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Label Review Manual

Chapter 1: Purpose of the Manual

<http://commons.wikimedia.org>, photo by "Daderot"



I. Purpose

This Label Review Manual (LRM) serves as a training tool for the Office of Pesticide Program's (OPP) employees and as guidance for product management team members who are responsible for performing label reviews. The goal of the LRM is to improve the quality and consistency of labels. In addition, this manual may be useful for state label reviewers, registrants and other individuals interested in producing readable, unambiguous, and enforceable pesticide labels.

Pesticide product labels provide critical information about how to safely handle and legally apply pesticide products. Unlike most other types of product labels, pesticide labels are enforceable, and all of them carry the statement: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." In other words, the label is the law.

For EPA, a critical function of the label is to translate the results of the science evaluations into a set of conditions, directions and precautions that define who may use a pesticide, as well as where, how, how much and how often it may be used.

The label reviewer's work, therefore, affects individuals and companies that register their pesticide products; EPA, which uses the label to manage the potential risks pesticides may pose; state and federal agencies that enforce pesticide label requirements; educational programs that certify pesticide users; and, of course, pesticide users, who use the labels to make decisions that could affect human health and the environment.

It is important to note that the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and its implementing regulations include specific requirements for label language and format and, therefore, govern what must (and what cannot) appear on the label. Documents such as this one and Pesticide Registration Notices ("PRN's") provide guidance on how the Agency interprets the applicable law.

In addition to considering the guidance provided in this manual, it is the responsibility of the label reviewer or writer to consider **all** chemical and product specific information affecting labeling such as science reviews, Federal Register Notices and Reregistration Eligibility Decision documents ("REDs") when choosing appropriate label language for each product. The Agency considers this manual to be an instructional aid that does not establish new requirements, policies or guidance, but instead summarizes and cites current requirements, policies and guidance that are found in published regulations, publicly available documents or historically established practices. Finally, this manual is useful in understanding how labels should generally be drafted. As always, the Agency will consider each label on its own merits and will consider deviations from Agency policy in labeling under the appropriate provisions of FIFRA and its implementing regulations.

II. Approach

Information in the manual is roughly arranged in the order of use by reviewers. The chapters of this manual have been numbered independently to aid future updating. Individual chapters can be updated as new policy is instituted which changes the guidance contained in a particular chapter. Each chapter will display its current issuance date.

This manual provides a systematic approach to the label review process. Most label reviews involve products that make reference to another label and which are not accompanied by data. When reviewers compare new, proposed labels to previously registered labels, the existing, registered label may have errors or be out-of-date. If the existing label has deficiencies, the proposed label may bear the same errors. Consequently, label reviewers should not rely solely on a label-to-label comparison, but review a label based on applicable law and guidance.

III. Availability

The LRM is located on the Internet at: <http://www2.epa.gov/pesticide-registration/label-review-manual>. A PDF is available on the Webpage for ease of printing.

IV. Maintenance/Update

For accurate maintenance of this manual, it is imperative that OPP staff bring to the attention of the Labeling Committee any document which affects generic labeling policy. If users at anytime come across a document or create a document that establishes labeling policy or find any discrepancies, contact a representative on the Labeling Committee or visit www.epa.gov/opp00001/regulating/labels/label_review.htm

The Label Review Manual Team will update the existing Chapters of the LRM on an ongoing, as needs basis. Each Chapter will maintain its own “Current as of...” date. Therefore, the documents on the Webpage will always be the most up-to-date Chapters. OPP will announce when certain Chapters have been updated.