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Label Review Manual

Chapter 11: Directions for Use



USDA NRCS



I. Introduction

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

II. Purpose of directions for use

The Directions for Use portion of a pesticide label describes how the product can legally be used and how the product must not be used. The specific requirements for the directions for use section are found in the regulations at *40 CFR 156.10(i)*, but in general the information necessary is as follows:

- ▶ the site(s) where the product can be used
- ▶ the pest(s) that the product can be used to control;
- ▶ the application methods that are required or preferred;
- ▶ how much pesticide can be applied and the rate of application;
- ▶ whether there are any restrictions on use for factors such as weather, time of day, season of the year, contamination of sensitive areas, exposure of nontarget species, etc.;
- ▶ the application methods that are prohibited;
- ▶ how often the pesticide should or can be applied;
- ▶ maximum application rates (per treatment and per year);
- ▶ all restricted entry intervals (REIs) pertaining to existing uses, as applicable;
- ▶ preharvest intervals (PHIs); and
- ▶ any other requirements for safe effective use of this product, as necessary.

Special Reminder to Reviewers

The Directions for Use section should provide basic application information. Further, any applicator, and especially the general consumer, who is a non-technical and occasional applicator, should be able to easily understand and be expected to follow the directions for use.

The directions for use reflect the Agency's determination that the use of the product in such a manner 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 of directions for use

When writing and reviewing labels it is critical to distinguish the statements that are intended to be enforceable from those that are included for informational purposes. *If you aren't able to distinguish the difference, applicators and enforcement agents won't be able to either.* The registrant should be required to clarify the intent of any unclear statements on the label. Use of the following list will help to eliminate some common enforceability problems in the Directions for Use portion of labels:

- ▶ **Any direction or precaution that is necessary to achieve effective, safe use of the product must be stated in mandatory terms (e.g., must, will, do not)** Do not allow the use of terms such as “can”, “should” or “may” if the statement is intended to be mandatory. 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, as described in Chapter 3 discussion of mandatory versus advisory language.
- ▶ **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 “in winds strong enough to move spray away from treatment area”, would be preferable to “windy”. To define a soil type use of USDA standard terminology, such as “sandy loam”, is appropriate. (For soil classifications see <http://websoilsurvey.nrcs.usda.gov/app/> or *Soil Properties: Texture*)
- ▶ **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 to all material contained beneath it.** For example, if a heading includes the term “recommended”, everything in that section must be intended to be purely advisory and need not be followed for safe and effective use of the product. If we believe a statement is necessary for proper use, the term “recommended” would not be accepted.

- ▶ **“For Use Only by” statements should not be approved unless it refers 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 and unenforceable, and may be considered misleading.
- ▶ **Avoid “avoid”.** The term “avoid” poses particular problems. The Agency views the term as mandatory, however it also recognizes that some users may perceive the term as advisory, or may see 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. Review strategy for directions for use

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 presented so they are easy to read and understand by the user. The *Consumer Label Initiative (CLI)* research, as well as other label research done around the world, shows that in many cases graphics (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 they provide accurate information in a clear, concise and complete manner.

Subheadings, like paragraph headings in a book, help to organize the information and also 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 more lengthy and complicated information is required, a tabular format may be easier to follow.

Due to the variety in size 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) **Bulleted Format.** When using the bulleted approach, the intent is not to leave information out, but to make it visually easier to follow. Either partial, or complete, sentences can be used. Any type of character could be used as the “bullet”.

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 rinse is required.

To Control Mildew:

1. Pre-clean surface
2. Spray until thoroughly 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.
 2. Spray until thoroughly wet.
 3. Let stand 10 minutes before wiping or rinsing.
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(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 and numbering 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 simple and use correct grammar and punctuation.

Examples of Modified Paragraph Format:

Application Instructions:

BROCCOLI (PHI) : Pests: Application Method(Spray, Broadcast); **Dose** (amount per unit area); **Type of Equipment** (Sprayer, Aircraft, Spreader); **Timing** (Spring, Foliar, Pre-plant, Pre-plant Incorporated); **Application Intervals; Phytotoxicity** concerns as it applies to timing and method of application; **Restrictions** (Grazing, haying, maximum dose per application, maximum dose per crop cycle or per year, maximum number of application per year.). **Other comments** which apply to this site. **CAULIFLOWER.....**

FOR HOUSEHOLD USE: SHAKE WELL BEFORE EACH USE. Apply to surfaces only. Hold container upright 12" from surface and spray. Spray until surfaces are 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, door and window frames, and other surfaces where insects congregate.

(c) **Tabular Format.** When the label is in a tabular format make sure that all the appropriate information is included, that it is easy to follow, and that types of information are clearly divided or discernible.

2. **Answer Key Questions.** The questions contained in the *Label Reviewer's Checklist* (Appendix A) should be addressed when reviewing the Directions for Use section of the label. When answering these questions the reviewer should refer, as appropriate, to the references mentioned below under section IV. A. 2.

The reviewer must not assume that because a registrant claims to be modifying only one part of this section that the rest of the directions for use are 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 guidance such as PR Notices may have been updated or clarified.

Therefore, the entire Directions for Use section needs to be reviewed very carefully before accepting the label.

3. **Consult Essential Document References.** Various policy documents including Pesticide Registration Notices provide guidance on particular issues. Label reviewers should use the guidance along with the applicable laws to make case-by-case determinations on the acceptability of label language. In addition, reviewers should consult:

- ▶ Applicable documents and guidance policies for the active ingredient(s) including: Registration Review Decision documents, Reregistration Eligibility Decisions (RED, IRED, TRED) Biopesticide Registration Action Documents (BRAD), Science assessments, etc.
- ▶ Applicable product-specific data evaluation records and assessments,
- ▶ Labels of substantially similar or identical products,
- ▶ The Registration Standard (if there is one not superseded by a RED),

- ▶ For new or revised uses, available science/technical reviews, or the efficacy reviewer,
- ▶ The *40 CFR, Part 180* for published tolerances supporting food/feed uses, and
- ▶ Current Pesticide Registration (PR) Notices.

Table 1. Toxicity Categories

Crop	Phi	Target Pests	Rate	Special Directions
Broccoli For use only in California, Oregon, and Washington Do not apply within X days of harvest	Do not apply within X days of harvest	Aphids Flea beetles Leafhoppers Whiteflies	X fl. oz in <u>X</u> gal of water (diluent) by ground or X gal of water (diluent) by aircraft	Method of Application Spray, Broadcast, Chemigation, Ultra Low Volume. Equipment Sprayer, Sprinkler Irrigation, Mist Sprayer, Spreader. Timing Foliar, Pre-plant, Post-plant, Post-harvest, Dormant. Application Interval Can be X-X days as needed. No more than X times per year. Notes: (applying to a specific pest)
		Armyworms Lygus bugs	X fl. oz in <u>X</u> gal of water (diluent) by ground or X gal of water (diluent) by aircraft <i>(different than above)</i>	<i>Same as above but with different timing, pre-plant incorporated including a different type of equipment</i>
		Limitations: 1. Do not apply more than X fl. oz. of Product per acre per application 2. No more than <u>X</u> gallons per acre per year. 3. Make no more than X applications per year. Note; Gallons or applications "per season" is NOT acceptable by itself without a "per year" statement. There may be more than one growing season per year for some crops; EPA needs a hard number for risk assessment. Grazing Restrictions: Describe grazing restrictions here NOTES: Information on phytotoxicity, pest resistance, or other comments that apply to the site.		

Pesticide Registration (PR) Notices are issued by the Office of Pesticide Programs to 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. These documents are available at: [Pesticide Registration \(PR\) Notices | Pesticides | US EPA](#).

If a Reregistration Eligibility Decision (RED) Document has been issued for the active ingredient in the product undergoing review, the reviewer must ensure that:

- ▶ All of the use sites on the label are in Appendix A of the RED (or have been evaluated and approved by OPP in a subsequent regulatory document);
- ▶ 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* of the active ingredients. If there is more than one a.i. in the product and a RED is available for each, all sites on a label must be listed in each RED.

4. **Consult Subject Matter Experts.** The “Directions for Use” portion of a label 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 first consult PM/team leaders or efficacy reviewers. PM/team leaders may raise more difficult questions to their branch chief, or, in cases of “mandatory or advisory” issues or other enforceability questions, may directly contact staff in the Office of Enforcement and Compliance Assurance for advice.

At the discretion of branch chiefs, or PM/team leaders, label questions may be forwarded to OPP’s Label Committee, which includes representatives of OPP’s registering divisions, plus PRD, FEAD, OGC and OECA. Other authorities or sources of information may be consulted as appropriate such as commodity groups, State FIFRA Issues Research and Evaluation Group (SFIREG), or Regional offices of EPA.

5. **Identify the Intended User.** 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/household users” the application sites listed on the label should be appropriate for use on or in and around the home, yard, and 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 in regulation at 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 Section V. D, E and F of this chapter.

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)*, see also *40 CFR Part 152 Subpart I*). In that case, a restricted use product can only be sold to and used by a certified applicator. (The regulations at *40 CFR Part 171* set out the requirements for certification of applicators.)

It should be noted that although some of the above mentioned statements restrict **who** can **use** the product, none of the statements restrict who may **purchase** the product, unless the pesticide is classified for restricted use. The only way to restrict sale of the product is through classification of the product as a Restricted Use Pesticide, as described in [Chapter 6](#). Therefore a label statement that includes a “not for sale to (type of person)” is not acceptable if the product is not classified for restricted use.

- 6. Clarity.** The text in the Directions for Use section should be expressed in complete sentences unless a bulleted format is used in a chart. 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.

EXAMPLE: Consider the following statement taken from the Directions for Use section of a pesticide product's label:

“Mix 1/2 to 2 pints of (pesticide) in 100 gals. of water. Apply 100 to 200 gals. per acre depending on spray equipment and tree size”.

It is not clear to what the language “Apply 100 to 200 gals per acre...” refers. Does it refer to undiluted product, or does it refer to the diluted spray solution? Is the applicator to simply add more water to a 100-gallon spray mix to cover larger trees or to use twice as much of spray solution mixed as directed by the first sentence?

Assuming that 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 in the Directions for Use.** If an error is discovered in the Directions for Use portion of the cited, registered label, the reviewer must take the time to contact the registrant about the error(s) 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 Section 6 or 13 limiting the time by which the registrant can sell the existing stocks.

B. Identical or Substantially Similar Product Application Label Review of Directions for Use

If the application is for a product identical or substantially similar to another (see [Chapter 4](#)), reviewing the directions for use is fairly 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 (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 *new use sites or pests* 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.

Note: 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 appropriate product manager, if mistakes are found.

C. Not Identical or Substantially Similar Label Review of Directions for Use

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 due to 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 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.

V. Additional review strategies for specific products

A. Manufacturing-Use Product (MP)

If the pesticide is an MP intended only for use by formulators preparing end-use products, the directions for use on the label may be greatly reduced in scope. See regulation at [40 CFR 156.10\(i\)\(1\)\(iii\)](#). However, these products must still have the following:

1. "Directions for Use" heading;
2. Misuse Statement(s);
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 the end-uses product (EP) may be registered and uses for experimental purposes that are in compliance with FIFRA.

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

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

MPs intended for formulation into end-use pesticides (EPs) should not also be labeled for end uses for several reasons:

- ▶ Unique Environmental Hazards statements are required for MPs,
- ▶ Personal Protective Equipment (PPE) is not specified by the Agency for MPs,
- ▶ In some cases, only limited Directions For Use are required for MPs,
- ▶ Use Classification is not appropriate for MPs, and
- ▶ WPS labeling, if applicable to end uses, would not be appropriate for MPs

Labeling which specified both pesticide manufacturing use and end use would require different, sometimes conflicting, label statements, in these and possibly other areas of the label and may result in user confusion and/or misuse of the product.

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

Also, the Agency has allowed EPs to be used as an active ingredient source for other EPs if the purchased source of the active ingredient is registered for the same (or more) use patterns (i.e., sites, rates, timing, etc.) as the reformulated product.

B. Typical End-Use Pesticide 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”*, as long as the reviewer has determined that it is not necessary for such directions to appear on the container label. (see [40 CFR 156.10\(i\)](#))

The manner in which 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:

- ▶ the misuse statement, Worker Protection Standard boxes, etc.
- ▶ lists of permitted use sites;
- ▶ 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
- ▶ “Storage and Disposal” instructions

C. Experimental Use Permits

In general, the directions for use on experimental use permit 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 [Section III.\(I\) of Chapter 4](#) for more information on Experimental Use Permits.

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

“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 Product 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. However, this provision applies only when the product is also classified as a drug

and regulated as such under the provisions of the *Federal Food, Drug and Cosmetic Act (FFDCA)* (see *40 CFR 156.10(i)(1)(iii)(B)(3)*).

If the product is intended for use only by veterinarians, then the label must state that the product can only be used by veterinarians or physicians. The following statement is an acceptable one to meet this requirement: *40 CFR 156.10(i)(1)(iii)(B)*.

“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* 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. (See *PR Notice 2005-1*.)

“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”.

VI. 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)
- ▶ I Instructions and Information Subheading (if applicable)
- ▶ Use Restrictions (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***”. It **may not have any other title**. 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 to give it proper 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(j)(2)(i)*. Consult Chapter 6 of this manual for further guidance on restricted use pesticide label requirements.

C. Misuse Statement

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), Notification to Workers Statements and Non-agricultural Use Requirements.

The following statements must appear on all WPS labels near the beginning of the Direction for Use section of the labeling under the heading Agricultural Use Requirements.

“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 wide-area treatments, see section 3c below under Directions for Use)

“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 concerning 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 precautions, 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 Section III of *Chapter 3* for discussion of mandatory labeling statements). Use restrictions may also be phrased as requirements by using words such as “must”, “never”, and “always”. Any precautions and 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 Precautions and 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 a restriction like:

“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 Limitations 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 label use directions for compliance with *40 CFR 180.1071*.

G. Resistance Management Labeling Considerations

The Office of Pesticide Programs (OPP) of the EPA has developed voluntary pesticide resistance management labeling guidelines based on target site/mode of action (MOA) for agricultural uses of herbicides, fungicides, bactericides, insecticides, and acaricides. MOA refers to the biochemical mechanism by which the pesticide acts to control 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 the Federal Food, Drug, and Cosmetics Act (FFDCA).

Rotation of MOA action was selected as a primary pest/pesticide resistance management strategy for this voluntary regulatory initiative rather than metabolic resistance, because it is the easiest for reducing the likelihood of resistance, especially monogenic resistance, and it will help reduce the likelihood of resistance caused by other mechanisms. 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 *Pesticide Registration Notice 2001-5*. 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 as *Regulatory Directive 99-06*. 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/mode of action resistance.

The objective of the voluntary resistance management labeling guidelines (*PR Notice 2001-5*) 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. When used, the mode of action (MOA) numerical classification symbol(s) are recommended to be placed in the upper right hand corner of the front-panel of end-use product labels, although the numerical classification symbol can be placed elsewhere on the label. The numerical MOA classifications are found in the Appendices of PR Notice 2001-5. A sample of this is:

GROUP	1	HERBICIDE
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In addition to the MOA classification symbols, a registrant may choose to have resistance management statements on the label. If used, these statements should be included in the “Use Directions” for end-use products 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 (see *PR Notice 2000-5*, “Guidance for Mandatory and Advisory Labeling Statements”) on the pesticide label to avoid confusion to the users.

Pesticide Registration Notice 2001-5 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. Alternatively, registrants may supply their own resistance management labeling statements that address these same areas. Registrants may also choose to have specific mandatory statements regarding resistance management, but these statements would not fall under “Resistance Management Recommendations”.

H. Chemigation Information

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;
- ▶ 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 REDs for any chemigation text specific to the active ingredient(s) in the product under review.

I. Spray Drift Labeling

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 RED or reregistration documents for required spray drift language as well as work with the risk assessors to craft appropriate spray drift risk mitigating label language.

J. Endangered Species Label Statement

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 assessor, 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 EFED, AD or BPPD 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.

VII. Where the product is issued

All application or treatment site(s) must be 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, for example, 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 (e.g., “domestic dwellings”) that would be awkward or confusing on a label. 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” or lists ending with “etc.”, where food uses may be involved.

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.

VIII. The pests being claimed

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”, or “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, i.e., “and more listed on the back panel”. The reviewer must make sure that the directions for use are actually included and are applicable to all pests listed anywhere else on the labeling. This consistency is necessary to ensure that the product is not considered misbranded.

B. Pest Groupings

While target pests may be named very generally in the directions for use section of some labels (e.g., ants), other labels may identify them specifically, (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. Pests and Use Sites

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.

IX. 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, granulars, 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 (pounds, ounces), and units by volume for liquids (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 correct English units. The diluent must be specified, even if it is water.

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 for the use site to indicate the appropriate amount of spray volume to apply per unit area for aircraft or for ground equipment. It also may be necessary for the label to indicate the diluent spray volume amounts for aircraft or ground equipment.

- 1. Tank Mixing Statement.** When the label bears a reference to mixing with other products, the Agency recommends that the registrant add a statement such as the following:

“Follow the most restrictive of the labeling limitations and precautions of all products used in mixtures”.

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.

X. 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 is 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) limitations statements;
- ▶ other use limitations and requirements such as those statements pertaining to Chemigation, Spray Drift Labeling, seasonal restrictions, weather or time-of-day restrictions, requirements intended to protect nontarget 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 preplanting, 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 RED to determine if any regulatory intervals were recommended for the product's label. The residue chemistry assessment for a given product or active ingredient may specify the following 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. Preslaughter intervals and pregrazing intervals should be expressed similar to the PHIs.

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 in order for the treatment to be effective. This information should be clearly stated on the label. 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. When necessary 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 that brand and model are appropriate for reasons of safety or efficacy. Some types of equipment are designed specially to apply 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 should 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:

- (a) *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.
- (b) *General Area Spray.* Application to broad surfaces, such as walls, floors and ceilings.
- (c) *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.
- (d) *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 may 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 ounces, teaspoons/gallon, or pounds/square foot. Such rates and units of measure are more appropriate for the 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. Note: 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 one of the reasons below (a. or b.) 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.

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, application frequency (within the requirements for tolerance, appropriate for controlling pests, etc.), minimum volume of diluent for spraying for each type of equipment, application intervals, maximum amount of product or pounds a.i. per acre per application, or per season or year, phytotoxicity effects or warnings, number of applications per season and grazing or feeding restrictions. In cases where a maximum limit of a.i./crop, season, etc., is required, ensure that liquid products include a statement of weight/volume of either product or active ingredient.

XI. 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* of the 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.

XII. 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. Information about and requirements for Storage and Disposal instructions are given in *Chapter 13*.

Appendix A—Directions for Use Checklist

Standard Elements
<p>1. Does the label have:</p> <p>The correct heading “Directions for Use”?</p> <p>The required Misuse Statement? If the product has additional misuse statements are they acceptable?</p> <p>Appropriate Storage and Disposal information?</p> <p>Appropriate labeling required in RED(s) or latest risk assessment document?</p>

Technical Elements

Elements to Consider
<p>2. Is the product subject to the guidance set out in PR Notice 87-1 (chemigation)? If so, is there adequate chemigation information or a chemigation prohibition statement?</p>
<p>3. Is the product subject to the Worker Protection Standard (WPS)? If so, does the proposed label contain all the required, accurate WPS information as set forth in the regulations and the guidance in Chapter 10 Is the Re-entry Interval in the Agricultural Use Requirements box correct?</p>
<p>4. Are the following elements (<i>if applicable</i>) adequately expressed: Instructions and Information Subheading? Use Restrictions? Spray Drift Language? Endangered Species Statement? Pollinator Protection Statement?</p>

Sites and Pests

<p>5. Are the sites and pests identified?</p>
<p>6. Are there appropriate tolerances or exemptions from tolerance for all of the ingredients in the product to cover all the food use sites listed?</p>
<p>7. If peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, milk, Crustacean, or wheat commodities are listed on the confidential statement of formula, do the use sites and application methods comply with 40 CFR 180.1071?</p>
<p>8. Is the formulation acceptable for this site/pest combination?</p>
<p>9. If a RED has been issued, is the site eligible for Reregistration?</p>
<p>10. If the product contains more than one active ingredient, are all the uses acceptable for all the active ingredients (AI)?</p>

Application Instructions

<p>11. Are adequate preparation and handling instructions included?</p>
<p>12. Are the application rates indicated?</p>
<p>13. Are the rates appropriate and calculated correctly?</p>
<p>14. Does the product density (eg. lbs of AI/gallon) times the application rate agree with the tables that list the weight of AI applied to a given area?</p>
<p>15. Do the rates deviate from a standard use pattern?</p>
<p>16. Is the rate of application consistent with the packaging of the product?</p>

Application Instructions

17. Is the application frequency acceptable?
18. Is all equipment (e.g. for mixing, loading or application) identified/specified and is the equipment practical for the user?
19. Are all methods of application appropriate?
20. Is the timing of the applications appropriate?

Use Restrictions

21. Should there be a Use Restrictions sub-heading and section?
22. Is the Pre-harvest Interval, Pre-grazing, Pre-feeding, Pre-silage or Pre-slaughter Interval correct?
23. Are site specific precautions and restrictions clearly listed with each site/pest combination?

Overall Quality and Consistency

24. Is the Directions for Use heading prominent enough (e.g., bold, larger font, underlined, etc.) so that it is clear to the user that everything that follows falls under the Directions for Use section?
25. Does the label contain complete Directions for Use? Or are the detailed directions for use omitted because the product is an MUP or for veterinary use or for use in non-pesticide manufacturing?
26. Are the Directions for Use clearly written with no contradictory or ambiguous language?
27. Are terms with clear definitions used?
28. Is the label free of false and misleading claims?
29. Are label statements worded appropriately as mandatory or advisory?
30. Is the label organized in such a fashion that it is clear what is mandatory, and what is advisory?
31. Are terms such as "recommended" and "avoid" absent from all mandatory directions? (Ensure the phrase "recommended use rates" is not stated on the label.)
32. Are the Directions for Use presented in the most effective, clearly understood and efficient way possible? Could the label benefit from the use of chart or graphs?
33. Are there questions on enforceability? If so, has OECA been consulted?
34. Are Precautions and Restrictions clearly presented?
35. Does the label comply with all applicable Pesticide Registration (PR) Notices? See <http://www2.epa.gov/pesticide-registration/pesticide-registration-notices-year>

Check [40 CFR 156.10](#) for further guidance.