

# **Revised March 2018**

# **Label Review Manual**

# **Chapter 3: General Labeling Requirements**



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# What's changed in this version?

- Updated cover page.
- > Added *Table of Contents*.
- > Added What's changed in this version? section.
- > Reformatted text and style to improve readability.
- Updated hyperlinks.
- Reorganized sections and subsections.
- Added note on using supplemental distributor labeling terminology.
- > Updated web-distributed labeling section to include container label language example.
- Updated label submission requirements section to include e-Submission methods.
- Added note on submitting five replicates for paper copy submissions.
- Updated final printed labeling section to reflect current practices.
- ➤ Updated MOA symbol reference from PR Notice 2001-5 to PR Notice 2017-1.
- Updated first aid statement location per EPA's guidance document EPA's Guidance for Pesticide Registrants on Location of the First Aid Statement per 40 CFR 156.68.

#### I. Introduction

This chapter describes the various types of pesticide labels and also addresses general labeling requirements concerning text format, label contents and placement, mandatory versus advisory statements, and final printed labeling. The last section of this chapter explains how to submit labels for EPA review.

# II. Types of labels and labeling

This section defines "label" and "labeling" and discusses the various types of pesticide labels and labeling. Final printed labeling is discussed separately towards the end of this chapter.

#### A. Definitions

FIFRA 2(p) defines pesticide "label" and "labeling" as:

LABEL	The written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.
LABELING	All labels and all other written, printed, or graphic matter accompanying the pesticide or device at any time, or to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, and the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

#### B. Master label

A master label contains all of the approved uses for a given pesticide product and all associated labeling. Master labels must be submitted for EPA approval. Approved master labels are stamped "ACCEPTED" and placed in the official record. Labeling for a given product must not contain any text beyond that which is approved in the master label (except for supplemental labeling as explained below).

## C. Final printed labeling

A final printed labeling is the label or labeling of a pesticide product when it is distributed or sold. Pursuant to 40 CFR 156.10(a)(6), with certain limited exceptions, "final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency."

## D. Sub-label or split-label

A "sub-label" (or "split-label") contains a subset of the approved uses under a given master label, but is a complete, standalone label, containing all of the required labeling elements. A registrant may distribute or sell a product under a sub-label provided that in limiting the uses identified on the label, no changes would be necessary to the precautionary statements, use classification, or packaging of the product. 40 CFR 152.130(b). Since sub-labels only contain text which already appears on the master label, they are not stamped "ACCEPTED" separately. Final printed labeling must be submitted according to 40 CFR 156.10(a)(6). A distributor product with a sub-label containing an alternate brand name must meet the requirements of 40 CFR 152.132 and 40 CFR 156.10(b)(2)(ii).

Registrants submitting a sub-label should clearly:

- Indicate when the sub-label does not contain the entire use profile of the product.
- Annotate specific label changes on the sub-label.
- If proposed changes to a sub-label require changes to the master label, the registrant must submit a new master label incorporating and annotating any additions or changes.
- Indicate at the top of the label whether it is a "Sub-Label" or "Split-Label," for example:

SUB-LABEL - Revises Master Label dated XX-XX-XX

A new master label containing all currently-approved uses is required when a sub-label is submitted with additions not on the approved master label. Only the master label will be stamped "ACCEPTED." The previously-approved labeling may be distributed or sold for a period of 18 months after approval of the revision. 40 CFR 152.130(c).

## E. Supplemental labeling

Supplemental labeling contains modifications to the pesticide label since the last-approved master label (e.g. new use, change application timing). Supplemental labels must be submitted for EPA approval, and approved labels are stamped "ACCEPTED" and placed in the official record. Supplemental labels are partial labels distributed with the product by the registrant or distributors in addition to the complete product label. Since these are partial labels, they must bear a statement referring the user to the product label for complete directions, precautions, and a statement that both the product label and supplemental labeling must be in the possession of the user when using the product. Compliance with both the product label and supplemental labeling is required to safely and effectively use the product.

Supplemental labeling must include the following:

- Product name
- EPA Registration Number
- Restricted use classification statement (if applicable)
- "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
- "This labeling must be in possession of the user at the time of application."
- "Read the label affixed to the container for [product name] before applying."
- "Use of [product name] according to this labeling is subject to the use precautions and limitations imposed by the label affixed to the container for [product name]."

Typically, supplemental labeling will be incorporated into the master label at the next printing of the product label (final printed label) or within 18 months, whichever comes first. However, there are circumstances when this might not be done; for example, if the directions for use on the supplemental labeling are subject to continual, frequent change (e.g., California aerial application county restrictions can change every six months.). Supplemental labeling must be approved prior to distribution.

Supplemental labeling also includes state registration of special local need (SLN) under <u>FIFRA 24(c)</u>. Refer to <u>40 CFR 162.153(e)(3)</u> for state registration label requirements.

#### F. Distributor label

A distributor label is used when a product is registered to one company, but is distributed or sold (known as "supplemental distribution") by another company (known as the "distributor" or "sub-registrant"). 40 CFR 152.132. Distributor labels are not submitted for approval, but a Notice of Supplemental Distribution must be submitted to EPA before supplemental distribution of the product. The registrant is responsible for the contents of both the distributor product and the distributor label.

A distributor label must be the same as that of the registered product label except for:

- Product name
- Distributor name and address
- EPA Establishment Number
- EPA Registration Number (a third set of numbers is added at the end denoting the distributor's company number, e.g. EPA Reg. No. 1234-56-7890.)
- Product claims (specific claims may be deleted so long as no other changes are necessary, but new claims cannot be added)
- Warranty statements (if allowed by contract between the registrant and the distributor and such change is not false or misleading)

▶ The term "supplemental distributor labeling" is sometimes used, but is not proper EPA terminology and is often confused with the term "supplemental labeling." The correct term is "distributor label." A supplemental label is used to add new uses or directions for a product, while a distributor label cannot include any uses or directions that differ from the registered product's labeling.

## G. Collateral labeling

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written, printed or graphic matter referenced on the label or accompanying the product are known as "collateral labeling." Such labeling is subject to applicable requirements of FIFRA and the Agency's regulations. In addition, collateral labeling may not bear claims or representations that substantially differ from those accepted in connection with registration of the product. FIFRA 12(a)(1)(B). Collateral labeling must be submitted along with the application for registration and must be accepted by EPA before it can be referenced on the label and/or distributed along with the product. However, official publications of certain federal and state agencies and institutions referenced on or accompanying a label or labeling are exempted by FIFRA 2(p)(2)(B) from the definition of label and labeling, and therefore do not require review.

## H. Safety data sheets

The Occupational Safety and Health Administration (OSHA) has direct authority over Safety Data Sheets (SDS), formerly called Material Safety Data Sheets (MSDS). When an SDS is distributed with a pesticide it becomes a part of the pesticide labeling because it is accompanying the product. FIFRA 2(p)(2)(A). Therefore, if an SDS includes warnings, precautions or any other information that conflict with the FIFRA-approved label, it could be misleading to users of the pesticide and therefore cause the pesticide to be considered misbranded and unlawful for sale or distribution. For example, in 2012 OSHA adopted a revised Hazard Communication Rule for SDSs which utilizes the criteria for signal words adopted by multiple countries under the Globally Harmonized System (GHS) for hazard communication language and symbols. EPA has not adopted the GHS criteria, and thus an OSHA SDS may have a signal word that differs from the one EPA requires for a pesticide product label. PR Notice 2012-1 explains how a company can explain and justify such a difference if it occurs in order to prevent users from being misled by the inconsistencies.

## I. Web-distributed labeling

A <u>web-distributed labeling</u> is a legally-valid, enforceable labeling for a pesticide product that is accessible online, and can be tailored to provide users with instructions specific to the use site and the state in which the product will be used. <u>PR Notice 2014-1</u> provides guidance on web-distributed labeling, with instructions on how to submit websites and web-distributed labels for review.

To add web-distributed labeling, the container label should include a statement at the beginning of the Directions for Use section, immediately after any required text, that:

- directs users to the website with the web-distributed labeling;
- indicates that the web-distributed labeling is legally valid; and
- informs users that they may choose which label to follow (container vs. website) in cases where the labels conflict. In areas of conflict, the user must use only one set of labeling instructions.

#### **EXAMPLE OF CONTAINER LABEL DIRECTIONS FOR WEB-DISTRIBUTED LABELING**

You may obtain additional labeling from [website address]. If using the additional labeling to apply the product, you must possess a copy of this additional labeling at the time of application. It is a violation of federal law to use this product in a manner inconsistent with its attached label or any additional labeling, including any web-distributed labeling. In instances where the additional web-distributed labeling conflicts with the container label, the user may choose a single, valid version of the labeling to follow. However, for areas of overlap or conflict, the user must use only one set of labeling instructions, either the attached container label or the web-distributed labeling. Do not mix and match labeling directions.

The release for shipment date is in DDMMYYYY format and can be found on the neck of the container. The unique identifier format is AAAAA-11111 and it can be found on the neck of the container below the release for shipment date.

#### J. Websites

If a label references a company's website, either by listing a web address or URL, including a Quick Response Code (QR Code), or using similar identifiers that direct to a website, then the website becomes "labeling" under FIFRA and is subject to EPA review. PR Notice 2014-1. If the website contains false or misleading information, then the product may be considered misbranded and unlawful to sell or distribute under FIFRA 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA considers misbranding. Also, regardless of whether a website is referenced on a product's label, claims made on the website may not substantially differ from approved claims related to that product. Claims that do substantially differ from what was approved may result in a pesticide product that is unlawful to sell or distribute under FIFRA 12(a)(1)(B).

## K. Non-FIFRA labeling

Some labels submitted to the Agency have information addressing non-FIFRA issues (e.g., Department of Transportation (DOT) shipping rules; New York City fire code symbols; Hazardous Materials Identification System (HMIS), National Paints and

Coatings Association (NPCA), and National Fire Protection Association (NFPA) hazard codes and rating systems; Food and Drug Administration or Department of Agriculture numbers; and bar codes). A registrant may choose to place such text on the label but the text may not replace, obscure, conflict with, or supersede the FIFRA-required text.

#### III. Label format

## A. Prominence and legibility

All words, statements, graphic representations, designs or other information that are legally required to appear on labeling must be clearly legible, conspicuous, and easily understood to the reader. All required label text must be set in 6-point or larger type, appear on a clear contrasting background, and not be obscured or crowded.

40 CFR 156.10(a)(2).

## B. Label placement on container

The label must appear on or be securely attached to the immediate container of the pesticide product. "Securely attached" means that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is part of the package as customarily distributed or sold. 40 CFR 156.10(a)(4)(ii). Requirements for label placement on tank cars and other bulk containers during transport and storage are described in 40 CFR 156.10(a)(4)(ii).

## C. Front panel minimum type size requirements

All required front panel warning statements (signal word, child hazard warning, and in certain cases the first aid statement) must be grouped together, and appear with sufficient prominence relative to other front panel text and graphics. 40 CFR 156.60.

The tables below show the minimum type size requirements and type size examples based on various front panel sizes.

FRONT PANEL MINIMUM TYPE SIZE REQUIREMENTS <sup>1</sup>				
Front Panel Label Size (in²)	Minimum Signal Word Type Size	Minimum KOOROC Type Size		
≤5	6 point	6 point		
>5 – 10	10 point	6 point		
>10 – 15	12 point	8 point		
>15 – 30	14 point	10 point		
>30	18 point	12 point		

<sup>&</sup>lt;sup>1</sup> No type size on any label can be less than 6 point.

	Example for front panel size ≤5 in <sup>2</sup>			
6 point	POISON	DANGER	WARNING	CAUTION
6 point	KEEP OUT OF REACH OF CHILDREN			
6 point	Keep Out of Reach of Children			
	Example for front panel size >5-10 in <sup>2</sup>			
10 point	POISON	DANGER	WARNING	CAUTION
6 point	KEEP OUT OF REACH OF CHILDREN			
6 point	Keep Out of Reach of Children			
	Example for front panel size >10-15 in <sup>2</sup>			
12 point	POISON	DANGER	WARNING	CAUTION
8 point	KEEP OUT OF REACH OF CHILDREN			
8 point	Keep Out of Reach of Children			
	Example for front panel size >15-30 in <sup>2</sup>			
14 point	POISON	DANGER	WARNING	CAUTION
10 point	KEEP OUT OF REACH OF CHILDREN			
10 point	Keep Out of Reach of Children			
	Example for front panel size >30 in <sup>2</sup>			
18 point	POISON	DANGER	WARNING	CAUTION
12 point	12 point KEEP OUT OF REACH OF CHILDREN			
12 point	Keep Out of Reach of Children			

# IV. Label contents and placement

Listed below are the various sections of the label in the *approximate* order they should appear on a label. Each section corresponds to the chapter in this manual which discusses that particular part of the label in more detail. Different formats are used for certain classes of products (e.g., rodenticide baits). Unless otherwise noted, panel sub-headings in this section represent the panel(s) on which the label information listed under each sub-heading is recommended for inclusion.

## A. Front panel label contents

#### 1. Restricted use pesticide statement (Chapter 6)

A product classified as a "restricted use" pesticide (RUP) under <u>FIFRA Section</u> 3(d)(1)(c) must include the required RUP statements at the top of the front panel, under the heading "Restricted Use Pesticide." 40 CFR 156.10(j)(2).

### 2. Product name, brand or trademark (Chapter 12)

The name, brand or trademark under which the pesticide product is sold must appear on the front panel of the label. 40 CFR 156.10(b)(1).

#### 3. Ingredient statement (Chapter 5)

The name and percentage by weight of each active ingredient and the total percentage by weight of all other/inert ingredients must be on the front panel of the label. It must also be on the outside container or wrapper if the ingredient statement is not clearly visible. If the size or form of the product package makes it impractical to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere. 40 CFR 156.10(g)(2).

## 4. Keep Out of Reach of Children statement (Chapter 7)

The statement "Keep Out of Reach of Children," also known as KOOROC or the child hazard warning statement, must be placed on the front panel of the label near the signal word. EPA may waive the child hazard statement requirement if a product meets certain criteria. EPA may also approve an alternative child hazard warning if it more appropriately reflects the product's use or exposure to children. 40 CFR 156.66.

#### 5. Signal word (Chapter 7)

The signal word corresponding to the highest/most toxic acute toxicity category to which a pesticide product is assigned must appear on the front panel of the label. Products classified as Toxicity Category I based on acute oral, acute dermal, or acute inhalation hazard; or certain inert ingredients must also include the word "Poison" (in red on a contrasting background color) next to the signal word DANGER, with the skull and crossbones symbol in close proximity.

#### 6. First aid for toxicity category I (Chapter 7)

Each product must bear a first aid statement if the product has systemic effects in Toxicity Category I, II or III, or skin or eye irritation effects in Toxicity Category I or II. First aid statements for products classified as Toxicity Category I must appear on the front visible panel unless EPA permits reasonable variations in placement of the statement and a reference such as "See side/back panel for first aid statement." appears on the front panel. 40 CFR 156.68 and EPA's Guidance for Pesticide Registrants on Location of the First Aid Statement per 40 CFR 156.68.

#### 7. Net contents/net weight (Chapter 17)

The net contents/net weight statement identifies the weight or volume of a pesticide in the container. There is no required location for this statement, but the preferred location is at the bottom of the front panel below the company name and address.

### B. Other label contents

## 1. EPA registration number (Chapter 14)

The EPA registration number is the single most important piece of information for tracking pesticide products. This identifier must appear on the label of the product, preceded by the phrase "EPA Registration No.," or "EPA Reg. No.," and be set in type size and style similar, and run parallel to, other print on that part of the label on which it appears. 40 CFR 156.10(e).

## 2. EPA establishment number (Chapter 14)

The EPA establishment number identifies the final physical location where the pesticide product was produced or labeled. This identifier must be preceded by the phrase "EPA Est. No.," and may appear on any suitable location on the label

or immediate container; however, it must appear on the wrapper or outside container of the package if the number cannot be clearly read through the wrapper or container. 40 CFR 156.10(f).

### 3. Company name and address (Chapter 15)

The name and address of the producer, registrant, or person for whom the product is produced. 40 CFR 156.10(a)(1)(ii).

#### 4. Mode of action classification symbol (Chapter 11)

When applicable, the mode of action (MOA) classification symbol is recommended to be placed in the upper right hand corner of the front panel of end-use product labels, although it may be placed elsewhere on the label.

PR Notice 2017-1.

#### 5. Hazard and precautionary statements (Chapter 7)

Hazard and precautionary statements that are not required on the front panel may appear on other panels of the label. These statements must appear together on the label under the heading "Precautionary Statements" and under the appropriate subheadings.

## 6. Hazards to humans and domestic animals (Chapter 7)

When an acute hazard may exist to humans or domestic animals, the label must include precautionary statements describing the particular hazard, route(s) of exposure and precautions to be taken to avoid accident, injury or toxic effect or to mitigate the effect. The precautionary paragraph should be placed under a subheading *similar to* "Hazards to Humans and Domestic Animals," and must be preceded by the appropriate signal word. The phrase "domestic animals" may be omitted if domestic animal exposure is not expected. These statements may be placed on any panel of the label. <u>40 CFR 156.70</u>.

## 7. First aid for toxicity category II, III, or IV (Chapter 7)

First aid statements for products classified as Toxicity Category II, III, or IV may appear on the front, side, back, or inside panel, with a referral statement such as "See side/back/inside panel for additional precautionary statements." on the front visible panel near the signal word. Products classified as Toxicity Category IV are not required to include a first aid statement, but it is highly recommended. PR Notice 2001-1 and EPA's Guidance for Pesticide Registrants on Location of the First Aid Statement per 40 CFR 156.68.

#### 8. Environmental hazards (Chapter 8)

Where environmental hazards exist, including hazards to non-target organisms, statements that identify the nature of the hazard and the precautions necessary to avoid potential accident, injury, or damage must appear on the label, under the heading "Environmental Hazards." These statements may appear on any panel of the label. 40 CFR 156.80.

#### 9. Physical or chemical hazards (Chapter 9)

When applicable, flammability and/or explosivity statements and the various precautions to be taken must be identified on the label. Warning statements pertaining to other physical or chemical hazards (e.g., oxidizing potential, conductivity, chemical reactions leading to production of toxic substances) may be required on a case-by-case basis. These statements should be placed under the subheading "Physical or Chemical Hazards" on any panel of the label. 40 CFR 156.78.

♣ The regulations only require a heading *similar to* "Physical or Chemical Hazards." The heading "Physical and Chemical Hazards" is also acceptable.

#### 10. Worker protection labeling (Chapter 10)

Worker protection statements are required for pesticide products in use settings covered under the Worker Protection Standard (WPS) and in non-WPS settings. 40 CFR 156 Subpart K.

## 11. Directions for use (Chapter 11)

This section of the label provides instructions for how to safely and effectively use the pesticide product, including where and when to use it, which pest(s) to use it on, how much to apply, and which types of application equipment are appropriate. This section also includes certain WPS statements and any other information that is necessary to protect human health and the environment. These instructions must be placed under the heading "Directions for Use" and may appear on any panel of the label. 40 CFR 156.10(i).

## 12. Warranty statement (Chapter 12)

This is a disclaimer included *voluntarily* on most pesticide products by the registrant. When it is included, it must conform to specific requirements.

## 13. Storage and disposal (Chapter 13)

Instructions for storing the pesticide product and disposing of unused pesticide and its container must be placed under the heading "Storage and Disposal." 40 CFR 156.10(i)(2)(ix).

#### C. Container label booklet

A booklet or other "pull-off" type labeling may be used when it is not feasible to fit the entire label text directly on the product container. The table below lists the label contents that must be on the label which is on or "securely-attached" to the container, subject to the exceptions in 40 CFR 156.10, and the minimum contents that should be on the booklet or other "pull-off" labeling. The securely-attached container label should also include a referral statement to the booklet for Directions for Use and other information, as applicable.

Label Content	Securely-attached container label	Detachable label booklet
Name and address of the producer, registrant, or person for whom produced	✓	✓
Restricted Use statement (if applicable)	✓	✓
Product name, brand, or trademark	✓	✓
Signal word, including skull and crossbones symbol (if applicable)	✓	✓
"Keep Out of Reach of Children"	✓	✓
Precautionary Statements, including First Aid and Hazards to Humans and Domestic Animals statement	✓	✓
EPA Registration Number	✓	✓
EPA Establishment Number	✓	✓
Ingredient statement	✓	
Net Weight/ Net Contents	✓	
Storage and Disposal	✓	
Referral statement to booklet for Directions for Use (if applicable)	✓	
Directions for Use		✓

## V. Mandatory and advisory statements

Label and labeling statements need to be clearly mandatory or advisory in order to avoid confusion that may cause misuse and/or adverse effects to human health and the environment and to avoid making key requirements unenforceable. PR Notice 2000-5.

## A. Mandatory statements

Mandatory statements relate to the actions that are necessary to ensure the proper use of the pesticide and to prevent the occurrence of unreasonable adverse effects on the environment, which is defined in FIFRA. Mandatory statements include directions for use and restrictions that direct the user to take or avoid specific actions. The directions and restrictions specify where, when and how a pesticide is to be applied. Mandatory statements are generally written in imperative or directive sentences. 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 are necessary to ensure proper use of a pesticide and to prevent unreasonable adverse effects on the environment. The following are examples of mandatory statements:

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"Wear chemical-resistant gloves."
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"Do not apply within 66 feet of wells."

"Do not apply directly to water."

"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, are not false or misleading, and do not otherwise violate statutory or regulatory requirements.

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 may erroneously mislead the user to believe that he/she must comply with such statements; or conversely, that a non-recommended use is still permitted, leading to a possible misuse. Advisory statements should explain the purpose or benefit of doing something, instead of just asserting that it should be done. The following are examples of problematic statements and preferred alternatives:

#### **Precautionary Statements**

Problematic "Latex gloves are recommended."

Preferred "Latex gloves provide the best protection."

#### Physical and Chemical Hazards

Problematic "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."

Preferred "Opening aluminum phosphide containers outdoors or indoors

near an exhaust fan or other ventilation helps to ensure that the

gas will be rapidly dispersed if the product flashes."

#### Directions for Use

Problematic "Tank mixtures should be applied immediately after

preparation. If for any reason this is not possible, ensure that sufficient agitation has been provided to remix all products and

check for complete resuspension prior to application."

Preferred "Applying the product immediately after preparation will help

to ensure that it is in suspension. If application is delayed, agitation to remix the products and checking for resuspension

will ensure proper blending."

Problematic "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."

Preferred "The depth of treatment depends on the depth of the drain

system, soil type, and degree of soil compaction."

Problematic "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."

Preferred "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."

Problematic "The spray mixture should be directed to the soil around the

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."

Preferred "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."

# VI. Label submission requirements

Draft labels submitted for EPA review must follow the application procedures in 40 CFR 152.50. In addition, registrants are encouraged to follow the other steps outlined below to facilitate review. Registrants are also highly encouraged to submit applications and labels electronically, which increases review efficiency and improves the quality of labels provided to the public via the Pesticide Product Label System.

## A. Paper submissions

Paper submissions for new registrations or amendments must include five copies of all draft labeling (typescript or mock-up). <u>40 CFR 152.50</u>. For amendments, the Agency requests one marked copy of the draft label, indicating proposed changes. The other four copies should be "clean" and not annotated in any way, containing the proposed label changes.

All copies must be legible and should be of suitable quality for making legible photocopies. Draft labels should be submitted on standard, letter-sized 8 %" X 11" paper, set in at least 12-point font size.

Under current practices, submitting five copies of draft labeling may be unnecessary. Registrants should consult with the product manager or registration ombudsman before submitting a paper application with labels.

#### **B.** Electronic submissions

Registrants can submit draft labeling <u>electronically</u> using various methods depending on the type of application package.

- ➤ Electronic label with paper application: An electronic label ("e-label") as a text-searchable .pdf file may be submitted on a CD-ROM or DVD along with a paper application. In this case, only one paper copy of the label needs to be submitted with the paper application. A <a href="Certification with Respect to Label Integrity">Certification with Respect to Label Integrity</a> form must be completed and submitted with the e-label.
- ▶ Electronic label with electronic application: An e-Submission package can be generated and submitted using the Pesticide Submission Portal (PSP) through EPA's Central Data Exchange (CDX) Network, the e-Dossier Builder, or by using an XML file creation application. The e-label must be a text searchable .pdf file. No paper copies for any documents, including labeling, are needed with an e-Submission.