# Pesticide Registration Manual:

# Introduction

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This manual is intended as a resource for companies and individuals who wish to have their pesticide products registered by the U.S. Environmental Protection Agency (EPA). EPA's pesticide review and oversight is conducted by the Office of Pesticide Programs (OPP) within the Office of Chemical Safety and Pollution Prevention. OPP comprises nine divisions of scientists, regulatory specialists, and other staff. This manual includes information on many types of registration actions; however, it utilizes the procedures for registering a "new" pesticide product in most of its examples.

# Why Register Pesticides with EPA

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA regulates all pesticides that are sold and distributed in the United States. The term "pesticides" includes pesticides, herbicides, rodenticides, antimicrobial products, biopesticides, and other substances used to control a wide variety of pests. A pesticide product is defined as a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold and includes any physical apparatus used to deliver or apply the pesticide if distributed or sold with the pesticide. (40 CFR 152.3).

Before any pesticide product that EPA has not exempted from registration requirements can be lawfully sold or distributed, EPA performs a rigorous, comprehensive scientific assessment of the product, resulting in a registration decision. Under this review, the Agency evaluates

- the product's active ingredient(s),
- other constituent substances (including inert ingredients), and
- the proposed use pattern(s)

to ensure that, when the product is used according to labeled directions, no unreasonable adverse effects on human health or the environment will occur.

When EPA has determined that no unreasonable adverse effects to human health or the environment will result from the sale or distribution of a pesticide product, it grants the applicant a license or "registration" to legally sell and distribute the product in the United States. Once an EPA registration has been granted, applicants will then need to comply with the individual registration requirements imposed by the States in which they wish to market their product. Refer to Chapter 17 for information on State regulatory authorities. The establishment in which a pesticide product is produced must also be registered. Refer to Chapter 14 for information on pesticide producing establishments.

# The Label is the Law!

Once EPA has granted a registration, EPA not only notifies the requesting company of the decision but also will approve a submitted label for the product. All registered products must include an approved label on every package. The pesticide product's label is a legal document. The label is the law! Once EPA approves a label during the registration evaluation, it generally may not be altered or changed by the company unless specifically authorized by EPA during a subsequent label review.

A pesticide product's label is of utmost importance as the label is the primary mechanism to inform the end-user about how to use and apply the product to achieve the product's useful functions, as well as which precautions must be followed to protect both human health and the environment. Thus, as part of any registration application submitted to EPA, applicants must provide a proposed label containing detailed information. During its review, EPA can approve the label as submitted, approve the label with comments, or disapprove the submitted label.

For more information on labels, see Chapter 2 in this manual. More detailed information on labels can be found in EPA's Label Review Manual.

# How to Use This Manual

Companies and individuals seeking to obtain pesticide registrations are referred to as pesticide "applicants" throughout this manual. After applicants have a pesticide registered, they are referred to as "registrants."

Registered pesticides generally can be divided into two categories: manufacturing-use products that are used to formulate other pesticide products and end-use products that are distributed or sold to the user for controlling pests or defoliating, desiccating, or regulating the growth of plants. While both the manufacturing-use and end-use products must be registered, the focus of this manual is applications for the registration of end-use products. Applicants should contact a registration ombudsman for questions concerning the registration of manufacturing-use products that aren't addressed in this manual.

This manual is organized into 21 chapters (see Table of Contents at right) that comprehensively discuss issues related to the registration of pesticide products. Each chapter includes a list of references that can be used to further understand the issues presented.

In addition to describing EPA's registration process, this manual also provides detailed information about the responsibilities of applicants/registrants - before, during, and after the review process.

The manual begins with a high-level overview of the entire pesticide registration process aimed at those who have not previously registered a pesticide product. It summarizes the information in the other chapters of the manual.

In Chapter 1 there are discussions of the legal and statutory framework of EPA's oversight of pesticides in the United States and what types of products are required to undergo an EPA evaluation. Chapter 1 also provides an overview of how to have a pesticide evaluated by EPA - the types of data required, how it is submitted, and other supporting documentation.

Chapters 2, 3, and 4 provide specific information to help applicants determine data and other registration requirements depending on whether their product is classified as an antimicrobial, biopesticide, or conventional chemical pesticide.

Chapter 5 discusses changes that were made to EPA's pesticide review program following enactment of the Pesticide Registration Improvement Act of 2003 (PRIA), which was subsequently reauthorized by the Pesticide Registration Improvement Renewal Act of 2007 (PRIA 2) and the Pesticide Registration Improvement Extension Act of 2012 (PRIA 3). PRIA established pesticide registration fees for some registration actions, requiring applicants to pay a fee, in exchange for which, EPA is obligated to reach registration decisions within defined timeframes.

Chapters 6 and 7 discuss amendments to currently registered pesticides and instances that do not require EPA review but that can be accomplished by notification to EPA.

Chapter 8 explains how EPA considers inert ingredients in the evaluation of pesticide products and what type of documentation is required for review. Inert ingredients are pesticide product ingredients that are not active against target pests.

Chapter 9 explains what requirements must be adhered to when companies that are not the original registrant distribute a registered pesticide product.

Chapter 10 addresses data compensation issues that arise if an applicant chooses to cite a different company's proprietary data for EPA's review.

Chapter 11 discusses tolerance petitions, i.e., which data are required and how EPA evaluates food uses of pesticides to determine whether a maximum residue level of the chemical can remain on food without causing harm to people, including sensitive populations such as infants and children.

Chapter 12 discusses data requirements and EPA review procedures for "Experimental Use Permits" (EUPs). An EUP is a permit authorized under FIFRA section 5 that allows applicants to conduct testing of a new proposed pesticide or new proposed use.

In Chapter 13, "Devices" are discussed in detail. In general, if a pest is controlled by a physical or mechanical action, the product may be considered a "device" and may not require registration by EPA. Devices are subject to other types of regulatory oversight, as listed in 40 CFR 152.500.

Chapters 14, 15, and 16 provide specific information on obtaining an EPA Establishment Number, how to submit data and Confidential Business Information to EPA, and how to transfer product registrations and data rights to different companies.

Chapters 17 and 18 present useful information on the role played by state regulatory agencies and other federal agencies in pesticide oversight in the United States. Registrants may also have certain obligations under state and other federal agencies.

Chapters 19 and 20 provide detail on obtaining publications and forms related to pesticides.

Chapter 21 gives specific directions for submitting applications to EPA, and how to contact appropriate offices within the Office of Pesticide Programs.

# For More Information

Code of Federal Regulations citations are available in the e-CFR.