Pesticide Registration Manual:

How to Register a Pesticide – A Guide for Applicants New to the Process

Guidance Document: Registration Manual

How to Register a Pesticide Product – A Guide for Applicants New to the Process

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Summary: This document is an introductory resource for companies and individuals who wish to sell their pesticide products in the United States.

Overview

Welcome to the pesticide product registration process. This page is an introductory resource for companies and individuals who wish to sell their pesticide products in the United States. While this provides a high-level summary of the registration process, applicants are responsible for fully understanding the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and its regulations.

Under FIFRA, EPA regulates all pesticides that are sold or distributed in the United States. A pesticide is:

- A substance intended to prevent, destroy, repel or mitigate pests;
- A substance intended for use as a plant regulator, defoliant or desiccant; or
- Any nitrogen stabilizer.

The three major pesticide types are:

Conventional pesticides such as insecticides, herbicides, fungicides and rodenticides;

Antimicrobial pesticides such as sterilants, sporicides, disinfectants, sanitizers, germicides, and products that control growth of microorganisms of economic and aesthetic significance; and

Biopesticides such as biochemicals, microbe-containing (microbial) pesticides and plant-incorporated protectants (PIPs).

Most end-use pesticide products also contain inert (other) ingredients, or substances in addition to the active ingredient(s). Manufacturing-use products, on the other hand, are intended and labeled for formulation and repackaging into end-use pesticide products. They often do not contain intentionally added inert ingredients but may contain impurities that need to be specified. See Chapter 2 of this Registration Manual for more information.

Before a pesticide product can be lawfully sold or distributed, EPA performs a comprehensive scientific assessment of the product, resulting in a regulatory decision (i.e., whether or not to approve the product for sale and/or distribution in the United States). In accordance with FIFRA, registered pesticides cannot cause unreasonable risks to humans or the environment.

There are some pesticides EPA has exempted from the federal requirement for registration. To determine whether your product is exempt, please review 40 CFR 152.25 and this page about minimum risk pesticides. The linked pages provide information that should permit you to determine if your product meets the criteria for the exemption. If you determine the product does not meet the criteria, registration would be required.

Before you contact EPA with questions about the registration process, please read this webpage and review the materials it references. These resources will answer some of your questions and help you ask questions specific to your situation.

Learn about the pesticide product registration process.

First, read the Introduction and the first two chapters of this Pesticide Registration Manual, which is a valuable resource that provides all the information you need on this process. We also recommended you refer to the Label Review Manual for drafting the product label for your pesticide.

Determine what type of product you have.

Each pesticide type has a different process for registration:

- Conventional Pesticides
- Biopesticides
- Antimicrobial Pesticides

Determine what data you need to support your product.

In evaluating a pesticide registration application, EPA assesses a wide variety of studies to determine the likelihood of adverse effects (i.e., risk) to human health and the environment from exposures associated with use of the product.

Applicants must generate scientific data to address concerns about the identity, composition, potential adverse effects and environmental fate of each pesticide. These data allow us to evaluate whether a pesticide might affect a range of non-target organisms, including humans, plants, animals, and endangered or threatened species. Learn about data requirements

You may also discuss and confirm the data and labeling requirements with EPA before submitting your application. Answering the following questions may help you better determine your data needs:

- Will you provide data, cite data, or use other methods (e.g., data waiver or bridging, supported by scientific rationale) to support the proposed product?
    - All products must be supported by data (e.g., product chemistry, acute and chronic toxicity, environmental fate and ecological effects, etc.) for the proposed use pattern. Learn more about:
    - Health Effects Test Guidelines
    - Product Properties Test Guidelines
    - Ecological Effects Test Guidelines
    - Residue Chemistry Test Guidelines
    - Microbial Pesticide Test Guidelines
    - Biochemicals Test Guidelines
    - Data Requirements for Registration of Antimicrobial Pesticides
    - If your proposed product is substantially similar to another EPA-registered product, you may be able to rely on existing studies.

    - You must choose whether to conduct studies and submit the data, cite studies already evaluated by EPA, or use other methods available to fulfill data requirements.
    - If you are citing another company's data, you must first determine whether you need to pay or get authorization from the data's owner to use it.
- Learn about data compensation requirements.
- View a list of companies that have submitted data to EPA.
- If you do not own the source of the active ingredient (the technical source), the technical source is registered (has an EPA registration number), and you are relying on the citation of that product to fulfill the data requirements for the active ingredient (generic data), you can use the Formulator's Exemption form (Form 8570-27) to address the generic data requirements specific to the active ingredient.
- If the technical source is not EPA registered, or the use patterns on your proposed label are not supported by a technical source that is EPA registered, you will be responsible for addressing all generic data requirements by submitting studies, citing existing data from registered sources or using other methods (e.g., providing scientific rationale).
- Will you be making claims about your product's effectiveness against public health pests?
- Efficacy (product performance) data are required if your product will be making claims against public health pests, pests that affect building structure (e.g., termites), or certain invasive pests.
- Learn about product performance test guidelines
- Learn about efficacy testing for pesticides targeting certain invertebrate pests
- The Agency generally does not require submission of efficacy data to support non-public health-related claims (e.g., control of odor-causing bacteria, weeds, plant pathogens). However, the applicant is still responsible for ensuring that these products perform as intended by developing and keeping efficacy data on file. EPA retains the right to require submission of efficacy data for non-public health related claims on a case-by-case basis.
- Will your pesticide be used on food or feed crops or in a food processing or storage area? If so, a tolerance or an exemption from the requirement of a tolerance must be established for each active and inert ingredient in the formulation before the pesticide can be registered. See Chapter 5 of this Pesticide Registration Manual for more information on costs and timeframes.

Determine the registration fee and review timeframe for your product.

The Pesticide Registration Improvement Act (PRIA) requires that EPA charge registration fees and assign a review timeframe for each registration application. These fees and timeframes vary depending on the type of activity being requested.

- Before submitting the application, see the fee determination decision tree to identify the PRIA category of your application, EPA's interpretation of the category of your application, the required fee, and the review timeframe.
    - Fees may be reduced under some circumstances. There are provisions for waiving up to 75 percent of the fee if you qualify as a small business. The fee waiver application must be submitted with the registration application. Learn more about fee waivers for small businesses.
- In some circumstances, applications may be exempt from registration fees.
    - Learn more about Inter-Regional Project Number 4 (IR-4) exemptions
    - Learn more about exemptions for federal and state governments
- Learn more about fees.

Consider using a consultant.

If you have not previously registered a pesticide product, it may be helpful to obtain the services of a regulatory consultant. An experienced consultant can help you navigate the registration process, which will save time and resources. To identify a consultant, consider doing a web search on "pesticide regulatory consultant" or contacting a trade group for assistance.

EPA does not endorse or make any recommendations for any consultant. We strongly recommend you interview several consultants and check at least three recent references before selecting one.

Applicants located outside of the United States **must** have an agent residing in the United States to act on their behalf in all registration matters. This agent may or may not be a regulatory consultant.

The appropriate way to designate a consultant or agent is explained in Chapter 14 of this Pesticide Registration Manual.

Talk to EPA about your plans once you have read the guidance.

It is EPA's hope that the material in this preface and the rest of the Pesticide Registration Manual provides applicants with all of the information they need to submit a registration application.

If, however, you have additional questions that are not covered in these materials, EPA staff may be available to address your questions via email, phone calls or an in-person meeting. These opportunities provide avenues to discuss and confirm data needs, pesticidal claims, and labeling requirements that apply to your application. It is helpful if you provide as many details as possible about your proposed application in an introductory email to the appropriate EPA registration contact for your product.

- Contact the appropriate division based on your pesticide type.
- Learn more about pre-application meetings for antimicrobial pesticide applications.

Obtain an EPA company number.

An EPA company number is a unique identifier assigned to a company that wishes to register a pesticide with EPA. These companies are commonly called registrants.

Registrants must obtain a company number prior to registering their first product with the Agency. To obtain the company number, send a signed letter on company letterhead to request a company number and establish an official address with EPA.

Complete the application package.

Make sure you have all required contents of the application package.

Submit the application package and pay the fee.

For more information on submitting the package, review the following chapters of the Registration Manual:

- Chapter 15 (Submitting Data and Confidential Business Information)
- Chapter 20 (Forms and How to Obtain Them)
- Chapter 21 (Directions for Submitting Applications and Contacting EPA)

Learn more about paying PRIA application fees.

Respond to any issues raised during EPA's review process.

When EPA receives the application and applicable PRIA fee, the Agency has 21 days, known as the 21-day Content Screen, to determine if the application has all required components. EPA will determine whether it contains all:

- Forms;
- Composition;
- Labeling;
- Data formatted as described in the Agency's guidance (PR Notice 11-3); and
- Documentation of fee payment, including any requests for a fee reduction or waiver or exemption.

Any deficiencies identified during the 21-day Content Screen that are not corrected by the applicant during the screening process may lead to EPA's rejection of the application and retention of 25 percent of the fee.

Some examples of issues found during this part of the review process:

- Missing or unsigned forms.
- Missing data or scientific rationale in lieu of data, or unacceptable scientific rationale or bridging argument.
- Inert ingredients not approved by EPA.

Following the 21-day Content Screen, EPA checks to make sure the application is ready for comprehensive review, which is called the 45/90-day Preliminary Technical Screen. In conducting this screening, EPA determines whether the data and information submitted with the application are:

- Adequate and sufficient;
- Consistent with the proposed labeling and any proposed tolerance or tolerance exemption; and
- Sufficient such that a full review could result in the granting of the application.

If the application fails the technical screening and cannot correct the deficiencies within 10 business days after receipt of EPA's notification of the failure, EPA will reject the application and retain part of the application fee based on the Fee Reduction Tables.

Applicants can use the Checklists for 45/90 Preliminary Technical Screen to help ensure their applications are complete and may submit completed checklists with their applications.

Once your application passes both the 21-day Content Screen and 45/90-day Preliminary Technical Screen, EPA will complete a comprehensive science review. Any data deficiencies or additional information needed to complete the reviews will result in EPA notifying the applicant of the issues. The applicant will have 75 days to make corrections or additions to complete the application.

If the applicant believes that the deficiencies cannot be corrected within 75 days, the applicant can propose a new date by which the application will be complete. If, after 75 days, the applicant has not responded, or if the applicant subsequently fails to complete the application within the time scheduled for completion, EPA will terminate any action on the application and will treat the application as if it had been withdrawn by the applicant. Any refunds provided will be calculated using the Fee Reduction Tables.

EPA makes regulatory determination.

EPA will make a regulatory decision using risk assessments based on review of the submitted data, information and proposed label.

If EPA grants the registration, the registration may be either unconditional or conditional.

Apply for state registration.

If your application is approved by EPA, you must then apply for registration in the states where you plan to sell your product.

- Find contact information for state pesticide regulatory agencies.

Additional requirements for pesticide producers and applicants.

If you are producing or formulating a pesticide, you must comply with FIFRA Section 7, Registration of Establishments.

- Obtain an establishment number for each place or facility where you will manufacture the product.
- Note that annual reports are required for establishments, even if there is no production.

Once your product is registered, you also must pay annual registration maintenance fees.

This has been a general overview of the pesticide product registration process. The resources on this page have extensive information, but you may contact us if you still have questions.