ] § 174.3." 40 CFR 152.3. See also FIFRA 2(a).

- **Inert ingredient** – "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 [40 CFR ] § 174.3." 40 CFR 152.3. See also FIFRA 2(m).
- **Device** – Devices are described in a following section in this chapter, [FIFRA section 2\(h\)](#) and in detail in [Chapter 13](#).
- **Pests** – This term means "(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the [Agency] declares to be a pest under [[FIFRA section 25\(c\)\(1\)](#)]" FIFRA 2(t).

**Important Note:** For assistance in determining whether a product is a pesticide or device under FIFRA, you may contact the [Registration Division](#), the [Antimicrobials Division](#), or the [Biopesticides and Pollution Prevention Division](#) Ombudsmen in the Office of Pesticide Programs (OPP). The contact should be made in writing and should include detailed information about the intended uses and composition of the product. Submission of a proposed label for the product would also be helpful. The addresses and/or FAX numbers for the Regulatory Division Ombudsmen are found in [Chapter 21](#). **Please do not send any confidential information via FAX or e-mail.**

# Products or Substances that Are Regulated but Not Registered as Pesticides

## Adjuvants

For pesticide regulation, adjuvants are chemicals added to a pesticide by users to improve the pesticide's efficacy. Agricultural chemical adjuvants are grouped according to their intended purpose in a tank mix. Examples of adjuvants include:

- acidifying agents,
- buffering agents,
- anti-foam agents,
- defoaming agents,
- anti-transpirants,
- dyes and brighteners,
- compatibility agents,
- crop oil concentrates,
- oil surfactants,
- deposition agents,
- drift reduction agents,
- foam markers,
- feeding stimulants,
- herbicide safeners,
- spreaders, extenders,
- adhesive agents,
- suspension agents,
- gelling agents,
- synergists,
- wetting agents,
- emulsifiers,
- dispersing agents,
- penetrants,
- tank and equipment cleaners,
- neutralizers,
- water absorbents, and
- water softeners.

Such agents are often included in pesticide formulations as "other ingredients," in which case the ingredient is reviewed during registration and any necessary tolerances or exemptions from the requirement of a tolerance are established. Where a product label directs the user to add a particular adjuvant before use, the registering division will treat that adjuvant as if it were an "other ingredient" in making the registration decision, and will assure that any necessary tolerances or exemptions from the requirement of a tolerance are established. It also would be within the Agency's authority to treat any tank-mixed substance as part of the pesticide (and thus needing an FFDCA tolerance) in that it met the FIFRA definition of pesticide – i.e., a "mixture" of substances intended to kill a pest.

## Devices

A device is defined in [FIFRA section 2\(h\)](#) as “any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than humans 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.” Tamper-resistant bait boxes for rodenticides are an example of application equipment that does not fall within the definition of a device.

Items that depend more upon the performance of a person than on the performance of the device itself (e.g., flyswatters) are considered devices but are not subject to regulation.

As already stated, registration is not required for devices although devices are subject to other provisions of the law. Please refer to [Chapter 13](#) for further information. A nontechnical [fact sheet on devices](#) is also available.

## Pesticide Intermediates

Pesticide "intermediates" are substances that may not themselves be pesticides, but are used in the synthesis of the active ingredient or the manufacture of the pesticide product. Examples of intermediates are the starting materials used to synthesize by chemical reactions or purify a technical grade of the active ingredient. A pesticide intermediate may be produced at the same site as the final pesticide product or obtained from other sources. Some pesticide intermediates are also pesticides because they are intended for a pesticidal purpose. See 40 CFR section 152.15 for examples of what EPA considers a substance intended for a pesticidal purpose. Pesticide intermediates that are not also pesticides are not subject to registration under FIFRA but are subject to regulation under the [Toxic Substances Control Act \(TSCA\)](#). Questions regarding chemicals or compounds that are not pesticides should be referred to EPA's [Office of Pollution Prevention and Toxics \(OPPT\)](#).

# Pesticides and Pest Control Organisms Exempt from Registration Requirements

The following pesticides, pest control organisms, and treated articles are exempt from the registration requirements of FIFRA under 40 CFR Part 152, Subpart B:

## **Exemptions for pesticides regulated by another Federal Agency (40 CFR 152.20)**

- Certain biological control agents are exempt (except for eucaryotic microorganisms, including protozoa, algae, and fungi; procaryotic microorganisms, including bacteria; and viruses).
- All living plants intended for use as biological control agents are exempt from the requirements of FIFRA. However, plant-incorporated protectants are not exempt pursuant to this section. Regulations, including exemptions, for plant-incorporated protectants are addressed in 40 CFR Part 174.
- A nonliquid chemical sterilant, except ethylene oxide, that meets the criteria of 152.6(a)(2) with respect to its claims and 152.6(a)(3) with respect to its use sites is exempted from regulation under FIFRA.

## **Exemptions for pesticides of a character not requiring FIFRA regulation(40 CFR 152.25)**

- Treated articles or substances that meet the specific criteria of 40 CFR 152.25(a), pheromones and pheromone traps, preservatives for biological specimens, foods, natural cedar, and certain [minimum risk pesticides](#) listed in 40 CFR 152.25(f)(1) and on the [OPP Pesticide Tolerances Website](#) are exempt.

## **Pesticides that may be transferred sold or distributed without registration (40 CFR 152.30)**

- A pesticide transferred between registered establishments operated by the same producer. (40 CFR 152.30(a))
- A pesticide transferred between registered establishments not operated by the same producer. (40 CFR 152.30(b))
- A pesticide distributed or sold under an experimental use permit. (40 CFR 152.30(c))
- A pesticide transferred solely for export. (40 CFR 152.30(d))
- A pesticide distributed or sold under an emergency exemption. (40 CFR 152.30(e))
- A pesticide transferred for purposes of disposal. (40 CFR 152.30(f))
- Existing stocks of a formerly registered product. (40 CFR 152.30(g))



# Pesticides Intended for Use on Food or Feed

EPA establishes maximum residue levels (tolerances) for pesticides in food, including animal feed, under section 408 of the [Federal Food, Drug, and Cosmetic Act \(FFDCA\)](#). In the absence of a tolerance covering pesticide residues in a food, that food is considered adulterated and subject to seizure. For this reason, EPA regulations require that all needed tolerances be in place before a FIFRA registration will be granted.

Specifically, if the proposed product labeling bears instructions for use of the product on food or feed crops, or if the intended use of the product results or may be expected to result, directly or indirectly, in pesticide residues in or on food or feed (including residues of any active ingredient, inert ingredient, metabolite, or degradation product), the applicant must submit a statement indicating whether a tolerance or an exemption from the requirement of a tolerance has been established by the Agency under section 408 of the FFDCA for the pesticide residues resulting from the proposed use (40 CFR 152.50(i)).

If the appropriate tolerances or exemptions are not in place, the application must be accompanied by a petition for establishment of appropriate tolerances or exemptions from the requirement of a tolerance in accordance with 40 CFR Part 180 (40 CFR 152.50(i)). Please refer to [Chapter 11](#) for more detailed information on filing petitions for a tolerance.

## Import and Export of Pesticides

[FIFRA section 17](#) contains import and export requirements for pesticides. Except for certain exemptions from the requirements of FIFRA listed under 40 CFR Part 152, Subpart B, FIFRA requires that a registration be obtained from EPA before any person in any state or foreign country can sell or distribute any pesticide in the United States.

Pesticides produced by foreign manufacturers and imported for sale or distribution in the United States must comply with all requirements applicable to domestic producers. This includes registering the pesticide product (follow the guidance in [Chapter 2](#)) and obtaining an EPA Pesticide-Producing Establishment number before starting production (follow the guidance in [Chapter 14](#)). In addition, 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 United States.

Technical materials may be imported without registration in sufficient quantities to formulate a pesticide for which an Experimental Use Permit has been granted if the EUP application cites the planned import (40 CFR 172.7). Per 40 CFR 152.30(e). The unregistered product must be labeled in accordance with 40 CFR Part 156.

FIFRA section 17 states that no pesticide, device, or active ingredient used in producing a pesticide 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 pesticides, devices, and active ingredients are subject to [FIFRA](#) provisions on labels and labeling (section 2(p)) and misbranding (sections 2(q)(1)(A), (C), (D), (E), (G), and (H); 2(q)(2)(A), (B), (C)(i) and (iii); and (D), 7 and 8).

[FIFRA section 17\(a\)\(2\)](#) and its interpretation in 40 CFR 168.75 further state that before the export of any pesticide not registered under section 3 or sold under section 6(a)(1) of FIFRA, the foreign purchaser must have signed a Prior Informed Consent statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under FIFRA. The purchaser must transmit a copy of that statement to an appropriate official of the government of the importing country. Refer to 40 CFR Part 168, Subpart D, for more information. Related information can also be found at the pesticides [International Activities Website](#).

## **Types of Pesticide Registration**

Any company wishing to sell its own pesticide product must either:

- obtain a federal registration for its own product; or
- become a supplemental registrant (often termed a supplemental distributor or sub-registrant) for a product that is already federally registered.

These types of registrations, together with amendments to a registration, are described in more detail below. Before submitting a registration request to EPA, the company must obtain a [company number](#).

## Obtaining a Registration for a Pesticide Product

An applicant who wishes to obtain a registration for its own pesticide product is responsible for submitting or citing all of the information and data that are required to support the registration. The information required includes:

- forms,
- proposed product labeling,
- technical and scientific data that meet the data requirements related to the specific product the applicant intends to produce, and
- statement of how the applicant will comply with any data compensation requirements.
- 

[Registrant Summary of Pesticide Petitions for EPA's Notice of Filing](#) provide a company with the ability to electronically prepare a pesticide tolerance petition for submission to EPA.

[Chapter 2](#) contains detailed instructions on how to submit an application for pesticide registration.

## Obtaining a Supplemental Registration to Distribute a Product Registered by Someone Else

An applicant who does not wish to register and produce its own unique product may become a supplemental registrant for another company that has already registered a product. This supplemental registration allows the new registrant to market the product under its own company and brand name. To use the supplemental registration process, both parties (the original registrant and the supplemental distributor) must:

- enter into an agreement with one another,
- complete and file a [Notice of Supplemental Distribution of a Registered Pesticide Product \(EPA Form 8570-5\)](#) with EPA, and
- ensure that the supplemental product bears the identical label language apart from the exceptions listed at 40 CFR 152.132(d). Two of the exceptions include the supplemental label utilizing a different product name and the suppleme

Refer to [Chapter 9](#) for detailed instructions on how to submit an application for supplemental distribution of a pesticide product.

## **Amending the Registration of a Product Already Registered with EPA**

If a registrant has a product previously registered with EPA and wishes to make a change to the registration such as change the formulation or labeling text (i.e., add, delete, or change formulation components or label precautionary statements, or add or change uses), it must file an application to amend its registered product.

Refer to [Chapter 6](#) for detailed instructions on how to submit an application for amended registration of a pesticide product. There are certain changes that registrants may make that do not require an amendment application, but simply require that registrants notify the Agency of the change, and other changes that require no notification at all. Notifications are discussed in [Chapter 7](#) and in [PR Notice 98-10](#).

## **Unconditional/Conditional Registration**

EPA has discretion to make pesticide registration decisions under either the unconditional registration criteria of [FIFRA section 3\(c\)\(5\)](#) or the conditional registration criteria of FIFRA section 3(c)(7). These are described below.

### **Unconditional Registration**

An application will be approved under the unconditional registration criteria only if EPA has (as listed in 40 CFR 152.112):

- determined that the application was complete and was accompanied by all materials required by FIFRA, including but not limited to, evidence that the applicant had complied with the data compensation requirements;
- reviewed all relevant data in its possession;
- determined that no additional data were necessary to make the determinations required under FIFRA section 3(c)(5) with respect to the subject product;
- determined that the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data were required;
- determined that the product will perform its intended function without unreasonable adverse effects on the environment, and that when used in accordance with widespread and commonly recognized practice, the product will not generally cause unreasonable adverse effects on the environment;
- determined that the product was not misbranded as defined by FIFRA section 2(q) and 40 CFR Part 156;
- determined that, if the proposed labeling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues of any active or inert ingredient of the product in or on food or animal feed, all necessary tolerances or

exemptions from the requirement of a tolerance, and food additive regulations have been issued under FFDCa section 408, section 409, or both; and

- been notified by the FDA that the product complies with any requirements imposed by FDA if the product, in addition to being a pesticide, is a drug within the meaning of FFDCa section 201(q).

Unconditional registrations can be granted for a variety of applications – such as identical/substantially similar (me-toos) (described below), new uses, or new active ingredients – so long as all criteria above are met.

### **Conditional Registration under FIFRA 3(c)(7)**

EPA may conditionally approve an application for registration or amended registration of a pesticide product. This may occur if EPA determines that, while a registration decision can be made, further data, studies, or action by the registrant are required by EPA. This section further details how EPA grants a conditional registration depending on whether it is a new active ingredient, a new use, or an Identical/Substantially Similar (formerly "Me Too") product.

#### **Identical/Substantially Similar (Formerly Me-Too) Products:**

EPA may conditionally approve an application for registration or amended registration of a pesticide product under FIFRA section 3(c)(7)(A) if the Agency determines that:

- it possesses all data necessary to make the determinations required by FIFRA section 3(c)(7)(A) with respect to the pesticide product that is the subject of the application (including, at a minimum, data needed to characterize any incremental risk that would result from approval of the application);
- the pesticide and proposed uses are identical or substantially similar to any currently registered pesticide and its uses, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment (See [40 CFR 152.113\(b\)](#)); and
- approving the registration or amendment in the manner proposed would not significantly increase the risk of any unreasonable adverse effect on the environment (40 CFR 152.113(a)(2)).

Each registration issued under 3(c)(7)(A) must submit or cite the same data that would be required for unconditional registration of a similar product under FIFRA section 3(c)(5).

These data must be submitted or cited no later than the time that the data are required to be submitted for similar pesticide product(s) already registered. If a notice requiring these data has been issued under FIFRA section 3(c)(2)(B) before the application has been approved, the applicant must submit or cite those data at the time specified in the notice.

**New Uses:** EPA may conditionally amend the registration of a pesticide to permit additional uses, even if the data concerning the pesticide may be insufficient to support the unconditional registration, if the Agency determines under FIFRA section 3(c)(7)(B) that:

- the applicant has submitted satisfactory data pertaining to the proposed additional use,
- amending the registration would not significantly increase the risk of any unreasonable adverse effect on the environment, and

Each registration issued under 3(c)(7)(B) must submit or cite the same data that would be required for unconditional registration of a similar product under FIFRA section 3(c)(5).

**Note:** If an applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated (such as data required by a data call-in issued by EPA under FIFRA section 3(c)(2)(B)), the Agency may amend the registration to require the submission of those data at the same time that the data are required to be submitted with respect to similar pesticides already registered (FIFRA section 3(c)(7)(B)).

**New Active Ingredients:** EPA may conditionally register a pesticide containing an active ingredient not in any currently registered product for a period reasonably sufficient for the generation and submission of data necessary for registration under FIFRA section 3(c)(7)(C), if the Agency determines that:

- insufficient time has elapsed since the imposition of the data requirement for those data to be developed, on the condition that when the Agency receives such data that they do not meet or exceed risk criteria stated in the regulations issued under FIFRA and other conditions issued by the Agency;
- the use of the pesticide during such period will not cause any unreasonable risk to the environment; and
- the use of the pesticide is in the public interest.

**Note:** Additional requirements for conditional registration of new active ingredients are found in 40 CFR 152.114(b) and (c).

## **Pesticides that Do Not Qualify for Conditional Registration:**

EPA will not approve the conditional registration of a pesticide product for a new use if (40 CFR 152.113(c)):

- the pesticide is the subject of a Special Review, based on a use of the product that results in human dietary exposure; and
- the proposed new use is for a major food or feed crop, or involves use on a minor food or feed crop for which there is an effective alternative registered pesticide that does not meet the risk criteria associated with human dietary exposure.

## **Registrant Obligations**

Registrants are entirely responsible for their pesticide and pesticide labeling and are required by FIFRA and EPA regulations (40 CFR Part 152 and 169) to:

- ensure that each production facility is registered and has an [establishment number](#) (and ensure that any contractor facility they use is registered) (40 CFR 167.20);
- maintain a U.S. mailing address (40 CFR 152.122(a));
- notify EPA of name and/or address changes (if a registrant changes its name and/or address and fails to notify EPA of the change(s) and EPA's good faith attempts to contact the registrant are not successful, EPA will issue in the Federal Register a notice of intent to cancel all of the registrant's products under FIFRA section 6(b)) (40 CFR 152.122(a));
- notify EPA if the authorized agent changes (40 CFR 152.122(b));
- provide information on any adverse effects of a pesticide that have not been previously submitted to the Agency in accordance with FIFRA section 6(a)(2) (40 CFR 152.125);
- ensure that their product labeling is in compliance with FIFRA (FIFRA 2(q) and 40 CFR Part 156);
- ensure that supplemental distributor products and their distributor product labeling are in compliance with FIFRA (40 CFR Part 152.132);
- obtain permission to transfer registration of a product and/or data to another person (40 CFR 152.135); and
- [pay the annual pesticide registration maintenance fees.](#)

If a registrant owns the production facility, the registrant must:

- register the establishment number(s) for each production facility (40 CFR 167.20);
- maintain product data records (40 CFR 169.2); and
- report annual production volume (40 CFR 169.2(a)).

Refer to 40 CFR Part 152, Subpart G, and 40 CFR Part 169.

## State Pesticide Regulatory Agencies

The registration and use of pesticides are not only regulated by federal laws, but also by state laws and regulations, which differ from state to state. It is advisable to consult with each state and U.S. territory for information on their registration requirements. The National Pesticide Information Center provides the telephone numbers and addresses for the primary pesticide regulatory agency in each state and U.S. territory.

## Enforcement and Compliance

EPA's regulatory oversight of pesticides manufactured in, imported to, and/or used in the United States includes not only the science-based review and decision-making process performed by the Agency's Office of Pesticide Programs but also oversight to ensure compliance with federal laws and regulations related to pesticides. These efforts are conducted by EPA's [Office of Enforcement and Compliance Assurance \(OECA\)](#).

## Contacts for Additional Information

The following chapters of this manual are intended to provide detailed information regarding the pesticide registration process and obligations of applicants and registrants during that process. However, if during the registration process you require additional information or clarification concerning a pending application for registration, contact the Product Manager assigned to the pesticide in your product. A listing of Product Managers and a sampling of the pesticides they are responsible for can be found in [Chapter 21](#).

For questions of a general nature that do not pertain to any specific pesticide, or pertain to a new pesticide active ingredient not yet applied for, contact the respective Ombudsman for the type of pesticide (i.e., conventional chemical, biopesticide, or antimicrobial) for which you have a question. A listing of the various Ombudsmen can be found in [Chapter 21](#).



If you have any questions concerning devices, including whether they are subject to FIFRA or how to register an establishment, please contact:

U.S. EPA  
Toxics and Pesticides Enforcement Division  
1200 Pennsylvania Avenue, N.W. (2245A)  
Washington, D.C., 20460-0001  
Email: [OPPDeviceDeterminations@epa.gov](mailto:OPPDeviceDeterminations@epa.gov)

## References Cited in Chapter 1

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

[To find current Code of Federal Regulations citations, use the e-CFR.](#)

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

- Part 152 - Pesticide Registration and Classification Procedures
- Part 156 - Labeling Requirements for Pesticides and Devices
- Part 158 - Data Requirements for Registration
- Part 168 - Statements of Enforcement Policies and Interpretations
- Part 169 - Books and Records of Pesticide Production and Distribution
- Part 172 - Experimental Use Permits
- Part 180 - Tolerances and exemptions from tolerances for pesticide chemicals in food

### [Code of Federal Regulation, Title 21](#)

- Part 182 - Substance generally recognized as safe

[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 6 - Administrative review; suspension
- Section 7 - Registration of establishments

- Section 8 - Books and Records
- Section 17 - Imports and Exports

#### Federal Food, Drug and Cosmetic Act

- Section 201 - Definitions
- Section 408 - Requirement for Tolerance or Exemption