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FIFRA: Steps to Pesticide Registration

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All pesticides that will be sold or distributed in the United States must be registered with the Environmental Protection Agency (“EPA”) according to the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”). The registration process involves an evaluation of the required forms, proposed labeling, technical and scientific data, and a statement of how the registrant will comply with any data compensation requirements.

I. Preliminary Registration Considerations

First, the party seeking to register a pesticide (known as the registrant) must determine whether its product needs to be registered under FIFRA. The key to whether a product must be registered is whether the product is a “substance” or a “device.” If the product contains a substance that is intended to prevent, destroy, repel, or mitigate a pest or functions as a plant regulator, defoliant desiccant, or nitrogen stabilizer, then the product is considered to be a pesticide and will most likely require registration.¹ On the other hand, if the product is controlled by a physical or mechanical action, then it is considered a device and does not require registration². A product that includes a combination of these two methods must be registered unless it qualifies for an exemption.³

¹ 7 USCA § 136(u) (2020) <https://bit.ly/3lnyivf>.

² “Devices”, while not requiring registration, may be subject to further regulation by the EPA. More information is available here: <https://bit.ly/3d8i3iT>

³ *Pesticide Devices: A Guide for Consumers*, EPA, <https://bit.ly/3d8i3iT>.

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Adjuvants, or chemicals added by users to improve a pesticide's efficacy, are not required to be registered as pesticides.⁴

Next, a registrant must determine the pesticide's classification so that the registrant knows which registration requirements must be met. Although there are general registration requirements that apply to all classifications of pesticides, certain classifications have their own additional requirements.⁵ The registration process for conventional pesticides is the general process that each classification must satisfy.

A pesticide may be classified as a "conventional pesticide," "biopesticide," or "antimicrobial." Conventional pesticides are generally synthetic chemicals used predominantly to kill insects, weeds, and fungi.⁶ Biopesticides include naturally occurring substances that control pests, microorganisms that control pests, and pesticidal substances produced by plants containing added genetic material.⁷ Finally, antimicrobial pesticides are substances or mixtures of substances intended to destroy or suppress the growth of harmful microbiological organisms, and pesticides that protect inanimate objects and surfaces from organisms such as bacteria, viruses, or fungi.⁸

II. General Registration Process

As stated above, the registration process has slightly different requirements based on the classification of the pesticide. However, there are requirements that all registrants must meet regardless of the pesticide's classification. Those include: data requirements, labeling requirements, and the submission of certain forms.⁹

1. Forms

As part of any registration process, the registrant is required to submit certain forms to the EPA. At the start of the registration process, FIFRA requires each registrant to file a statement with the EPA. The statement must include the following information:

- The name and address of the registrant and of any other person whose name will appear on the labeling;
- The name of the pesticide;
- A complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

⁴ *Pesticide Registration Manual: Chapter 1 – Overview of Requirements for Pesticide Registration and Registrant Obligations*, EPA, <https://bit.ly/3j15PzN>.

⁵ Biopesticides and antimicrobials require slightly different considerations than conventional pesticides. More information regarding biopesticides may be found here: <https://bit.ly/33DQhr9>. Additionally, more information regarding antimicrobials may be found here: <https://bit.ly/33CGiSR>.

⁶ *Conventional Pesticide Registration*, EPA, <https://bit.ly/3nowvUh>.

⁷ *Biopesticide Registration*, EPA, <https://bit.ly/33DQhr9>.

⁸ *Antimicrobial Registration*, EPA <https://bit.ly/33CGiSR>.

⁹ 7 USCA § 136a.(c)(2) (2020) <https://bit.ly/30HVLQ2>.



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- The pesticide's complete formula;
- A request that the pesticide be classified for general use or for restricted use, or for both; and
- If requested, a full description of the tests made, and the results upon which the claims are based, or alternatively a citation to data that has previously been submitted to the EPA.
- The registrant is also required to pay a service fee.

The remaining required forms range from the general Application for Pesticide Registration/Amendment, to a Summary of the Physical/Chemical Properties of the pesticide. The forms generally cover much of the information discussed in this Fact Sheet. A complete list of these forms may be found on the EPA's website.¹⁰

2. Data Requirements

In addition to the required forms, registrants must also submit data to the EPA as part of the application process. The data is used to evaluate the potential human health and environmental effects associated with the use of the pesticide. The types of studies required include: product chemistry, product performance, data determining hazard to humans and domestic animals, data determining hazard to nontarget organisms, post-application exposure studies, user exposure studies, spray drift evaluations, environmental fate, and residue chemistry.¹¹

Generally, the EPA has broad authority to establish or modify the data requirements necessary for pesticide registration.¹² Further, the EPA is permitted to determine how much time the registrant will have to complete each registration requirement. In some instances, the EPA may require information in addition to the general requirements. When that happens, the EPA will provide the registrant with sufficient time to obtain the additional information.

In situations where a registrant is registering a new pesticide formulation that includes an already registered pesticide, the registrant will not be required to submit or cite data pertaining to the already registered product.

3. General Use vs. Restricted Use

In addition to setting data requirements, the EPA also reviews each product's label to ensure that it provides adequate instructions about how to safely use the pesticide product so as to avoid harm to human health and the environment.¹³ FIFRA provides that a product's labeling information shall not be false or misleading, shall not conflict with or detract from any statement required by law or the EPA as a condition of registration, and shall be substantiated at the request of the EPA.¹⁴ It is a violation of

¹⁰ *Pesticide Registration Manual: Chapter 20 – Forms and How to Obtain Them*, EPA, <https://bit.ly/2SNmo1D>.

¹¹ *Data Requirements for Pesticide Registration*, EPA, <https://bit.ly/2SNmo1D> (Includes specifics for each required study).

¹² *Data Requirements for Pesticide Registration*, EPA, <https://bit.ly/3d8bUTD>.

¹³ 7 USCA § 136a.(d)(1)(A) (2020) <https://bit.ly/30HVLQ2>.

¹⁴ 7 USCA § 136a.(c)(9)(B) (2020) <https://bit.ly/30HVLQ2>.



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federal law to use a pesticide in a manner inconsistent with its label.¹⁵

The EPA classifies pesticides for either “general” or “restricted” use. A registrant may request in its statement which classification it prefers, but the decision is ultimately the EPA’s.¹⁶ The classification of the pesticide is crucial to the product’s labeling requirements.

If the EPA determines that the pesticide will generally not cause unreasonable adverse effects on the environment when used according to its label, then the EPA will classify the pesticide as “general use.”¹⁷ However, if the EPA determines that the pesticide may cause unreasonable adverse effects to the applicator, other persons, or the environment when used according to its label, then the pesticide will be classified as “restricted use” and may only be used by or under the direct supervision of a certified applicator.¹⁸

In some cases, a pesticide can be classified as general use for some situations and restricted use for others. When that happens, the labeling directions for the pesticide’s general uses must be clearly separated and distinguished from the directions related to its restricted uses.¹⁹ Additionally, the EPA may require that the pesticide’s packaging and labeling for its general uses be clearly distinguishable from the packaging and labeling for its restricted uses.

Even after registration has been approved, the EPA may change a pesticide’s classification from general use to restricted use in order to prevent unreasonable adverse effects on the environment.²⁰ In some circumstances, the EPA may also change the classification from restricted use to general use.

III. Alternative Types of Registration

In certain circumstances, FIFRA also allows registrants to register for experimental use permits, emergency exemptions, or state-specific registration as a temporary alternative to the general registration process.²¹

The EPA may issue experimental use permits when a pesticide manufacturer seeks to field test a pesticide that is under development.²² Manufacturers of conventional pesticides are required to obtain experimental use permits prior to testing new pesticides or new uses of already registered pesticides if the experimental test is conducted on ten or more acres of land, or on one acre or more of water. Biopesticides also require experimental use permits for experimental testing.

¹⁵ 7 USCA § 136a.(c)(9) (2020) <https://bit.ly/30HVLO2>.

¹⁶ 7 USCA § 136a.(d)(1)(A) (2020) <https://bit.ly/30HVLO2>.

¹⁷ 7 USCA § 136a.(d)(1)(B) (2020) <https://bit.ly/30HVLO2>.

¹⁸ 7 USCA § 136a.(d)(1)(C) (2020) <https://bit.ly/30HVLO2>.

¹⁹ 7 USCA § 136a.(d)(1)(A) (2020) <https://bit.ly/30HVLO2>.

²⁰ 7 USCA § 136a.(d)(3) (2020) <https://bit.ly/30HVLO2>.

²¹ *Pesticide Registration Manual: Chapter 17 – State Regulatory Authority*, EPA, <https://bit.ly/2SNn9rv>.

²² 7 USCA § 136c(g) (2020) <https://bit.ly/3nqC0WB>.



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Emergency exemptions allow state and federal agencies to permit the use of an unregistered pesticide in a specific geographical area for a limited period of time if an emergency pest condition exists.²³ The duration of an emergency exemption may not be longer than one year for specific or public health exemptions, or three years for quarantine exemptions. An example of a specific or public health exemption would be the presence of a pest situation against which available tools or resources would be ineffective. A quarantine exemption, on the other hand, could be the spread of an invasive pest that was not known to have previously occurred in the United States. In either case, a pesticide may receive an emergency exemption to help against the identified pest.²⁴

State-specific registrations allow states to register a new pesticide product for any use, or a federally registered product for an additional use, as long as the state demonstrates a special local need for the use of the product.²⁵ A state-specific registration is similar to an emergency exemption except that the special need is local to that particular state. However, the EPA has the authority to disapprove or overrule a state's special local need registration application.²⁶

IV. Registration Approval or Denial

If the EPA determines that all of the requirements have been met, then the EPA shall register the pesticide.²⁷ The EPA may register the pesticide for “unconditional” registration or “conditional” registration. Unconditional registration will be granted when all registration requirements have been met, and the EPA has determined that the pesticide will “not generally cause unreasonable adverse effects on the environment.”²⁸ The EPA will make this determination on the basis that no additional data, testing, or actions by the registrant is required.

Conversely, the EPA will grant conditional registration, or amended registration of a pesticide product if the agency determines that a registration decision can be made, but further data, studies, or action by the registrant are required.²⁹ When the EPA conditionally registers or amends the registration of a pesticide, the pesticide may be used while the required additional data is being generated as long as the EPA decides that the use would not significantly increase the risk of unreasonable adverse effects on people or the environment.

Unreasonable adverse effects on the environment is defined as “(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues.” Ultimately, all conditional registrations must submit or cite the same data that would be required for unconditional registration.

Upon the approval of a pesticide's registration, the EPA shall conduct an initial review of the pesticide

²³ 7 USCA § 136p. (2020) <https://bit.ly/30HoLae>.

²⁴ *Emergency Exemption Database*, EPA, <https://bit.ly/3iGexgu>.

²⁵ *Guidance on FIFRA 24(c) Registrations*, EPA, <https://bit.ly/2i9Nlul> (Additional information on special local needs).

²⁶ *Guidance on FIFRA 24(c) Registrations*, EPA, <https://bit.ly/2i9Nlul> (Additional information on special local needs).

²⁷ 7 USCA § 136a.(c)(5) (2020) <https://bit.ly/30HVLQ2>.

²⁸ 7 USCA § 136a.(c)(5)(D) (2020) <https://bit.ly/30HVLQ2>.

²⁹ 7 USCA § 136a.(c)(7)(A) (2020) <https://bit.ly/30HVLQ2>.



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no later than fifteen years after the pesticide's registration date.³⁰ The EPA shall periodically conduct further review every fifteen years following the initial review.³¹ It is during this time that the EPA will review each active ingredient in the pesticide to determine whether any changes need to be made with the pesticide's labeling, use, classification, or to cancel the pesticide's approval all together.

If the EPA determines that the registration requirements have not been satisfied, then the agency must notify the registrant of the denial and provide the reasons for denial.³² The registrant has thirty days from the date they received the denial notification to correct the unsatisfied conditions. If the registrant does not correct the conditions, the EPA may refuse to register the pesticide. Whenever the pesticide's registration has been refused, the EPA must notify the registrant of the decision and the reasons for the decision. Additionally, the EPA will publish the denial and its reasons for denial in the Federal Register. The registrant has the same remedies as provided for in FIFRA section 136d,³³ which includes judicial review.

The general public may also provide commentary and challenge a pesticide's approval.³⁴ Each time the EPA receives an application for a new pesticide, an application to change the pesticide's use pattern, or when the EPA issues a notice of intent to cancel a pesticide's approval, the EPA must open a comment period for the general public. The mandatory comment period is done through the Federal Register and usually last for thirty days. After the comment period closes, the EPA evaluates the comments and revises its assessment as needed. The public comments can lead to the EPA holding a public hearing to determine whether the registration should be canceled or have its classification changed.³⁵

V. State Registration

In addition to compliance with FIFRA, pesticide registrants must also comply with state laws. FIFRA provides states with the authority to regulate the sale or use of any federally registered pesticide in that particular state.³⁶ However, a state may not permit the sale or use of a pesticide that has not been registered with the EPA.

Finally, FIFRA provides that states have the primary enforcement responsibility for pesticide use violations.³⁷ In order to do this, the state must adopt adequate laws and regulations, implement procedures to enforce the laws and regulations, and keep records of reports relating to compliance with those rules and regulations. If a state is not able to meet those requirements, then the EPA shall have primary enforcement authority.

³⁰ 7 USCA § 136a.(g)(1)(A)(iii)(II) (2020) <https://bit.ly/30HVLQ2>.

³¹ 7 USCA § 136a.(g)(1)(A)(iv) (2020) <https://bit.ly/30HVLQ2>.

³² 7 USCA § 136d(f)(2) (2020) <https://bit.ly/2F7y4J4>.

³³ 7 USCA § 136d(f)(2) (2020) <https://bit.ly/2F7y4J4>.

³⁴ *Public Participation Process for Registration Actions*, EPA, <https://bit.ly/2F8hIW3> (More information regarding public participation in the registration process).

³⁵ 7 USCA § 136d(f)(2) (2020) <https://bit.ly/2F7y4J4>.

³⁶ 7 USCA § 136v(a) (2020) <https://bit.ly/30JUk3l>.

³⁷ *About Pesticide Registration*, EPA, <https://bit.ly/2F7yxLk>.



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