



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

May 10, 2000

PESTICIDE REGISTRATION (PR) NOTICE 2000-5

**NOTICE TO MANUFACTURERS, PRODUCERS,
 FORMULATORS AND REGISTRANTS OF PESTICIDES**

ATTENTION: Persons Responsible for Registration and Reregistration of Pesticide Products

SUBJECT: Guidance for Mandatory and Advisory Labeling Statements

This notice provides guidance to the registrant for improving the clarity of labeling statements in order to avoid confusing directions and precautions, and to prevent the misuse of pesticides. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 2(ee) defines the term "to use any registered pesticide in a manner inconsistent with its labeling" (i.e., misuse) as use of "...any registered pesticide in a manner not permitted by the labeling...." For purposes of this notice, the term "use" includes storage, transportation, handling, pre-application activities, mixing and loading, worker notification and worker protection, application, post-application activities and disposal. Registrants are not required to submit applications in response to this notice, however, EPA will review applications in light of the guidance presented here and seek to clarify labeling statements that are unclear or ambiguous. Finally, registrants may no longer add or change advisory labeling statements to existing products by notification as previously permitted by PR Notices 95-2 and 98-10. This PR Notice supersedes those PR Notices concerning the use of notification for adding or modifying advisory statements.

I. Guidance on Mandatory and Advisory Labeling Statements

Statements on the pesticide labeling may be interpreted by users differently from what the registrant or EPA intended when the labeling was accepted. If EPA believes that misuse has occurred, an administrative law judge or a court may have to decide whether a product's labeling statements are clear enough for the user to understand how to lawfully use the product. ***Pesticide labeling needs to clearly identify what is required of the user to handle and apply a pesticide safely.*** The Agency is engaged in numerous efforts to improve pesticide product labels in general (e.g., the Consumer Labeling Initiative), as well as in specific areas of the labeling (e.g., bee precautionary labeling and pesticide drift labeling).

Mandatory statements, which commonly use imperative verbs such as "must" or "shall," either require action or prohibit the user from taking certain action. **Advisory statements** generally provide information, either in support of the mandatory statements or about the product in general. *To ensure that the intent of each labeling statement is clear, mandatory statements need to be clearly distinguishable from advisory statements.*

Currently, labeling provisions are enforced by taking into consideration all of the information presented on the label and by reading advisory statements in the context of the entire label. Problems can arise when advisory statements are either vague or ambiguous in meaning, or are inconsistent with mandatory labeling statements. In the past, advisory statements have commonly used suggestive verbs such as "should," "may" or "recommend" to encourage the user to achieve the directed behavior, but often these statements can be unclear as to whether they are mandatory or advisory. In a recent misuse enforcement action, for example, the person charged with the violation argued that advisory statements misled him into taking action which was inconsistent with the mandatory statements.

Advisory language using terms such as "should," "may" and "recommend" can create ambiguities as to the intent of the direction or precaution. Too often, common everyday speech using the word "should" creeps into mandatory label statements where the imperative tense is needed to communicate that certain action is required. Another problem is contradictory headings and statements. A set of mandatory directions preceded by an advisory heading such as "Use Recommendations" potentially conflicts as to the nature of the intended action. Lastly, the use of words such as "should" in advisory language can mistakenly imply that an unaccepted use is permissible. For example, the direction "you should remove all food articles prior to use" on a product that is not registered for any food uses could be mistakenly read to suggest that it is not mandatory to remove all food from the area to be treated. Consequently, such a statement would not be acceptable.

The Agency seeks to improve mandatory and advisory labeling statements by providing guidance (see Appendix) on how they can best be written. **Mandatory statements** are generally written in *imperative or directive terms* (such as "shall," "must," "do this," "do not") so that a typical user will understand that these statements direct the user to take or avoid certain actions, and that failure to follow these instructions is a misuse of the product. **Advisory statements** are generally best written in *descriptive or nondirective terms* to support the mandatory statements or provide information. Suggestive terms such as "should," "may" or "recommend" may be confusing or ambiguous, or potentially conflict with mandatory labeling statements; thus, they are to be avoided. EPA realizes that the use of descriptive terms for advisory statements is not appropriate for every situation and that there are times where it may be necessary to use "should," "may," "recommend" or similar words. However, in most cases it is best to craft advisory labeling statements in straightforward, descriptive language.

II. How to Change Labels

Registrants should follow the guidance above and in the Appendix whenever submitting new or revised labeling to EPA for registration or reregistration. Registrants of new or existing

products should draft their product labels to be consistent with the guidance, and submit them for acceptance as follows:

- Registrants may modify or add mandatory or advisory labeling statements for currently registered products **only by submitting an application for amended registration**. This application must include the following items: a completed EPA application form 8570-1, five copies of the draft label, and a description of the intended modification.
- Registrants may **no longer** add or change advisory labeling statements to existing products by **notification** as previously permitted by PR Notices 95-2 and 98-10. **This PR Notice supersedes those PR Notices concerning the use of notification for adding or modifying advisory statements.**
- Applicants for registration of new products should follow the guidance in this notice when drafting labeling to be submitted with an application.

Because of the importance of maintaining a clear distinction between mandatory and advisory statements, and of making these statements as clear as possible to pesticide users, EPA will review all new or changed mandatory and advisory labeling statements through the amendment process, except for those statements specifically permitted by other PR Notices (other than PR Notice 98-10) to be submitted by notification.

Registrants must submit applications for new products and amendment as follows:

U.S. Postal Service Deliveries

The following official mailing address must be used for all correspondence or data submissions sent to OPP by mail:

Document Processing Desk (AMEND) or (APPL), as applicable
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460-0001

Personal/Courier Service Deliveries

The following address must be used for all correspondence or data submissions that are hand-carried or sent by courier service Monday through Friday, from 8:00 AM to 4:30 PM, excluding Federal holidays:

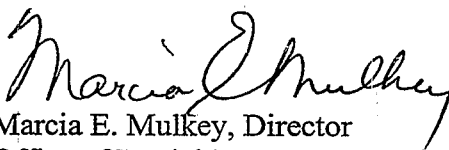
Document Processing Desk (AMEND) or (APPL), as applicable
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

III. Non-Binding Statement

This PR Notice provides guidance to EPA and to pesticide registrants. This notice is not binding on either EPA or pesticide registrants, and EPA may depart from the guidance provided in individual circumstances. Likewise, pesticide registrants may assert that the guidance is not appropriate for a specific pesticide or situation.

IV. For Further Information

If you have questions, contact the Labeling Team (703-308-9068/69), the appropriate Product Manager (Registration Division and Antimicrobial Division) or Regulatory Action Leader (Biopesticides and Pollution Prevention Division) for your product.


Marcia E. Mulkey, Director
Office of Pesticide Programs

APPENDIX TO PR NOTICE 2000-5: GUIDANCE FOR WRITING CLEAR LABELING

A. Mandatory Statements

Mandatory statements generally relate to the actions that are necessary to ensure the proper use of the pesticide and to prevent the occurrence of unreasonable adverse effects, which means any unreasonable risk to man or the environment (including all living organisms and non-living things such as water, soil, air, property, etc.). Mandatory statements include directions for use and precautions that direct the user to take or avoid specific actions. The directions and precautions specify where, when and how a pesticide is to be applied. Mandatory statements are generally written in imperative or directive sentences (e.g., "Wash application equipment...", "Do not use ...", "Users must...", "Apply to corn at a maximum rate of one to two pounds per acre 30 days prior to harvest."). Either EPA or the registrant may develop mandatory labeling statements. When writing mandatory statements, both EPA and the registrant need to ensure that such statements meet the criterion above that the statement is necessary to ensure proper use of a pesticide and to prevent unreasonable adverse effects.

The following directions and precautions are examples of mandatory statements:

- "Keep Out of Reach of Children."
- "Wear chemical resistant gloves."
- "If swallowed, call a doctor."
- "Do not induce vomiting."
- "Do not apply directly to water."
- "Do not apply within 66 feet of wells."
- "Keep away from heat, sparks and open flame."
- "Do not enter into treated areas for 12 hours."
- "Apply immediately after mixing."
- "Do not apply when wind speed exceeds 15 mph."

B. Advisory Statements

Advisory statements provide information to the product user on such topics as product characteristics and how to maximize safety and efficacy while using the product. Such statements are acceptable as long as they do not conflict with mandatory statements, and are not false or misleading.

Advisory statements are best written in *descriptive or nondirective terms*. Phrasing advisory statements in straightforward, factual terms minimizes the possibility that they will conflict with mandatory statements. The use of certain words such as "should," "may" or "recommend" in advisory statements has the potential to lead the product user to erroneously believe that he/she must comply with such statements, when in fact such statements do not have to be followed. These words may also give the user the erroneous impression that a use that is not recommended is still somehow permitted (that is, someone could believe that a particular use is permitted because a statement recommending against such use does not have to be followed). To avoid these potential problems,

the best way to express advisory statements is to use descriptive or nondirective language. Nevertheless, EPA will allow the use of "should," "may," "recommend" or similar terms as long as they do not appear to cause these kinds of problems.

Following are hypothetical advisory statements followed by examples of how they can be rewritten using descriptive terms, which is EPA's preference. These examples are arranged as follows:

- a. A typical label advisory statement as it may have been written prior to this PR Notice.
- b. The same advisory statement written in descriptive terms.

Precautionary Statements

1.
 - a. Latex gloves are recommended.
 - b. Latex gloves provide the best protection.

Physical and Chemical Hazards

1.
 - a. It is preferable to open containers of aluminum phosphide products in open air as under certain conditions they may flash upon opening. Containers may also be opened near a fan or other appropriate ventilation which will rapidly exhaust contaminated air.
 - b. Opening aluminum phosphide containers outdoors or indoors near an exhaust fan or other ventilation assures that the gas will be rapidly dispersed if the product flashes.

Directions for Use

Mixing

1.
 - a. Tank mixtures should be applied immediately after preparation. If for any reason this is not possible, ensure that sufficient agitation has been provided to re-mix all products and check for complete resuspension prior to application.
 - b. Applying the product immediately after preparation assures that it is in suspension. If application is delayed, agitation to re-mix the products and checking for resuspension ensures proper blending.

Application

1.
 - a. Factors such as depth to the drain system, soil type, and degree of compaction should be taken into account in determining the depth of treatment.

- b. The depth of treatment depends on the depth of the drain system, soil type, and degree of soil compaction.
- 2.
 - a. It may be necessary to treat along one side of interior partition walls if there are cracks in the slab, plumbing entry points, existing termite infestations, or other conditions which would make treatment appropriate.
 - b. Treatment along one side of interior partition walls where there are cracks in the slab, plumbing entry points, existing termite infestations, or evidence of other means of access prevents further infestation.
- 3.
 - a. Rotary hoeing is recommended for preemergence applications which do not receive adequate rainfall or sprinkler irrigation to wet the top 2 inches of soil or to the depth of germinating weeds within about 10 days after application.
 - b. If rainfall or sprinkler irrigation does not wet the top 2 inches of soil or depth of germinating weeds within 10 days of a preemergence application, rotary hoeing will ensure soil incorporation.
- 4.
 - a. The spray mixture should be directed to the soil around base of the cotton plants. Care should be taken to prevent the spray from striking the cotton leaves as injury will occur. The use of leaf lifters or shields on application equipment is recommended to avoid spraying the cotton foliage.
 - b. Directing the spray mixture around the base of the cotton plants and using leaf lifters and shields on application equipment will help minimize foliage contact and plant injury.

Cleaning

- 1.
 - a. It is recommended that the sprayer be thoroughly cleaned by flushing with a detergent solution at the end of each work day when any emulsifiable oil, oil concentrate, or other emulsifiable formulation has been used either alone or in tank mix combinations with other pesticide formulations, even if no obvious problems have been encountered. This precaution will ensure a clean sprayer and continued trouble-free operation.
 - b. If an emulsifiable oil, oil concentrate, or other emulsifiable formulation has been used, flushing the sprayer with a detergent solution at the end of the workday will ensure a clean sprayer and trouble-free operation.

