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# Label Review Manual

## Chapter 11: Directions for Use



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## What's changed in this version?

- Added *Table of Contents*.
- Added *What's changed in this version?* section.
- Updated hyperlinks.
- Editorial changes to text and style to improve readability.
- Revised resistance management section based on PR Notices 2017-1 and 2017-2.
- Under Section IX.B.1., added the additional tank mix statement example: "It is the pesticide user's responsibility to ensure that all products in the listed mixtures are registered for the intended use. Users must follow the most restrictive Directions for Use and precautionary statements of each product in the tank mixture."
- Expanded all references to RED/reregistration to also include registration review and decision documents for clarity.
- Added a Maximum Application Rate Section.
- Provided more concise examples throughout the chapter.
- Moved "Standard Elements" section to appear earlier in the chapter.

## I. Introduction

This chapter outlines the basic elements of the Directions for Use section of the label and provides a review strategy for ensuring that this information is presented in a clear, concise, and effective manner.

## II. Purpose

The Directions for Use section of the label describes how the pesticide product can legally be used and how it must not be used. [40 CFR 156.10\(i\)](#) provides the specific requirements for the Directions for Use section; but in general, the necessary components are:

- the site(s) where the product can be used;
- the pest(s) that the product can be used to control;
- the application method(s) that are required and/or prohibited;
- the application rate(s) for how much pesticide can be applied; the maximum application rates (pounds of active ingredient per treatment and per calendar year);
- use restrictions for factors such as weather, time of day, season of the year, contamination of sensitive areas, exposure of non-target species, etc.;
  - [“Bulletins Live”](#) on the EPA website is a resource to view restrictions to protect endangered species;
- how often the pesticide should or can be applied;
- all restricted entry intervals (REIs) pertaining to existing uses, if applicable;
- pre-harvest intervals (PHIs), if applicable; and
- any other requirements for safe and effective use of this product, as necessary.

The Directions for Use reflect the Agency’s determination that the use of the product in the manner described does not cause unreasonable adverse effects on the environment under FIFRA. The Directions for Use section should be organized and carefully worded so that the directions are understood by the person expected to use or to supervise the use of the pesticide.

Sentences should be written to indicate whether any actions are mandatory or advisory. Other sentences in the use directions may be used only to convey background information.

## III. Enforceability

The Directions for Use should clearly distinguish the directions that are intended to be enforceable from those that are intended for informational purposes. The following list presents ways to help eliminate some common enforceability problems in the Directions for Use:

**Any direction that is necessary to achieve effective, safe use of the product must be stated in**

**mandatory terms (e.g., “must,” “will,” “do not”).** If the directions are intended to be **mandatory**, do not allow the use of terms such as “can,” “should,” or “may.” See [PR Notice 2000-5](#) and Chapter 3 of this manual for more information on mandatory versus advisory language.

**Any direction that is not truly necessary for effective, safe use of the product, or which is too vague or subjective for a user to clearly follow, must NOT be stated in mandatory terms.** Such informational or advisory statements should be factual and provide a reason for the desired behavior.

**Use terms with specific definitions whenever possible.** Terms that are defined in FIFRA, by federal agencies, or give clear instruction are preferable. For example, terms such as “near,” “around,” and “windy” do not have clear definitions and may cause confusion. A clear statement, such as “do not apply when wind speeds are in excess of X mph,” is preferable to “windy.” As another example, [USDA soil classifications](#) should be used when defining soil types and [textures](#) (e.g., “sandy loam,” “silt”).

**Clearly separate advisory and mandatory statements.** Intermingling advisory and mandatory language can cause confusion and make the intent of the statement(s) or an entire section unclear. If separation is not practical, the intent of each statement as mandatory or advisory needs to be clear.

**Ensure that section headings are appropriate for the directions contained within.** For example, if a heading includes the term “recommended,” then the directions within that section are intended to be advisory and not mandatory for safe and effective use of the product.

**“For Use Only by” statements should not be approved unless they refer to a group that can be clearly defined by FIFRA, an applicable regulation, or an EPA policy which has defined an identifiable group of users—such as persons licensed by the state for termite control ([PR Notice 96-7](#)) or employees of mosquito control agencies ([PR Notice 2005-1](#)).** For example, statements such as “For professional use only” or “For commercial use only” do not have accepted definitions, and the apparent “limitation” is meaningless, unenforceable and may be considered misleading.

**Limit use of “avoid” when possible.** The Agency views the term “avoid” as mandatory; however, EPA also recognizes that some pesticide users may perceive the term as advisory or may interpret it as a weaker statement than the clear prohibition of “do not.” Reviewers should strongly discourage the use of the word “avoid” for this reason.

## IV. Standard Elements

All standard elements and language required by FIFRA and the applicable regulations to appear in the Directions for Use must be placed on the label in the locations specified for them if FIFRA

or applicable regulations do specify a location; however, not all elements have such a specified location. These elements should be presented on the label:

- Directions for Use heading;
- Use classification statement;
- Misuse and related statements;
- Worker Protection Standard (WPS) requirements (if applicable);
- Instructions and information subheading (if applicable);
- Use Restrictions (if applicable);
- Resistance management recommendations (if applicable);
- Chemigation information (if applicable);
- Spray drift language (if applicable);
- Endangered species statement (if applicable);
- Storage and disposal statements.

### A. Directions for Use heading

The heading of the Directions for Use section of the label must be “Directions for Use,” and may not have any other title. [40 CFR 156.10\(i\)\(2\)](#). Headings such as “General Directions,” “Use Directions,” “Recommendations for Use,” “Recommended Uses,” “How to Use,” or any other similar wording are not acceptable.

The heading “Directions for Use” may be capitalized, put in bold type, and/or underlined for emphasis. The heading must be of such prominence and placement on the label that it is clear that all subsequent components of the section fall under the main heading “Directions for Use.” Such prominence can be assured by putting the heading in the largest, most conspicuous type that is used in the section and by centering the heading on the label panel while left-justifying all subheadings within the section.

### B. Use classification statement

If a product is classified as restricted use the label must bear the phrase “Restricted Use Pesticide” under the heading “Directions for Use.” [40 CFR 156.10\(i\)\(2\)\(i\)](#). The phrase “Restricted Use Pesticide” must meet the minimum type size requirements of the human hazard signal words. [40 CFR 156.10\(i\)\(2\)\(i\)](#). Consult Chapter 6 of this manual for further guidance on restricted use pesticide label requirements.

### C. Misuse statement

Under [40 CFR 156.10\(i\)\(2\)\(ii\)](#), Experimental Use Permits and all registered pesticides, including all end-use and manufacturing use products, must bear labeling which has the following statement immediately below the use classification:

*“It is a violation of Federal law to use this product in a manner inconsistent with its labeling.”*

Other statements relating to misuse, such as those listed below, are acceptable for residential/household use products. These additional statements can appear on the label following the required general misuse statement mentioned above:

*“STOP! Read the label before using.”*

*“Use only as directed on this label.”*

*“Read label very carefully, including any special requirements which pertain to your growing area.”*

*“Failure to follow all precautions and directions is illegal.”*

### D. Worker Protection Standard (WPS)

The Worker Protection Standard (WPS) regulations ([40 CFR Part 156, subpart K](#)) require certain statements on the labeling of all pesticide products within the scope of the WPS. Required WPS statements should appear after the general misuse statement under the heading Agricultural Use Requirements ([40 CFR 156.206](#)). WPS statements generally include the subheadings General Statements, Restricted Entry Interval (REI), and Notification to Workers Statements.

The following statements must appear on all WPS labels near the beginning of the Direction for Use section of the labeling:

*“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”*

*“For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.”*

Chapter 10 provides the information necessary to determine whether the label under review is subject to the requirements of the WPS and specifies how the WPS requirements must be presented on the label.

### E. Instructions and information subheading

Labels may include a section containing instructions that explain how the product works and provide information that is applicable to all the use sites and pests listed on the label.

### F. Use restrictions

Non-site-specific restrictions or limitations of the product comprise another important type of use restriction information in the Directions for Use section. Such a restriction may consist of an imperative sentence—practically any sentence that begins with a verb and ends in a period—or any other sentence which requires or forbids certain action (see Chapter 3 on mandatory vs.



advisory language). Use restrictions may also be phrased as requirements by using words such as “must,” “never,” and “always.” Any restrictions that apply to specific site(s) and pest(s) must be included in the directions specific to that combination. Use restrictions may be required by the Agency to meet the unreasonable adverse effects standard or proposed by the registrant or applicant. Such restrictions may include, but are not limited to, the following categories:

- user restrictions;
- rate restrictions or limitations;
- site, pest, timing, weather, soil, geographic restrictions;
- equipment or application method restrictions;
- miscellaneous precautions such as staining, phytotoxicity, incompatibility with other products, etc.; and
- PHIs or rotational crop restrictions (unless site-specific).

### 1. Appropriateness of restrictions

The reviewer must carefully assess each restriction or limitation to make sure that it does not place on the product obligations that the user cannot reasonably carry out. For example, an aquatic herbicide for use in ponds and lakes might have the restriction: “POTABLE WATER: Delay the use of treated water for domestic purposes for a period of three weeks or until such time as an approved assay shows that the water contains no more than 0.1 ppm (herbicide active ingredient).” Because any number of applicators could be using the product in public ponds or lakes used by many households or municipalities, the applicator may have no reasonable way of complying with such a restriction. Either another risk mitigation measure must be developed, or the product should be given restricted use status.

Some proposed labels will contain various use restrictions desired by the registrant, (e.g., “Do not tank mix this product with [their competitor’s products],” or “Do not use this product for formulating into other products,” or other similar restrictions). Unless there is some risk-based reason for such use restrictions, such statements are not acceptable on product labels because they are false and/or misleading. Labels may prohibit use of the product on certain crop varieties based on risk or efficacy concerns.

When used in reference to the response of crops and weeds to the proposed pesticide product (e.g., an herbicide label), registrants should use the word “tolerant” instead of “resistant.” For example, the label should refer to the use of the product on herbicide tolerant crops, not herbicide-resistant crops.

### 2. Use-related restrictions

Any other appropriate information (precautions or restrictions) should be presented in the restrictions subsection unless such statements apply only to some of the uses

permitted by the label, in which case the statements belong with directions for specific site and pest groupings. Use related information can include restrictions regarding the timing of application, weather, soil conditions, geography, or other relevant considerations. This information should be appropriate for the intended user(s), site(s), and pest(s) listed on the label.

### 3. Use restrictions for specific ingredients

The label reviewer needs to check the Confidential Statement of Formula to determine if peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, milk, crustacean, or wheat commodities are listed. The reviewer should be aware that the presence of these common food allergens in pesticide products limits the acceptable use sites and application methods found in the Directions for Use. If the product contains these ingredients, evaluate the label use directions for compliance with the uses specified in the tolerance exemption at [40 CFR 180.1071](#).

## G. Resistance management

The Office of Pesticide Programs (OPP) of the EPA has developed pesticide resistance management labeling guidelines based on target mode of action (MOA) for agricultural uses of pesticides ([PR Notice 2017-1](#) and [PR Notice 2017-2](#)). MOA refers to the biochemical mechanism by which the pesticide acts within the pest and should not be interpreted to imply that these chemicals share a common toxicological mechanism for purposes of cumulative human health risk assessment under FIFRA and FFDCA.

Rotation of MOA chemistries were selected as a primary pest/pesticide resistance management strategy for this voluntary regulatory initiative, because it is the easiest option to implement to reduce the likelihood of resistance developing in target pests. The rotation of MOA is a scientifically-sound, flexible, and practical resistance management strategy. Other management practices that will reduce resistance include application timing, crop rotation and other cultural practices, and application equipment cleaning. The voluntary resistance management guidelines based on rotation of MOA are found in [PR Notice 2017-1](#), which supersedes [PR Notice 2001-5](#), and is similarly described for herbicides in [PR Notice 2017-2](#).

These guidelines were developed under the auspices of the North American Free Trade Agreement (NAFTA) by both the U.S. and Canada. Canada published similar guidelines to those of the U.S. in October 1999 and subsequently updated these guidelines in December 2013 under [Regulatory Directive 2013-04](#). Both countries agreed that uniform labeling guidance across North America would encourage adoption of resistance management strategies and help reduce the development of pest resistance. In support of these goals, the resistance management guidelines based on rotation of MOA provide guidance to users about pesticide classes and pesticide management

strategies. Adoption of these guidelines will provide users with easy access to information regarding target site/MOA resistance.

The objective of the resistance management labeling guidelines is to include pesticide mode of action symbols and resistance management recommendations on the labels of all new and existing pesticide products for agricultural uses. The management of pesticide resistance is an important part of sustainable pest management and this, in conjunction with alternative pest management strategies and Integrated Pest Management (IPM) programs, can make a significant contribution to reducing pesticide risk to humans and the environment.

### 1. Mode of action information

To ensure consistency in pesticide grouping and labeling, and to contribute to the management of pesticide resistance, the following labeling guidelines have been developed for all pesticides except for products that will be marketed exclusively to homeowners. The classification schemes shown in this section are based on the mode of action. Herbicides, fungicides/bactericides, and insecticides/acaricides are separately grouped according to their primary modes of action by various Resistance Action Committees (RACs). Typically, these committees consist of representatives of the pesticide industry, researchers, extension specialists, and regulatory officials. The pesticide groupings are provided by the [Herbicide Resistance Action Committee \(HRAC\)](#), the [Fungicide Resistance Action Committee \(FRAC\)](#), and the [Insecticide Resistance Action Committee \(IRAC\)](#). The MOA group identifiers may be accessed through the websites of the different RACs. If a product contains an active ingredient that currently does not have a known mode of action, registrants should use the “Unknown” group identifier, if the RAC uses this for the specific active ingredient. If the active ingredient is not included in an “Unknown” grouping by the RAC, the MOA group information box can be omitted, but generic resistance management guidance statements, as directed by PRN 2017-1, should be retained on labels. For plant growth regulators (PGRs) please consult the product manager to determine whether a MOA box is needed.

Manufacturers, producers, formulators, and registrants of herbicide products and devices should refer to the Pesticide Registration Notice (PRN) [2017-2](#) for guidance on herbicide-resistance management, labeling, education, and training.

**For herbicides**, the EPA recommends that registrants and staff use the grouping scheme maintained on either the WSSA or [HRAC website](#) to locate the MOA information that is current for the active ingredient involved. This recommendation modifies the relevant statement in PR Notices 2017-1 and 2017-2 which asked readers to use the WSSA MOA groupings only. This modification has been made because after the PRNs were issued, WSSA and HRAC worked together to develop a single set of MOA groups that both organizations provide on their websites.

**For fungicides and bactericides**, FRAC uses letters and numbers to classify groups according to their biochemical MOA in the biosynthetic pathways of plant pathogens. EPA recommends that the FRAC MOA identifier codes ([FRAC code list](#)) be used on fungicide labels.

**For insecticides and acaricides**, IRAC uses a combination of numbers and letters to identify various MOA groups. The letters “UN” are used for insecticides with unknown or uncertain MOA. EPA recommends that the [IRAC MOA identifiers](#) be used on insecticide labels.

### 2. Mode of action information box

The recommended MOA code should be provided on the end-use product label in a mode of action information box using the following standard format:

- **Location:** Upper right corner of front panel of label.
- **Content:**
  - Include the name of the ACTIVE INGREDIENT in the first column.
  - Include the word “GROUP” in the second column.
  - Include the MODE OF ACTION CODE in the third column.
  - Include the type of pesticide (e.g., HERBICIDE, FUNGICIDE, or INSECTICIDE) in the fourth column.
- **Appearance:** All text should be capitalized in black, bold font on a white background; except for the MOA code, which should be capitalized in white, bold font on a black background. Each column should be outlined using a solid, black border.

<b>ACTIVE INGREDIENT</b>	<b>GROUP</b>	<b>MOA CODE</b>	<b>TYPE OF PESTICIDE</b>
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### 3. Mode of action information box examples

The following are mode of action information box examples for various pesticide product scenarios:

- **Products containing a single active ingredient with a single MOA code.**

<b>DINOTEFURAN</b>	<b>GROUP</b>	<b>4A</b>	<b>INSECTICIDE</b>
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- **Products containing a single active ingredient with multiple MOA codes for same or different pesticide types.**

For products containing an active ingredient that has multiple MOA groups for either the same or different pesticide types, include all applicable MOA

codes.

TOLFENPYRAD	GROUP	21A	INSECTICIDE
		39	FUNGICIDE

➤ **Products containing multiple active ingredients.**

For products containing multiple active ingredients, include all applicable MOA codes for each active ingredient.

TEBUCONAZOLE	GROUP	3	FUNGICIDE
IMIDACLOPRID	GROUP	4A	INSECTICIDE

QUINCLORAC	GROUP	4	HERBICIDE
2,4-D	GROUP	4	HERBICIDE
DICAMBA	GROUP	4	HERBICIDE

QUINCLORAC	GROUP	4	HERBICIDES
2,4-D			
DICAMBA			

➤ **Products containing more than one registered product that are packaged and sold as a single unit (co-packs).**

The outer packaging label of a co-pack product should include the MOA information boxes of each component. The container label of each individual component should also include the appropriate MOA information box.

Outer packaging label

**COMPONENT A**

TEBUCONAZOLE	GROUP	3	FUNGICIDE
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**COMPONENT B**

CHLOROTHALONIL	GROUP	M05	FUNGICIDE
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Individual component container label

[Container label of Component A]

TEBUCONAZOLE	GROUP	3	FUNGICIDE
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[Container label of Component B]

CHLOROTHALONIL	GROUP	M05	FUNGICIDE
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#### 4. Resistance management statements

In addition to the MOA classification symbols, a registrant should have applicable resistance management statements on end-use product labels. If used, these statements should be included in the Directions for Use section for the control of weeds, plant pathogens (diseases), insects and mites under the heading “Resistance Management Recommendations.” These statements should be clearly distinguished from mandatory statements to avoid confusion to users.

[PR Notice 2017-1](#) provides examples of standard resistance management labeling statements that focus on the following areas: (1) avoid repeated or sequential use of products in the same MOA class through rotation of MOA; (2) if tank mixes or premixes are legally allowed, makes sure each compound is from a different MOA class; (3) use an effective IPM program; (4) monitor for loss of product performance; (5) contact your extension specialist, certified crop consultant, or manufacturer for the latest resistance management information; and (6) contact the pesticide producer to report loss of efficacy. Registrants may propose alternate resistance management labeling statements that address these areas.

Registrants who have specific mandatory statements regarding resistance management must avoid placing them under the Resistance Management Recommendations section, which is guidance and not mandatory for end-users to follow, and should be placed elsewhere (e.g., Use Restrictions).

Herbicides are the focus of a related PR Notice (PRN 2017-2) Since this guidance is more detailed, a brief description follows below.

#### 5. Herbicide resistance management statements

[PR Notice 2017-2](#) describes the standard resistance management labeling statements recommended for herbicides. Labels should include the following information (examples provided in italics):

- **Clearly express all currently required application parameters and product information on the label, including: maximum dose per application, maximum**

**dose per calendar year, and maximum number of applications per calendar year.**

*“Apply [X lb] of product ([X lb active ingredient]) per acre per calendar year.”*

*“Do not apply more than [X lb] of product ([X lb active ingredient]) per acre per application.”*

*“Do not make applications less than [X] days apart.”*

*“Do not apply more than [X lb] of product ([X lb active ingredient]) per acre per calendar year.”*

➤ **Recommendations that the field should be scouted both *before* and *after* pesticide application.**

*“Fields should be scouted prior to application to identify the weed species present and their growth stage to determine if the intended application will be effective.”*

*“Fields should be scouted after application to verify that the treatment was effective.”*

➤ **Label statement defining suspected resistance.**

*“Suspected herbicide-resistant weeds may be identified by these indicators: (1) failure to control a weed species normally controlled by the herbicide at the dose applied, especially if control is achieved on adjacent weeds; (2) a spreading patch of non-controlled plants of a particular weed species; and (3) surviving plants mixed with controlled individuals of the same species.”*

➤ **Label statement that the user should report lack of performance to the registrant or their representative and proactively take action.**

*“Report any incidence of non-performance of this product against a particular weed species to your [company] retailer, representative, or call [phone number]. If resistance is suspected, treat weed escapes with an herbicide having a different mechanism of action and/or use non-chemical means to remove escapes, as practical, with the goal of preventing further seed production.”*

➤ **Label statements describing best management practices for resistance management.**

*“Plant into weed-free fields and keep fields as weed-free as possible.”*

*“To the extent possible, use a diversified approach toward weed management. Whenever possible incorporate multiple weed-control practices such as mechanical cultivation, biological management practices, and crop rotation.”*

*“Fields with difficult to control weeds should be rotated to crops that allow the use of herbicides with alternative mechanisms of action or different management practices.”*

*“To the extent possible do not allow weed escapes to produce seeds, roots or tubers. Manage weed seeds at harvest and post-harvest to prevent a buildup of the weed seed-bank.”*

*“Prevent field-to-field and within-field movement of weed seed or vegetative propagules. Thoroughly clean plant residues from equipment before leaving fields.”*

*“Prevent an influx of weeds into the field by managing field borders.”*

*“Identify weeds present in the field through scouting and field history and understand their biology. The weed-control program should consider all weeds present.”*

*“Difficult to control weeds may require sequential applications of herbicides with differing mechanisms of action.”*

*“Apply this herbicide at the correct timing and rate needed to control the most difficult weed in the field.”*

*“Use a broad-spectrum, soil-applied herbicide with a mechanism of action that differs from this product as a foundation in a weed-control program. Do not use more than two applications of this or any other herbicide with the same mechanism of action within a single growing season unless mixed with an herbicide with another mechanism of action with an overlapping spectrum for the difficult-to-control weeds.”*

*“If resistance is suspected, treat weed escapes with an herbicide with a different MOA or use non-chemical methods to remove escapes.”*

➤ **Label statements on local resistant weeds.**

[For products formulated as a single active ingredient.]

*“Contact your local sales representative, crop advisor, or extension agent to find out if suspected resistant weeds to this MOA have been found in your region. If resistant biotypes of target weeds have been*



*reported, use the application rates of this product specified for your local conditions. Tank mix products so that there are multiple effective mechanisms of actions for each target weed.”*

[For products that are mixtures of herbicides.]

*“Contact your local sales representative, crop advisor, or extension agent to find out if suspected resistant weeds to these MOAs have been found in your region. Do not assume that each listed weed is being controlled by multiple mechanisms of action. Co-formulated active ingredients are intended to broaden the spectrum of weeds that are controlled. Some weeds may be controlled by only one of the active ingredients in this product.”*

### H. Chemigation

Review of labels for agricultural uses, nursery uses, uses on golf courses, sod farms or in greenhouses should be conducted with reference to the guidance contained in [PR Notice 87-1](#) (chemigation), unless the product is solely for residential use, direct injection into plants, post-harvest application, or is applied as a gas or solid (pellets, tablets, granules, or dusts). Subject labels (as specified above) must either include labeling statements regarding chemigation contained in PR Notice 87-1 or the statement:

*“Do not apply this product through any type of irrigation system.”*

Any product used on agricultural sites that may be applied by chemigation should contain information such as the following:

- types of irrigation systems to be used;
- consequences of improper chemigation;
- to whom questions about chemigation can be directed;
- warnings against connecting irrigation equipment to public water supplies without safety mechanisms;
- personnel required for adjustment of chemigation equipment; and
- statements required for Toxicity Category I products.

Note [PR Notice 87-1](#) contains the complete wording of all the chemigation text categories indicated above. Check relevant decision documents for any chemigation text specific to the active ingredient(s) in the product under review.

### I. Mandatory and Advisory Spray Drift Language

Generic label language for spray drift prevention is still pending. In the meantime, OPP is developing spray drift management label language on a case-by-case basis. Typically, risk from

potential spray drift, based on the use patterns for any given product will be identified in the risk assessment. The label reviewer should check the relevant decision documents for required spray drift language as well as work with the risk assessors to craft appropriate spray drift risk mitigation statements.

### J. Endangered species

To address Endangered Species Act and FIFRA obligations, some products are required to carry a statement informing the user of potential risk to endangered species. This language will generally be required only after the Agency has created an Endangered Species Protection Bulletin (Bulletin) following EPA's determination, informed by an endangered species risk assessment, that additional use restrictions are necessary to address risks to listed species. The Bulletins will contain all necessary information to convey the use limitations. Because compliance with these Bulletins will be a requirement of product labeling, any restrictions in the Bulletins will be enforceable under FIFRA.

If the Agency has determined that a product requires endangered species labeling, EPA will request that the registrant amend its labeling to place the following statement at the beginning of the Directions for Use section under the heading "ENDANGERED SPECIES PROTECTION REQUIREMENTS:"

*"This product may have effects on endangered species. When using this product, you must follow the measures contained in the Endangered Species Protection Bulletin for the county in which you are applying the product. To obtain Bulletins, no more than six months before using this product, consult <http://www.epa.gov/espp/> or call 1-800-447-3813. You must use the Bulletin valid for the month in which you will apply the product."*

This statement is intentionally generic and cannot be altered by staff absent the approval of senior OPP management. No geographically specific endangered species statements can appear on the label in conjunction with this statement, as it specifically references Bulletins. If geographically specific endangered species information appears on the labeling as a means of addressing the risks to listed species, EFED, AD, or BPPD should be notified as appropriate so they may incorporate any such geographically specific information into the referenced Bulletins.

### V. Use Sites

All application or treatment site(s) must be clearly identified on the label and clearly associated with the pest controlled. Many labels identify such sites near the beginning of the use directions (e.g., in the "Use Restrictions" subsection) and/or in the text presenting specific application directions.

### A. Consistency of listed sites

Wherever the sites are listed on the label, they must be consistent with sites listed elsewhere on the label. For example, if the front panel lists ornamentals as a site, then the Directions for Use must include the appropriate treatment directions for ornamentals.

### B. Complete site information

Treatment sites must be clearly identified. For example, if residential sites are listed as an application site, exactly where the pesticide is applied must be specified (e.g., bathrooms or kitchens). Reviewers should require the use of the most specific site terminology reasonable. If possible, refer to site indices in OPPIN to identify appropriate site terminology but avoid the use of site categories that would be awkward or confusing on a label (e.g., domestic dwellings). The use of uniform site terminology is useful for the purposes of exposure reviews. The label reviewer may need to inform the registrant that the application sites need to be identified more specifically, for example, cracks and crevices in kitchen areas of residences instead of “dwellings.”

### C. Site groupings

If the use site is indicated by a broad crop grouping, such as “ornamentals,” the registrant should be instructed to specifically identify sites on which the product may be applied in the Directions for Use: “Ornamentals: Christmas tree plantings, conifer seed orchards, and rhododendrons.” In this example, the product user is restricted to using the product only on those three use sites. However, if a use site were indicated as “Non-cropland industrial sites, such as, airports, fence rows, roadsides, and associated rights -of-ways”, then the user could use the product on any place that would fall under the category as non-cropland industrial sites. Reviewers should not accept an open-ended site list, including those extended by “such as”, lists ending with “etc.”, or ‘other [such use sites]’ or lists beginning with “including”.

### D. Site-pest considerations

Site-pest combinations must be appropriate. Pests for which control is claimed must occur as pests at the sites with which the label associates them. Claims for control of a pest on or at an inappropriate site could mislead the user and possibly result in a misapplication of the pesticide. Examples of inappropriate pest/site claims include control of algae in toilet bowls and brown dog ticks in commercial kitchens. If such inappropriate site-pest combinations are detected during label review the registrant must be advised that such claims are unacceptable.

### E. Sites and the intended user

The listed sites should be appropriate for the intended end-user. For example, sites listed on the

labels of residential use products should be typical household/garden sites and not commercial agricultural sites such as cotton, tobacco, or cranberries.

## VI. Target pests

The term pest is defined by statute and by regulation in [FIFRA 2\(t\)](#) and [40 CFR 152.5](#). The label must clearly state the pest(s) (associated with a site) that are controlled by the product ([FIFRA 2\(ee\)](#)). Pest claims may be made in the Use Restrictions section or with specific application instructions. In addition, pest claims often may appear on the front panel as part of the name of the product or in promotional statements appearing under the product's name or elsewhere on the label.

### A. Consistency of listed pests

Wherever the pests are listed on the label, they must be consistent with pests listed elsewhere on the label. For example, if the front panel lists fire ants as a target pest, then the Directions for Use must include the appropriate treatment directions for fire ants. If the front panel lists several pests and then references other pests controlled by using phrases like “and more,” “plus others,” or “and many more,” these phrases will only be acceptable if they are followed by a direct reference to the Directions for Use section for the complete listing of pests controlled, e.g., “and more listed on the back panel.” The reviewer must make sure that the Directions for Use is included and are applicable to all pests listed on the labeling to ensure that the product is not misbranded.

### B. Pest groupings

While target pests may be named generically in the Directions for Use section of some labels (e.g., ants), other labels may be more specific (e.g., carpenter ants). In the case of public health antimicrobial products, however, each strain of a pest listed on the label must be supported by appropriate efficacy data so that both the common and generic terms may be used if appropriate. The Directions for Use should be determined by and reflect the strain, location, and behavior of the pest as closely as possible.

### C. Product formulation and pests

When evaluating the target pests, it is important to keep in mind the relationships among pests, application methods, and product formulations. For example, a liquid formulation of a pesticide such as parathion restricted to foliar aerial application would be unlikely to control soil-inhabiting insects such as corn rootworm larvae. If the reviewer is unsure whether a formulation could be expected to control a certain pest on a label, the reviewer must consult with the appropriate efficacy reviewer(s). The applicant must be informed if the proposed use is not found to be acceptable. The applicant may appeal such a decision. Typically, the applicant would

then be required to supply information (such as product performance data) to the Agency indicating that its formulation is appropriate for the proposed use.

### D. Pest-site considerations

The pests listed on the label should be appropriate for the intended use sites for the product. For example, pests listed on the labels of residential/household use products should be typical household/garden pests. An agricultural crop specific pest such as the cotton bollworm would not be an appropriate pest claim for the label of a product intended only for use around the home.

## VII. How the product is prepared and handled

Complete information on how to prepare, handle, and apply the pesticide product must appear on the label. In order to satisfy the unreasonable adverse effects standard of FIFRA, label reviewers will, on occasion, need to disapprove of or modify label language submitted in the application for registration. Such modification may take the form of specific prohibitions (“Do not apply this product by use of aircraft”) or general statements limiting use to methods indicated on the label (“Apply this product only by the methods listed and described on this label.”)

### A. Formulation type

Information regarding the product’s formulation is essential for the proper preparation, handling, and application of a product. For example, the label must clearly identify the formulation type of the product (dry, liquid, bait, or a gas, such as certain fumigants). The label must also specify if the formulation is “ready-to-use” or a concentrate which requires dilution and/or mixing. Aerosols, dusts, baits, granules, and some liquids are examples of ready-to-use formulations.

### B. Mixing instructions

Some products must be mixed or diluted with other materials prior to application for pest control purposes. Labels for liquid formulation identified as concentrates, and dry products identified as “wettable powders” must have directions for mixing or diluting. Mixing directions must be as clear as possible and presented in easily measurable units (e.g., not “add 2.678 ounces to a gallon”). The units of measurement must be units by weight for dry formulations (e.g., pounds, ounces), and units by volume for liquids (e.g., pints, quarts, fluid ounces) or their standard abbreviations. One of the most frequent labeling errors observed is the use of “oz.” for liquids instead of “fl. oz.” Metric units may be used in parentheses after the standard units. The diluent must be specified, even if it is water. A standard unit of measurement on some labels is

parts per million (ppm).

Dilution instructions may be presented in the form of a chart or table. Basically, the dilution directions should state mix “X” amount of pesticide with “Y” amount of water (or other diluents such as oil) to achieve a particular dilution, such as a 1% emulsion.

While the label may include a general statement such as “Use sufficient water to obtain full coverage of foliage,” the label also should give specific directions indicating the appropriate amount of spray volume to apply per unit area for aerial and ground applications. It also may be necessary for the label to indicate the diluent spray volume amounts for aircraft or ground equipment.

### 1. Tank mixing

When the label bears a reference to mixing with other products, the Agency recommends including one of the following statements:

*“It is the pesticide user's responsibility to ensure that all products in the listed mixtures are registered for the intended use. Users must follow the most restrictive Directions for Use and precautionary statements of each product in the tank mixture.”*

*“It is the pesticide user's responsibility to ensure that all the products are registered for the intended use. Read and follow the applicable restrictions and limitations and Directions for Use on all product labels involved in tank mixing. Users must follow the most restrictive Directions for Use and precautionary statements of each product in the tank mixture.”*

Please refer to [PRN 82-1](#) for further guidance on label claims for tank mixing.

## C. Compatibility with other products

EPA will not accept or require a label prohibition against the use of one pesticide product with another product unless that statement is necessary to protect human health or the environment, or to prevent illegal pesticide residues under Federal Food, Drug and Cosmetic Act (FFDCA). For example, a label statement prohibiting the mixing of products, if mixing would cause an explosive chemical reaction, would be acceptable. When compatibility with other pesticides or liquid fertilizers is being addressed, the label should include specific instructions or recommend a jar test.

## VIII. Application information

What goes in this subsection will vary considerably according to the type of pesticide product and the intended user. However, this subset of the Directions for Use section should indicate use precautions and restrictions that apply to all sites and pests claimed on the label. For

products with many registered uses, it may be useful and efficient to provide separate directions which pertain to specific sites and pest combinations claimed for the product. In such cases, each site and pest would have its own subsection which would be further divided into subsections such as “USE RESTRICTIONS” and the other elements specific to that grouping.

Some requirements specific to how the products are to be applied might be more efficiently placed under subsections pertaining to applications rather than under “USE RESTRICTIONS.” The Use Restrictions subsection generally indicates the following:

- the pests for which control is claimed;
- the sites where the product may be used;
- any FIFRA 2(ee) restrictions; and
- other use restrictions such as those pertaining to chemigation, spray drift, seasonal, weather or time-of-day restrictions, requirements intended to protect non-target species or contaminations of food or feed crops, and other basic requirements pertinent to safe and effective use of the product.

### A. Timing

The label should clearly specify when the product should be applied to maximize the effectiveness of the product while complying with any regulatory requirements. If appropriate, the season, and/or the stage of growth of the plant when the pesticide is to be applied should be specified. Other timing/application descriptions include pre-planting, at planting, post-harvest, dormant, or delayed dormant. If one of these timings is present, it should be so stated in a Special Directions column. The label’s information concerning the timing of applications needs to be consistent with any regulatory intervals specified in OPP’s regulatory documents to mitigate risk from residues of the active ingredient (or product).

#### 1. Regulatory intervals to mitigate risk

The label reviewer should check the residue chemistry assessment and decision documents to determine if any restrictive intervals were identified for the product’s label. The residue chemistry assessment for a given product or active ingredient may specify the following types of intervals:

- Pre-harvest interval (PHI)
- Pre-slaughter intervals
- Pre-grazing intervals
- Pre-feeding intervals
- Pre-silage intervals

If required to meet the FIFRA standard, the PHI should be indicated as numbers of weeks or days. Pre-slaughter intervals and pre-grazing intervals should be expressed similarly.

### 2. Regulatory interval for antimicrobials

The key timing factor for antimicrobial disinfectants or sanitizers is the length of time the product must be in contact with the surface being treated for the treatment to be effective. This information should be clearly stated on the label and associated with the correct target organism. The final disinfectant test guidelines for use of antimicrobials on hard surfaces (OCSPP 810.2200) issued in 2012 specify that disinfection of hard surfaces be achieved within a disinfectant product contact time of 10 minutes or less.

## B. Application methods

### 1. Methods and types of equipment

The label must indicate the types of equipment that may be used in applying the pesticide. The type of equipment should be identified in a level of detail sufficient to promote safe and effective use of the product. For example, ground and aircraft sprayers should be described by type and performance requirements (output and safety specifications) to the extent that such descriptions are needed. The same concept applies to spreaders, injectors, burrow builders, and any other specialized equipment. Specific brands and models of equipment should not be indicated unless specific information is provided to indicate that only the brand and model are appropriate for reasons of safety or efficacy. Some types of equipment are designed specially to apply to particular types of pesticide or to interface with particular containers in which certain especially hazardous products are packaged. Use directions should prohibit use of types of equipment known to be inappropriate for handling the product or any of the mixtures that the label directs users to prepare. When the method of application and necessary equipment are specific to each site and pest combination, they should be indicated in the directions that pertain to each combination.

The label reviewer should make sure that the methods of application and equipment recommended are appropriate for the product formulation, the intended user, and the site and pest to which the pesticide product is being applied. Complete information on how to apply the product should be included. For example, the statement “*Apply this product to the soil.*” is not sufficient. Labels which state that the pesticide must be applied to the soil and immediately incorporated must specify what kind of equipment must be used.

### 2. Liquid spray instructions

Labels for liquid formulations generally refer to “spraying” the product as the method of application. Labels that have directions which instruct users to mix a spray solution should provide special instructions devoted to preparing spray mixes and indicate the spray volume to be applied per acre or per unit area. For some applications it may be



acceptable for the label to indicate, “*apply sufficient volume for thorough coverage*” or similar language. The following types of spray applications are generally used:

- **Space Spray.** Dispersal of the product into the air by foggers, misters, aerosol devices, or vapor dispensers for control of flying pests and exposed crawling pests.
- **General Area Spray.** Application to broad surfaces, such as walls, floors, and ceilings.
- **Spot Spray.** Application to small areas on which pests are likely to occur. These areas may be on floors, walls, bases, or undersides of equipment. To limit potential exposure in a commercial food area, a “spot” should not exceed two square feet.
- **Crack and Crevice.** Application of small amounts of pesticide into cracks and/or crevices in which pests hide or through which they may enter a building. Such openings commonly occur at expansion joints, between elements of construction, and between equipment and floors.

If a label being reviewed uses any of the application terms mentioned above, determine if the terms are appropriate, considering the use patterns on the label.

### 3. Dust formulations

For dust applications, a statement such as “*apply uniformly for thorough coverage of plant surfaces*” may adequately substitute for a specific application rate. However, a maximum application rate must be specified in order to avoid over-exposure.

### 4. Aerial applications

For aerial applications, spray volumes should be stated.

### 5. Spreader settings

Spreader settings vary from product to product. Such changes in spreader settings are not usually considered significant.

### 6. Total release foggers

If the product label being reviewed is a total release fogger that contains a highly flammable ingredient, the following label text must be included in the Directions for Use [40 CFR 156.10\(i\)\(2\)\(x\)\(D\)](#), preferably with this statement from [PR Notice 98-6](#):

*“DO NOT use more than one fogger per room. DO NOT use in small, enclosed spaces such as closets, cabinets, or under counters or tables. DO NOT use in a room 5 ft. x 5 ft. or smaller. Instead, allow fog to enter from other rooms. Turn off ALL ignition sources such as pilot lights (shut off gas valves), other open flames or running electrical appliances that cycle off and on (e.g., refrigerators, thermostats, etc.). Call your gas utility or management company if you need assistance with your pilot lights.”*

### C. Application rate

#### 1. Agricultural products

The actual application rate (e.g., how much product to apply per unit area or per placement) must be stated in the Directions for Use. Labels for agricultural products usually express the application rate in terms of pints/acre for liquid formulations, or pounds/acre for solid formulation. The Directions for Use for an agricultural pesticide used in a spray solution also must indicate the spray volume/unit area or other measurement of coverage, depending on the type of formulation.

#### 2. Residential use

Labels for residential use products should express the application rate in smaller units, such as fluid ounces per gallon or pounds per square foot. Such rates and units of measure are more appropriate for the dwelling, home garden or yard. Any pesticide application equipment required by a residential user should be readily available, like simple equipment such as drop-spreaders or hose-end sprayers. The public generally does not have access to (and does not use) specialized equipment. When percentages are included in application rates, it should be clear whether percentages are by weight or volume and whether the percentage refers to the product or active ingredient. Percentage application rates should never be used alone. The specific amount of product to use per unit area should always be clearly stated in the Directions for Use.

#### 3. Net contents and application rate

The Directions for Use should not call for use of more than the net contents of the product's container (i.e., if a granular product is packaged as a 1 lb. unit, its application rate should not require 200 lbs. of product). If the product is a liquid, the specified treatment rate should be fl. oz. or gal. per unit area. If a solid, the rate should be expressed oz. or lb. per unit area. Many labels of liquid formulations incorrectly omit the “fluid” (fl.) with the oz. when specifying application rate.

### 4. Minimum application rate

For certain justified reasons, minimum application rates are acceptable on product labels in certain situations. However, if either one of the reasons below cannot be documented, the minimum application rate should be stated in advisory language. Enforceable (mandatory) minimum application rates are only warranted for the following reasons:

- (a) When there is a risk that reduced application of the product may result in increased pest resistance to the active ingredient; or
- (b) When there is documentation that a product's efficacy is substantially compromised under a certain application rate.

### 5. Maximum application rate

Labels should state rates for maximum application parameters, including- the single maximum use rate (including corresponding lbs. of Active Ingredient (AI) or acid equivalent (ae)/acre), total maximum yearly application use rate (including corresponding lbs. of AI or ae/acre), maximum number of applications per year, minimum retreatment interval, and pre-harvest interval (PHI) for all uses. If the maximum rates are defined as maximum rates per crop season, the number of seasons in a calendar year should also be listed.

## D. Frequency of applications

The label should clearly specify how often the product should be applied to maximize the effectiveness of the product while complying with any regulatory requirements.

## E. Other information pertaining to specific applications

Other information may include: method of application, equipment, minimum volume of diluent for spraying for each type of equipment, phytotoxicity effects or warnings, and grazing or feeding restrictions. Liquid products should include a statement of weight (AI or ae)/volume (product).

## IX. Additional application information

This subsection of the Directions for Use may be given any of several headings, including *"Application Instructions," "How to Apply"* (especially for household/residential use), and *"Baiting"* as appropriate. In cases for which there is only one site/pest category but several application methods, it may be appropriate to have separate application subsections for each method (e.g., *"Area-wide Spraying," "Spot Treatment,"* etc.).

This Directions for Use subsection contains the specific instructions and information needed to apply the product on each relevant crop/site for each target pest. Directions may be grouped according to the sites and pests to be treated (e.g., broccoli, cabbage, cauliflower: cutworms, fall armyworms, cabbage loopers). If geographical restrictions are required, individual States or counties should be listed; geographical regions (e.g., the Northwest) are unacceptable because they are not specific enough to be enforceable.

Unique, detailed sets of application directions will be required for certain pests (e.g., fire ants, pocket gopher). Furthermore, fungicide grouping may be used ONLY if all pests occur and are controlled on all crops in the group. Plant diseases are commonly specific to a site, (e.g., Black Spot on roses). Any geographic restrictions need to be included with their appropriate sites/crops.

## X. Storage and disposal instructions

Labels for pesticide products are required to bear labeling instructions for the storage and disposal of pesticides and pesticide containers in the Directions for Use section of the label. It is preferred that the Storage and Disposal instructions appear at the end of the Directions for Use section. Storage and disposal instructions are covered in detail in Chapter 13 of this manual.

## XI. Review Strategies

This section presents strategies for reviewing the Directions for Use section of pesticide labels. It provides a list of key questions that reviewers must ask as they review the label. It also discusses some common problems and issues that reviewers face when reviewing the Directions for Use section.

### A. General strategy for all labels

#### 1. Charts, tables and formats

Labels should be easy to read and understand. The [Consumer Labeling Initiative \(CLI\)](#) research, as well as other label research done around the world, shows that in many cases graphics (e.g., charts, graphs, symbols, or pictures) can be used to help convey information and may be useful in the Directions for Use portion of the label. However, care needs to be taken that the graphics do not contain or imply false or misleading information and that they provide accurate information in a clear, concise, and complete manner.

Subheadings, like paragraph headings in a book, help to organize the information and make it easier to find. Information presented in a “bulleted” format is easier to read and understand than longer narrative paragraphs, even when the same type size is used.

When lengthier and complex information is required, a tabular format may be easier to follow.

Due to the variety in sizes and shapes of labels, not all format recommendations may work on all labels; however, consideration should be given to them whenever feasible. Products labels must remain consistent with applicable statutory and regulatory requirements. The following are some suggested formats:

### a. Bullet format

When using bullets, the intent is not to leave information out, but to make it visually easier to follow. Either partial or complete sentences can be used, and any bullet icon can be used. Numbers can also be used instead of bullets.

#### Example of Bulleted Format

##### **DIRECTIONS FOR USE**

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

##### **Precautions**

- Use may damage marble surfaces.

##### **Restrictions**

- Do not apply to porous surfaces.

##### **Application Instructions**

- Turn nozzle to “Spray” or “Stream.”

##### **For Cleaning:**

1. Hold nozzle 6-8 inches from surface.
2. Spray soiled area.
3. Wipe clean.
4. For surfaces in direct contact with food, a potable water rinse is required.

##### **To Control Mildew:**

1. Pre-clean surface.
2. Spray until the surface is visibly wet.
3. Let air dry.
4. Repeat weekly or when new growth appears.

##### **To Disinfect:**

1. For heavily soiled surfaces, pre-clean according to cleaning directions.

Let the surface remain visibly wet for 10 minutes before wiping or rinsing. For surfaces in direct contact with food, a potable water rinse is required.

### b. Modified paragraph format

The modified paragraph format presents text in a series of full sentences, like the old standard narrative format, but includes subheadings to make it easier to locate information. If a paragraph format must be used, it is helpful to the reader to include either subheadings, or to highlight key words/phrases. The language should be easy to understand and use correct grammar and punctuation.

#### Modified paragraph format examples

##### Application Instructions

**BROCCOLI** (7-day PHI): **Pests** (Aphids, Cutworms, Cabbageworms, Loopers); **Application Method** (Aerial, Ground); **Dose** (2.0-6.5 fl.oz./A); **Application Equipment** (Sprayer, Aircraft); **Timing** (Foliar); When applying by air, use 1-2 quarts of emulsified oil instead of water. **Restrictions:** Do not make more than 5 applications after bloom. Do not make repeat applications less than 7 days apart. Do not apply more than 1 qt of product (0.5 lb ai) per acre crop season. Do not apply more than 1 qt of product (0.5 lb ai) per acre per year.

##### Application Instructions

**FOR HOUSEHOLD USE:** SHAKE WELL BEFORE EACH USE. Apply only to surfaces listed on this label. Hold container upright 12" from surface and spray. Spray until surfaces are visibly wet. Over-wetting asphalt tile, rubber, and plastic materials may cause damage. Repeat treatment as necessary, but no more than once a week. **ROACHES, CRICKETS, SILVERFISH, SPIDERS:** Spray directly on insects when possible. Thoroughly spray cracks, baseboards, underneath kitchen shelves, and other places where insects live. **ANTS, EARWIGS:** Spray door sills, wood frames, outside foundations, and porches. Spray directly on ant hills. **FLIES, MOSQUITOES, GNATS, WASPS:** Apply on screens, walls, doors, window frames, and other surfaces where insects congregate.

### c. Table format

When the label is in a table format, make sure that all the appropriate information is included, that it is easy to follow, and that the types of information are clearly divided or discernible.

#### *Table Tips:*

- i.* Tables should be placed in consecutive numerical order.
- ii.* Tables that contain use directions should not have "Recommendations" in the table name.

*iii.* If the units are listed in the column headings, there is no need to repeat them in the columns below.

*iv.* Column headings should accurately represent information in the columns below, for example: if the heading is "Use Precautions" all the statements below should be precautionary.

Table format example				
Table 1. Crop Use Directions				
Crop	Disease	Product Rate (oz/A)	Instructions	Use Restrictions
Almonds	Brown rot blossom blight	5-10	Apply by ground or by air at 10% bloom. Use a minimum of 20 gal/A of spray by air.	Do not apply more than 30 oz/A of product (1.5 lb ai/A) per calendar year. Do not apply within 60 days of harvest.
Grapes	Botrytis bunch rot	10	Apply by ground or by air at early bloom.	Make no more than 2 applications by air. Do not apply more than 30 oz/A (1.5 lb ai/A) per calendar year. Do not apply within 7 days of harvest.

### 2. Answer key questions

The questions contained in the *Label Reviewer's Checklist* (see Appendix A) should be addressed when reviewing the Directions for Use section of the label. When answering these questions, the reviewer should consult, as appropriate, the references mentioned in the next section.

If a registrant claims to be modifying only one part of the Directions for Use section of a label, the reviewer must not assume that the rest of the section is acceptable even though the label has been accepted in the past. A complete review is advisable because:

- Some labels may be very old.
- Previously accepted uses and language may no longer be recommended.
- Agency regulations, policies, and/or guidance such as PR Notices may have been updated. Therefore, the entire Directions for Use section needs to be reviewed very carefully before accepting the label.

### 3. Consult essential document references


Label reviewers should use a variety of reference, guidance, and policy documents along with any applicable laws and regulations to make case-by-case determinations on the acceptability of label language. Reviewers should consult any relevant:

- Registration Review Decisions (e.g., IDs and FDs),
- Reregistration Eligibility Decisions (REDs, Interim Reregistration Eligibility Decisions (IREDs),
- Tolerance Reassessment Decisions (TREDs),
- Biopesticide Registration Action Documents (BRAD),
- Applicable product-specific data evaluation records (DER) and reviews,
- [Labels](#) of substantially similar or identical products,
- The Registration Standard (if not superseded by the RED or Registration Review decision),
- For new or revised uses, available science, technical, or efficacy reviews,
- The [40 CFR Part 180](#) for published tolerances supporting food/feed uses,
- Current [Pesticide Registration \(PR\) Notices](#), and
- Any additional guidance not listed in the categories above.

These records are available in a variety of locations, including but not limited to [OPP's Pesticide Chemical Search website](#), under a chemical-specific docket in Regulations.gov, the Pesticide Product and Label System ([PPLS](#)), or elsewhere on the EPA website. Pesticide Registration (PR) Notices inform pesticide registrants and



other interested persons about important policies, procedures, and regulatory decisions. PR Notices are important resources to help the label reviewer stay informed about current regulatory policies in OPP.

 If the product contains active ingredients that have been reassessed through reregistration and/or registration review, the reviewer must ensure that those active ingredients and their uses on the label are eligible for continued registration.

If a Reregistration Eligibility Decision (RED), interim registration review decision (ID), or final registration review decision has been issued for the active ingredient in the product undergoing review, the reviewer must ensure that:

- All the use sites on the label are in Appendix A of the RED, or sites that have been evaluated and approved by OPP in a subsequent regulatory document;
- All relevant and current reregistration or registration review label changes (from the label table) are captured;
- The site(s)/pest(s) are all eligible for reregistration; and
- If any of the uses have been declared ineligible for reregistration, the use may not be reregistered.

Further, if the product contains more than one active ingredient, *all uses on the label must be acceptable for all active ingredients*. If there is more than one active ingredient in the product and a RED, ID, or final registration review decision is available for each, all sites on a label must be listed in each RED or evaluated and approved by OPP in a subsequent regulatory document.

#### 4. Consult subject matter experts

The use directions can become very complex depending on the number of sites, pests claimed, and application methods. If a label seems to present problems of clarity, organization, enforceability, or consistency with EPA policy, reviewers should seek advice.

Reviewers should consult Product Managers (PMs)/team leaders or a member from the Pesticide Efficacy Review Committee (PERC). PM/team leaders may raise more difficult questions to their branch chief, OPP's Labeling Consistency Committee, or in cases of mandatory vs. advisory issues or other enforceability questions, may directly contact staff in the Office of Enforcement and Compliance Assurance and the Office of

General Counsel for advice.

### 5. Identify the intended user of each pesticide product

Although this information generally will not be stated specifically on the label, it is very important to keep the intended user of the product in mind when reviewing any pesticide label. For example, if the product is primarily intended for use by general consumers or residential users, the application sites listed on the label should be appropriate for use on or in and around the home, yard, garden, or on pets. Such sites might include home flower or vegetable gardens, ornamentals (shrubs and trees), home lawns, or residential greenhouses. Note that “residential use,” which defines the use site rather than the person applying the product, is defined under [40 CFR part 152.3](#).

The phrases, “*For use only by [a certain type of user],*” “*For Commercial Use Only,*” or “*For Professional Use Only*” should not appear on a product label. Such statements are often used by registrants solely for marketing purposes; however, neither FIFRA nor the applicable regulations provide for labeling statements such as for “professional use,” “commercial use,” “industrial use,” or other such terms. The registration process does not involve a determination that a product should be used, for example, only by “service persons.” Such statements are vague, and they can mislead customers into believing that a product with such a statement is somehow more efficacious than another product. Furthermore, such statements are also not likely to be enforceable under FIFRA.

Note that it is allowable to say, “Intended for use by [type of user],” but not with the word “only.” “Intended for use” statements are recognized by state regulators as advisory and not enforceable. The terms “maintenance applicator” and “service technician” are defined in [FIFRA section 2 \(jj\) and \(kk\)](#) respectively, but these terms do not seem to be in use by pesticide registrants. Several specific user groups that can be identified as the only allowable users for non-RUP products in certain situations are described in Sections XII.D-F below.

The Agency can designate pesticides for “restricted use” if the Agency determines that the product may cause unreasonable adverse effects without additional regulatory restrictions. [FIFRA 3\(d\)](#) and [40 CFR Part 152 Subpart I](#). In that case, a restricted use product can only be sold to and used by or under the direct supervision of a certified applicator. The regulations at [40 CFR Part 171](#) set out the requirements for certification of applicators. For more information on “restricted use” and “Restricted Use Pesticides,” please see Chapter 6 of the Label Review Manual.

### 6. Clarity

The text in the Directions for Use section should be expressed in complete sentences unless a bullet or table format is used. These sentences should be direct and to-the-

point, while covering all necessary information. Directions should be expressed as clearly and concisely as possible. Long or complicated paragraphs of narrative instructions should be avoided wherever possible. The label reviewer should direct registrants to alter any text which appears to be incorrect, confusing, or contradictory to other label statements. If the reviewer knows what the registrant intends to write (or what EPA permits to be written) on a particular matter, the reviewer can draft corrected text. If the label reviewer cannot determine the registrant's intent, the reviewer should identify the area of concern for the registrant, explain the problem with the information, and inform the registrant that revised text is needed to meet FIFRA standards.

For example, consider the use direction: *“Mix 1/2 to 2 pints of product in 100 gals. of water. Apply 100 to 200 gals. per acre depending on spray equipment and tree size.”* It is not clear as to what the language “Apply 100 to 200 gals. per acre...” refers. Does it refer to the undiluted product, or does it refer to the diluted spray solution? Should the applicator add more water to a 100-gallon spray mix to cover larger trees or use twice as much of spray solution mixed as directed by the first sentence?

Assuming the “100 to 200 gals.” refers to diluted spray mix, improved instructions would be: *“To make spray solution, mix 1/2 to 2 pints of this product in 100 gals. of water. Apply 100 to 200 gals. of diluted spray solution per acre to trees depending on tree size and the coverage obtained with the spray equipment used.”*

### 7. Errors

If an error is discovered in the Directions for Use portion of a registered label, the EPA reviewer must contact the registrant about the error and request that the registrant submit a corrected label within a suitable time frame such as 30 days. If there are risk issues associated with the error, the Agency can issue an order under FIFRA Sections 6 or 13 limiting the time by which the registrant can sell the existing stocks.


### B. Identical or substantially similar label review

If the application is for a product identical or substantially similar to another (see Chapter 4), reviewing the Directions for Use is straightforward: The label reviewer should make a side-by-side comparison of the proposed set of use directions to the use directions on the label for the registered product(s) which are identified in the identical or substantially similar application. Because only one source may be listed on the confidential statement of formula for 100% repacks, the label may not vary in meaning from the source product label.

Target pests or use sites found on the registered product's label may be omitted from the identical or substantially similar product's labeling. For example, an identical application is made

for an insecticide formulation to add structural perimeter treatments for crickets, ants, and sowbugs. The registered product referenced in the identical application must be labeled for this site, and its label must claim crickets, ants, and sowbugs, although other species (e.g., earwigs, millipedes) also may be claimed on the registered label. While the pending submission need not have all the pests listed on the registered label, no additional use sites, pests, or increased application rates may appear on the label for the pending identical or substantially similar product.

The format for the presentation of use information on the identical or substantially similar label need not be identical to the format on the registered (cited) label as long as the critical information as described above remains the same and the identical product meets applicable legal requirements on labeling.

 Be aware of the possible presence of an unacceptable use or other error on the label of the cited registered product when doing side-by-side comparisons. Follow-up with the appropriate product manager if mistakes are found.

### C. Not identical or substantially similar label review

When a registrant's application is not for an identical or substantially similar product, as when a registrant proposes a new use, new application rate, preharvest interval (PHI) change, or another action not previously approved by the Agency, a more extensive review than the simple comparison is necessary. Such applications usually must be accompanied by relevant data and/or data citations and should be sent for technical review. The "Directions for Use" on the proposed label may need to be altered based on the outcome of the science/technical review (i.e., use rates on crops, PHIs, reentry intervals, restrictions such as bee hazard warning statements, application rates and methods may have to be added or modified). The use rate, or application rate, may be the most difficult part of this section to interpret and review. Application rates and number of applications per season or calendar year for agricultural products may be affected by the residue data submitted or cited by the registrant. Approval of most agricultural uses requires that an appropriate tolerance be established because of the pesticide chemical residue on food. Additional review strategies for specific products

## XII. Additional Review Strategies

### A. Manufacturing use products (MUPs)

If the pesticide is a manufacturing-use product (MUP) intended only for use by formulators to prepare end-use products (EPs), the Directions for Use on the label may be greatly reduced in scope. [40 CFR 156.10\(i\)\(1\)\(iii\)](#). However, under 40 CFR 156.10(i)(1)(iii)(C) and (i)(2), MUP labels must include the following:

1. “Directions for Use” heading.
2. Misuse statement, *“It is a violation of Federal law to use this product in a manner inconsistent with its labeling.”*
3. The statement, *“For formulation into a [type of pesticide]”* followed by a continued statement of the uses (crops/sites or other uses) for which end-use products may be registered and uses for experimental purposes that are in compliance with FIFRA.

Any registrants wishing to do so may add one of the following statements to a manufacturing use product label under “Directions for Use” to permit the reformulation of their product for a specific use or all additional uses supported by a formulator or user group:

*“This product may be used to formulate products for specific use(s) not listed on manufacturing use product label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s).”*

*“This product may be used to formulate products for any additional uses not listed on the manufacturing use product’ label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s).”*

Manufacturing use products intended for formulation into end use products should not also be labeled for end uses because:

- Unique Environmental Hazards statements are required for manufacturing use products;
- Personal Protective Equipment (PPE) is not specified by the Agency for manufacturing use products;
- In some cases, only limited Directions for Use are required for manufacturing use products;
- Restricted Use classification is not appropriate for manufacturing use products; and
- WPS labeling, if applicable to end uses, would not be appropriate for manufacturing use products.

Moreover, labeling which specifies both manufacturing use and end use would require different label statements and may result in misinterpretation and/or misuse of the product.

Pesticide products used to manufacture products not required to be registered (i.e., treated articles or substances that qualify for exemption under 40 CFR 152.25(a)) are considered end-use products. Labels for such source products must bear complete Directions for Use.

Also, the Agency has allowed end use products to be used as a source for other end use products if the purchased source is registered for the same (or more) use patterns (i.e., sites, rates, timing, etc.) as the reformulated product and there are no prohibitions on the end use product stating it cannot be used as a source on other end use products.

### B. Typical end use products

The Directions for Use for typical end-use products may appear on the container label and/or may be securely attached to the packaging as long as the container label makes reference to the attachment with a statement such as “*See Directions for Use on enclosed brochure,*” and the reviewer has determined that it is not necessary for such directions to appear on the container label. [40 CFR 156.10\(i\)](#).

The way information is conveyed in the Directions for Use section of many pesticide labels varies greatly from label to label. Within categories of pesticides, specific formats for the Directions for Use section may have been implemented through specific regulatory actions on products. Such formats take precedence over the general information presented in this section, but not over the requirements of [40 CFR 156.10\(i\)](#). As a result, the starting point for analysis of Directions for Use for end use products is the regulations.

For typical end-use products, the Directions for Use section will cover the following standard requirements, such as:

- Directions for Use heading;
- Use classification statement;
- Misuse and related statements;
- Worker Protection Standard statements (if applicable);
- Lists of permitted use sites;
- Resistance management recommendations (if applicable);
- Lists of target pests for which control is claimed;
- Restrictions and other limitations on use;
- General information about the product and its use;
- Specific application instructions including maximum application rates;
- “Storage and Disposal” instructions;
- Endangered species statement (if applicable); and
- Spray drift language (if applicable).

### C. Experimental use permits

In general, the Directions for Use on experimental use permit (EUP) labels must follow the same label requirements as products registered under FIFRA Section 3. The Directions for Use must be consistent with section G of the permit. The label reviewer should ensure that the site, pests, and application method on the submitted label match those listed in their permit. Refer to Chapter 4 for more information on EUPs.

Under the Directions for Use heading and after the use classification statement (if required), the statement to be used for EUPs reads as follows ([40 CFR 172.6\(a\)\(1\)](#)):

*“For Experimental Use Only.”*

This statement should also be prominently displayed on the front panel. An example of statements that are often included prominently on the front panel of the experimental use permit labels is provided below:

*“For Experimental Use Only*

*For use only at an application site of a cooperator or participant and in accordance with the terms and conditions of the Experimental Use Permit.*

*Not for sale to any person other than a participant or cooperator of the EPA -approved Experimental Use Permit program. This label must be in possession of the user at the time of pesticide application. For use in the following states only: [insert states listed on permit].”*

### **D. Pesticide products intended for use only by physicians, veterinarians, or pharmacists**

Directions for Use sections on labels for products of these types may be very limited in content [40 CFR 156.10\(i\)\(1\)\(iii\)\(B\)](#). However, this provision applies only when the product is also classified as a drug and regulated under the [Federal Food, Drug and Cosmetic Act \(FFDCA\) 40 CFR 156.10\(i\)\(1\)\(iii\)\(B\)\(3\)](#). If the product is intended for use only by veterinarians or physicians, then the label must state that the product can only be used by veterinarians or physicians, such as the acceptable statement:

*“This product may only be used by veterinarians/physicians.”*

### **E. Termiticides**

Most currently registered termiticide products are not classified for restricted use but contain label statements limiting their use to commercial applicators. If the product is a termiticide that is not classified as restricted use, then the Agency has historically taken the position that the label should contain the following statement:

*“For use by individuals/firms licensed or registered by the state to apply termiticide products. States may have more restrictive requirements regarding qualifications of persons using this product. Consult the structural pest control regulatory agency of your state prior to use of this product.”*

Termiticide products already classified for “Restricted Use” will remain so classified and must bear the required restricted use statements on product labeling. Consult [PR Notice 96-7 and 810.3600 and 810.3800 guidelines \(Structural Treatments and Methods](#)

[For Efficacy Testing of Termite Baits](#)) for further guidance on termiticide labeling.

## F. Adult mosquito control products

If the product is an adult mosquito control product, applications should be limited to trained personnel. [PR Notice 2005-1](#). It is the Agency’s position that the following statement should appear on the label of non-restricted use products labeled for wide-area adult mosquito control:

*“For use only by federal, state, tribal or local government officials responsible for public health or vector control or by persons certified in the appropriate category or otherwise authorized by the state or tribal lead pesticide regulatory agency to perform adult mosquito control applications, or by persons under their direct supervision.”*

## XIII. Appendix A: Directions for Use Checklist

STANDARD ELEMENTS	
1. Does the label have:	<ul style="list-style-type: none"> <li><input type="checkbox"/> The correct heading, “Directions for Use”?</li> <li><input type="checkbox"/> The required misuse statement, “It is a violation of Federal law to use this product in a manner inconsistent with its labeling.”? If the product has additional misuse statements, are they acceptable?</li> <li><input type="checkbox"/> Appropriate Storage and Disposal information (Chapter 13)?</li> <li><input type="checkbox"/> Appropriate labeling required in regulatory decision documents (e.g., RED; registration review decision documents)?</li> </ul>
TECHNICAL ELEMENTS	
Elements to Consider	
2. Is the product subject to the guidance set out in PR Notice 87-1 for chemigation?	If so, is there adequate chemigation information or a chemigation prohibition statement?
3. Is the product subject to the Worker Protection Standard (WPS)?	If so, does the proposed label contain all the required WPS statements (Chapter 10)? If so, is the re-entry interval (REI) in the Agricultural Use Requirements box correct?
4. Are the following elements (if applicable) adequately expressed?	<ul style="list-style-type: none"> <li><input type="checkbox"/> Instructions and information subheading</li> <li><input type="checkbox"/> Use restrictions</li> <li><input type="checkbox"/> Spray drift language (mandatory and advisory)</li> <li><input type="checkbox"/> Resistance management</li> <li><input type="checkbox"/> Endangered species statement</li> <li><input type="checkbox"/> Pollinator protection statement</li> </ul>
Sites and Pests	
5. Are the sites and pests identified?	
6. Are there appropriate tolerances or tolerance exemptions established for listed food uses for all ingredients?	
7. If peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, milk, crustacean, or	



wheat commodities are used in the product’s formulation, do the use sites and application methods comply with 40 CFR 180.1071?
8. Is the formulation acceptable for the listed site(s)/pest(s)?
9. If a decision document has been issued, are the listed site(s)/pest(s) eligible for reregistration/continued registration?
10. If the product contains more than one active ingredient, are listed sites/pests approved for each active ingredient?
11. Is the mode of action (MOA) correct (refer to tables above) and present on the label?
<b>Application Instructions</b>
11. Are adequate preparation and handling instructions included?
12. Are the application rates indicated?
13. Are the application rates appropriate and calculated correctly?
14. For liquid formulations, was the product density (e.g., lb/gal) used to calculate the amount of active ingredient per unit area (e.g., lb ai/acre)?
15. Do the application rates deviate from a standard use pattern?
16. Are the application rates appropriate for the packaging size(s) of the product?
17. Are the application frequencies/intervals acceptable?
18. Are all mixing, loading, and application equipment specified and practical for the user?
19. Are all application methods appropriate?
20. Are all application timings appropriate?
<b>Use Restrictions</b>
21. Is a “Use Restrictions” subsection appropriate for this product?
22. Are any of the following intervals proposed or required? If so, are they correct? Pre-harvest interval (PHI) Pre-grazing interval (PGI) Pre-feeding interval Pre-silage interval Pre-slaughter interval
23. Are site-specific restrictions and precautions included for each of the listed site(s)/pest(s)?
<b>Overall Quality and Consistency</b>
24. Is the “Directions for Use” heading displayed prominently and distinguishable from normal text? Is it obvious that the use directions are located under this heading?
25. Are the Directions for Use: Complete for typical end-use products? Condensed but adequate for MUPs, veterinary/physician/pharmacist use only products, or for manufacturing into non-pesticide products?
26. Are the use directions written clearly with no contradictory or ambiguous language?
27. Are terms with clear definitions used?
28. Is the label free from false or misleading claims?
29. Is mandatory vs. advisory language clearly discernable?
30. Are the use directions well-organized?
31. Are terms such as “avoid,” “suggested,” “recommend,” and “recommended use rates,” absent

from mandatory directions?

32. Are the use directions presented in the most effective, clearly understood, and efficient way possible? Could the label benefit from the use of charts or graphs?

33. Are there questions on enforceability or legality? If so, has OECA and/or OGC been consulted?

34. Are the precautions vs. restrictions clearly presented?

35. Does the label comply with all applicable PR Notices or other EPA guidance or policies?