

Revised December 2016

Label Review Manual

Chapter 1: Purpose of the Manual



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What's changed in this version?

> Reinstate presentation of the Label Review Manual in its entirety (Chapters 1-18).

I. Purpose

This Label Review Manual (LRM or Manual) provides guidance on pesticide labeling with the goal of improving the quality and consistency of pesticide labels. Historically, the LRM was developed as a training tool for EPA staff in the Office of Pesticide Programs (OPP). However, over time, its audience has grown from OPP label reviewers to include other federal agencies as well as external parties such as state, local, and tribal agencies, pesticide registrants, and other individuals who work with pesticide labeling.

II. Background

Pesticide product labels provide critical information about how to safely and legally handle and apply pesticides. Unlike other types of product labels, pesticide labels are enforceable and must include the statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." 40 CFR 156.10(i)(2)(ii). In other words, the label is the law.

A critical function of the label is to translate the results of the science evaluations into a set of conditions, directions, precautions, and restrictions that define who may use a pesticide, as well as where, how, how much, and how often it may be used. Therefore, the accuracy of a label is vital as it can impact:

- EPA and other agencies that use the label to manage and mitigate pesticide risks.
- EPA and other agencies that enforce pesticide production, distribution, and use.
- Registrants, including pesticide manufacturers, and their supplemental distributors.
- Pesticide applicators who rely on the label for hazard and safety information and use directions.
- Bystanders and other individuals who may be exposed to the pesticide.

III. Considerations

The <u>Federal Insecticide</u>, <u>Fungicide</u>, <u>and Rodenticide Act</u> (FIFRA) and its implementing regulations under Title 40, Chapter I, Subchapter E in the <u>Code of Federal Regulations</u> (CFR) govern pesticide registration and labeling requirements. FIFRA and its implementing regulations govern what **must** be included on pesticide labels.

Other EPA documents such as <u>Pesticide Registration Notices</u> (PR Notices or PRN) and this Manual provide guidance on what **should** be included on pesticide labels.

Additional labeling information based on chemical- and/or product-specific information must also be considered. These include product chemistry and acute toxicity reviews on the product's formulation, science reviews on an active or inert ingredient and its registered use(s), Reregistration Eligibility Decisions, and Registration Review Decisions.

It is important to note that **this Manual does not establish new requirements, policies, or guidance**; instead, it summarizes current requirements, policies, and guidance that are found in published regulations, publicly available documents, and historically established practices. It also provides clarification and examples of labeling requirements and includes hyperlinks to source references. It is meant as a guide to understanding the various parts of a pesticide label.

Instructions directed toward EPA staff and label reviewers will be marked accordingly, using a ... symbol where possible.

IV. Format

This Manual is organized by individual chapters focusing on specific label topics. It is designed as a living document that can be updated as needed to reflect current policies or changes to existing laws or regulations.

The LRM is available in its entirety as well as individual chapters on EPA's pesticides webpage.

V. Maintenance

The Label Review Manual Subcommittee (LRMS), under the Labeling Consistency Committee (LCC), maintains and updates the LRM regularly. An announcement will be made on the EPA's pesticides webpage if and when revised chapters become available.

The "Revised [Date]" at the top of each chapter's cover page indicates when the individual chapter was revised.

The What's changed in this version? section summarizes significant changes to each chapter since its last revision.

VI. Change requests

LRM change requests may be submitted by anyone, including OPP and other EPA staff, other federal, state, local, and tribal agencies, pesticide registrants, researchers, and private citizens. All requests will be reviewed by the LRMS and/or the LCC before a decision is made.

• Notify the LCC of any OPP policy changes that affect generic pesticide labeling and would be appropriate for inclusion in the LRM.

Internal EPA staff can submit requests by:

- Emailing the LRMS or the LCC directly via its chairs or your division's representatives.
- Filling out the <u>Labeling Consistency Question Form</u> online.

External parties can submit requests by:

Filling out the Labeling Consistency Question Form online.