United States Environmental Protection Agency
Office of Prevention, Pesticides & Toxic Substances (7506C)
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Label Review Manual

3rd Edition

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LABEL REVIEW MANUAL, 3rd EDITION

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NOTE TO READER:

The Agency is interested in optimizing the usefulness of the LRM as a tool for understanding the pesticide labeling process. If you notice errors in or ways to improve the LRM, please contact the Office of Pesticide Programs at 703 308-9068. The Agency considers this document to be an instructional aid that does not establish new guidance, but instead compiles extant interpretations of statutory and regulatory provisions and reiterates extant Agency policies. This tool is also useful in understanding approaches for how labels should generally be drafted. As always, the Agency will consider each label on its own merits and will consider deviations from Agency policy in labeling under the appropriate provisions of FIFRA and its implementing regulations.

Chapter 1 **PURPOSE OF MANUAL**

I. PURPOSE

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

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

C. In addition to considering the guidance provided in this manual, it is the responsibility of the label reviewer or writer to consider **all** chemical and product specific information affecting labeling such as science reviews, Federal Register Notices and Reregistration Eligibility Decision documents ("REDs").

D. The approach and information set forth in this document is intended solely as guidance. This manual does not impose binding obligations on either existing registrants, applicants for registration or EPA.

II. CONTENT

A. The second chapter of this manual provides a definition of a "pesticide" and describes pesticide labels and labeling. The third chapter discusses general label format and legibility requirements, identifies the major parts of the label, and directs the user to the appropriate chapters in this manual where additional information can be found. The remainder of the manual provides step-by-step instructions concerning the review of a pesticide label and any associated actions and situations that may arise during label review. Information in the manual is roughly arranged in the order of use by reviewers. Chapter 18 provides information about how unique labeling issues have been handled in the past, so that reviewers can apply this information to future similar situations.

III. APPROACH

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

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

IV. AVAILABILITY

A. INTERNALLY. All chapters in this manual are included in the *Labeling Policy Directory*, which is located under Vol #1 on DCCMAPPS01 under M:\APPS\OPP\SHARED\RD\LABELING, under the subdirectory label.man on OPP's Local Area Network (LAN). The *Labeling Policy Directory* contains all policy documents (such as letters, memos, relevant PR Notices, etc.) related to labeling. In the manual, chapters are organized following the sections of a pesticide label. The reader should refer to the INDEX under the directory for the chapter names.

B. EXTERNALLY. The LRM is available from the National Technical Information Service (NTIS) in Springfield, Virginia. To order documents from NTIS, call 1-800-553-6847. The LRM is also located on the Internet at: **www.epa.gov/oppfead1/labeling/lrm**. For additional information, contact the Labeling Team at 703-308-9068.

V. MAINTENANCE/UPDATE

A. For accurate maintenance of this manual, it is imperative that OPP staff bring to the attention of the Labeling Team any document which affects generic labeling policy. Discrepancies or problems should be brought to the attention of the Labeling Team by calling 703-308-9068.

Chapter 2 **WHAT IS A PESTICIDE?**

I. INTRODUCTION

A. This chapter discusses the statutory and regulatory criteria used to determine whether or not a product is a pesticide requiring registration under FIFRA. Relevant FIFRA definitions are found in section 2 of the statute and the applicable regulations are at 40 CFR Part 152, Subparts A and B. Label reviewers should use the statute and regulations when evaluating the "pesticide" status of products or potential products. It is acceptable to discuss whether hypothetical products are pesticides with anyone, including state enforcement personnel, registrants, applicants or the general public. Whether or not a particular product that is the subject of an application is a pesticide under FIFRA must be treated confidentially through applicable CBI protections. A final decision about the pesticide status of a particular product must be made in writing to the applicant or registrant and should be in response to a written request for an Agency determination which includes proposed labeling and the composition of the product.

B. As discussed in detail below, there are a number of types of products that the Agency has determined are not pesticides and others that the Agency has exempted from regulation even though they are pesticides. If a label reviewer determines that a product is a pesticide, the label reviewer should consider whether the pesticide has been exempted from the FIFRA registration requirements.

C. If the label reviewer determines that the product is not a pesticide, the label reviewer must consider whether the product is a device. The last section of this chapter addresses this topic.

II. PRODUCTS THAT ARE NOT PESTICIDES

A. Some substances and products may be excluded from FIFRA registration if they meet certain conditions or criteria. 40 CFR 152.6 sets out the following types of products which can fall into this category.

1. **Liquid chemical sterilants**. A liquid chemical sterilant product is not a pesticide under section 2(u) of FIFRA if it meets all of the following criteria. Excluded products are regulated by the Food and Drug Administration (FDA). Products excluded are those meeting all of the following criteria:

a. Composition. The product must be in liquid form as sold or distributed. Pressurized gases or products in dry or semi-solid form are not excluded by this provision. Ethylene oxide products are not liquid products and are not excluded by this provision.

b. Claims. The product must bear a sterilant claim, or a sterilant plus subordinate level disinfection claim. Products that bear antimicrobial claims solely at a level less than "sterilant" are not excluded and are jointly regulated by EPA and FDA.

c. Use site.

(1) The product must be intended and labeled only for use on "critical or semi-critical devices." A "critical device" is any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body. A semi-critical device is any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

(2) Liquid chemical sterilants that bear claims solely for use on non-critical medical devices are jointly regulated by EPA and FDA.

(3) Liquid chemical sterilants that bear claims solely for use on sites that are not medical devices, such as veterinary equipment, are not excluded and are regulated solely by EPA.

2. **Nitrogen stabilizers**. A nitrogen stabilizer is excluded from regulation under FIFRA if it is a substance (or mixture of substances), meeting all of the following criteria:

a. The substance prevents or hinders the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria and is distributed and sold solely for those purposes and no other pesticidal purposes. For purposes of 40 CFR 152.6, living organisms are not considered to be substances, and the actions of living organisms are not relevant to whether a substance is deemed to be a nitrogen stabilizer.

b. The substance was in "commercial agronomic use" in the United States before January 1, 1992. EPA considers a substance to be in commercial agronomic use if it is available for sale or distribution to users for direct agronomic benefit, as opposed to limited research, experimental or demonstration use.

c. The substance was not registered under FIFRA before January 1, 1992.

d. Since January 1, 1992, the distributor or seller has made no claim that the product prevents or hinders the process of nitrification, denitrification, ammonia volatilization or urease production. See 40 CFR 152.6 to learn what EPA considers to be a claim that the product prevents or hinders nitrification, denitrification, ammonia volatilization or urease production and for further information on this topic.

3. **Products intended for use only for the control of fungi, bacteria, viruses, or other microorganisms in or on living man or animals, and labeled accordingly**. Such products include, for example: Athlete's foot remedies, dandruff medications, aquaculture and aquarium additives for treatment of fish diseases, and dermal disinfectants. Note: These exceptions apply only to antimicrobials (fungicides, disinfectants, viricides, etc.). Insecticides (pesticides that kill insects as opposed to microbes) are not included in the "living body" exception. Thus, products such as mosquito repellents, flea and tick remedies for pets, and other insecticides and acaricides (except head and body lice products) used directly on the living body of humans, pets, and livestock have historically been considered to be pesticides and are required to be registered. Note that contact lens solutions that disinfect the lens in the contact lens holder are exempt from federal registration under FIFRA through an agreement with the Food and Drug Administration. An animal feed containing an animal drug is not a pesticide under section 2(u) of FIFRA. An animal feed containing an animal drug is subject to regulation by the FDA under the FFDCA.

4. **Products intended for use only for control of internal invertebrate parasites or nematodes in living man or animals, and labeled accordingly**.

5. **Products intended only to aid in the growth of desirable plants** such as those products that fall within one of the categories (a-g) below.

As an initial matter, it is important to note that there is an important distinction between plant nutrients, which may be exempt from registration, and plant regulators, which require registration (and are defined in FIFRA at 2(v)). Plant nutrients are described below. Whether a product is considered to be a plant growth regulator basically turns on whether the plant response or mode of action being claimed would go beyond what would be expected from simple nutrition. Claims such as increased blossom set, stimulation of root growth, prevention of sucker growth, delayed onset of sprouting of harvested root crops and abscission stimulation for fruit crops can be considered to be plant growth regulator claims. In this area, the composition of the product may aid in making the determination. Compounds such as auxins, cytokinins, and gibberellins have no other uses except as plant growth regulators. Therefore, the presence of any of those compounds generally causes a product to be considered to be a plant growth regulator. However, products containing auxins, cytokinins, and gibberellins may be exempt from registration if the labeling meets the criteria for vitamin-hormone horticultural products under 40 CFR 152.6(f)

Products that aid in the growth of desirable plants can include:

a. Plant or leaf coatings designed to protect against frost or to retard water loss through transpiration. These types of products are usually glycerol-based. Similar products are sometimes sold as cut-flower preservatives. As long as plant disease or plant regulator claims are not made for the product and its composition is not such that pesticide benefits would be delivered, registration has historically not been required.

b. Products sold as vase water additives for cut flowers, although such products bear special scrutiny. If they are composed, as many are, of simple sugars intended to supply nourishment to the cut flower, they are likely not under the purview of FIFRA. Historically, however, products with claims to prevent bacterial or fungal growth in the vase water, claims such as “delays flower opening”, claims to control stem rot or decay or products with chemicals that only have pesticidal uses have been subject to FIFRA registration.

c. Food washing products that do not claim to remove bacteria such as e-coli or salmonella.

d. Fertilizer products not containing a pesticide, such as sphagnum moss used as plant growth media to retard damping-off.

e. Plant inoculant products consisting of microorganisms applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system.

f. Soil amendment (e.g., vermiculite, sand, lime) products containing a substance or substances added to the soil for the purpose of improving soil characteristics favorable for plant

growth. See 152.6(g)(3) [previously 40 CFR 152.8(c)(4)]. Soil amendments are intended to increase porosity, retain moisture, adjust pH, and other uses intended to benefit crop production. For example, although normally considered to be a fungicide or miticide, products containing sulfur when applied to soil to solely adjust the pH have historically not been subject to registration. Sulfur may also have nonpesticidal uses as a foliar plant nutrient at low concentrations.

g. Plant nutrient products consisting of one or more macronutrients or micronutrient trace elements necessary to normal growth of plants and in a form readily useable by plants.

6. **Antimicrobial products used solely in processed foods or feeds, in beverages, or in pharmaceuticals**. Cracking, milling, grinding and other processes that cause a physical change in the commodity are methods that meet the definition of "processed." Substances used in these processes against microbes in or on the processed food are not pesticides under FIFRA and are regulated by FDA, not EPA. Drying, husking and shelling do not meet the definition of "processed" so that products used during these processes are FIFRA pesticides and are regulated by EPA under FIFRA. Cosmetics are pharmaceuticals regulated by FDA. See 40 CFR 152.5(d).

B. Products that are not intended to prevent, destroy, repel, or mitigate a pest, or to defoliate, desiccate, or regulate the growth of plants are not considered to be pesticides. Some of these products may appear to be pesticides, but are not considered as such unless pesticidal claims are made on their labeling or in connection with their sale and distribution. 40 CFR 152.10 lists products which fall under this category.

1. **Deodorizers, bleaches, and cleaning agents**. OPP has treated products bearing claims for sanitizing or disinfecting properties as pesticides requiring registration. For example, a bleach which consists of 5.25% sodium hypochlorite would likely require registration if the label states that bacteria will be killed at certain doses. An identical bleach would not likely need to be registered if the labeling only claims to whiten, bleach or clean laundry, and does not contain an explicit or implicit antimicrobial claim.

2. **Products not containing toxicants intended only to attract pests for survey or detection purposes, and labeled accordingly**.

3. **Products that are intended to exclude pests only by providing a physical barrier against pest access, and which contain no toxicants**. Examples might include: pruning for trees; latex or asphalt tree wound dressings that make claims of preventing the entrance of insects or fungi into fresh cut surfaces of plants; cocoa bark or pine bark mulches that claim suppression of weed growth; black plastic or tar-paper used to suppress weeds or prevent the entrance of insects.

III. WHAT MAKES A PRODUCT A PESTICIDE?

A. The term "pesticide" is defined at FIFRA 2(u). One of the most important words in the FIFRA definition of "pesticide" is *"intended*." One of the analytical steps to determining whether a product is a pesticide is to consider whether the product is "intended" to be used as a pesticide. Products are generally considered to be pesticides if they are intended for preventing, destroying, repelling, or mitigating any pest or intended for use as a plant regulator, defoliant, or desiccant. OPP

determines **intent** by examining claims on the label, advertising; composition/use; and/or mode of action of the product as distributed or sold. Section 40 CFR 152.15 sets forth the criteria to help establish intent. If the regulatory criteria are met the label reviewer can conclude that the product is a pesticide and must be registered. The regulatory criteria are described below:

1. **Claims**. If a person who distributes or sells the product claims, states or implies by labeling or otherwise (such as, advertising, collateral literature, or verbal statements), that the product can or should be used as a pesticide or that the product contains an active ingredient and that it can be used to manufacture a pesticide, then the product is a pesticide. See 40 CFR 152.15(a)(1) and (a)(2).

2. **Composition**. If a product is composed of one or more active ingredients that have no other significant commercially valuable use other than for a pesticidal purpose or for use in manufacturing a pesticide then the product historically has been considered to be a pesticide. For example, a company markets a granular product that has labeling identifying the presence of 2,4-D, directions to apply it to lawns at a certain dosage rate, and warns the user about over-application, but does not claim that broad-leaved weeds will be killed, is the product a pesticide? Most likely, the product is a pesticide because 2,4-D is a well known herbicide and has no other significant commercially valuable use.

3. **Knowledge that the substances will be used as a pesticide.** Even if pesticidal claims are not made for the product, if the person who distributes or sells the substance has actual or constructive knowledge that the substances will be used, or is intended to be used, for a pesticidal purpose, the product is a pesticide product required to be registered.

IV. PESTICIDES EXEMPTED FROM REGISTRATION

A. The Agency has exempted certain pesticides from regulation under FIFRA under the authority of FIFRA 25(b) because the pesticides have been determined to be (1) adequately regulated by another Federal agency or (2) of a character which is unnecessary to be subject to FIFRA. Just because a pesticide is exempted under FIFRA, however, does not mean that the Federal Food, Drug and Cosmetic Act (FFDCA) or state laws may not apply. For example, even if a pesticide product meets the conditions for exemption from regulation under FIFRA, it might still be subject to FFDCA requirements requiring a tolerance or tolerance exemption if there is a pesticide chemical residue on food. The following are examples of products exempted from FIFRA under 25(b):

1. **Pesticides Regulated by Another Federal Agency**

a. Certain Biological Control Agents. Biological control agents are generally exempt from FIFRA regulation. However, the Agency has determined (40 CFR 152.20(a)(3)) that the following biological control agents are <u>not exempt</u> and are subject to FIFRA.

(1) Eucaryotic microorganisms, including protozoa, algae, and fungi;

(2) Procaryotic microorganisms, including bacteria; and

(3) Viruses.

b. Certain Human Drugs**.** A product that is intended solely for human use and also is a new drug within the meaning of FFDCA 201(p) or is an article that has been determined by the Secretary of Health and Human Services not to be a new drug by a regulation establishing conditions of use for the article, is exempt from the requirements of FIFRA. See 40 CFR 152.20(b) for more details.

2. **Pesticide Not of a Character Requiring FIFRA Regulation**

a. Treated Articles or Substances. This covers article or substance treated with, or containing, a pesticide to protect the article or substance itself, if the pesticide is registered for such use. Generally speaking, claims about such products should be limited to the protection of the article itself and the pesticides used for those purposes must be registered and bear appropriate directions for such uses. See 40 CFR 152.25(a) and PR Notice 2000-1. Examples include:

(1) Paints that have been treated with an antimicrobial pesticide and bear claims that the dried paint film will be resistant to mildew. Historically, OPP has not accepted, expressed or implied claims made for protection of the surface beneath the paint film or for prevention of mold spores that could infect foods or beverages. Paints that are to be used in canneries, breweries, hospitals, or other areas where a crucial consideration is prevention of bacteria or mold that would pose a health risk are generally not subject to the treated articles exemption and, therefore, generally not exempt from FIFRA regulation.

(2) Shower curtains treated with a fungicide to retard mildew growth; lumber treated with a wood preservative; bathroom caulks impregnated with a mildewcide; and fabrics and leather treated with preservative compounds are other examples of products that OPP has historically viewed as treated articles.

b. Pheromones and Pheromone Traps. Pheromones and identical or substantially similar compounds labeled for use only in pheromone traps (or labeled for use in a manner which the Administrator determines poses no greater risk of adverse effects on the environment than use in pheromone traps), and pheromone traps in which those compounds are the sole active ingredient are not subject to FIFRA regulation. Refer to 40 CFR 152.25(b)(1), (b)(2), and (b)(3) to determine whether a substance is a pheromone for purposes of this exemption. Refer to 40 CFR 152.25(b)(4) to determine whether the pheromone trap falls within the exemption. Pheromones are chemicals used in intra-species communication. A chemical used in inter-species communication (i.e., using fox urine to repel rabbits) is an "allomone" and would be subject to FIFRA.

c. Preservatives for Biological Specimens

(1) *Embalming Fluids*. Mortuary supplies intended to prevent or mitigate mold and bacteria on or in human cadavers are exempt because: The rationale for this exemption is that the use is limited to embalmers and morticians who are specially trained to handle such products and do not require the protection afforded by registration. The general public would not be exposed to such products. See 40 CFR 152.25(c)(1).

(2) *Animal and animal organ preservatives*. This includes products used to preserve animal or animal organ specimens in mortuaries, laboratories, hospitals, museums, and institutions of learning. See 40 CFR 152.25(c)(2).

(3) *Preservatives for Laboratory Analysis.* Products used to preserve the integrity of milk, urine, blood, or other bodily fluids for laboratory analysis. See 40 CFR 152.25(3).

d. Vitamin Hormone Products. See 40 CFR 152.6(f) (previously 40 CFR 152.25(d).

e. Foods**.** Products consisting of foods and containing no active ingredients, which are used to attract pests. See 40 CFR. 152.25(d)).

f. Natural cedar. Natural cedar blocks, chips, shavings, balls, chests, drawer liners, paneling, and needles that meet all of the following criteria:

(1) The product consists totally of cedarwood or natural cedar;

(2) The product is not treated, combined or impregnated with any additional substance(s); and

(3) The product bears claims or directions for use solely to repel arthropods other than ticks or to retard mildew, and no additional claims are made in sale or distribution. The labeling must be limited to specific arthropods, or must exclude ticks if any general term such as "arthropods," "insects," "bugs," or any other broad inclusive term, is used. The exemption does not apply to natural cedar products claimed to repel ticks. The exemption does not apply to cedar oil, or formulated products which contain cedar oil, other cedar extracts, or ground cedar wood as part of a mixture. See 40 CFR 152.25(e).

g. Minimum Risk Pesticides. 40 CFR Section 152.25(f) (previously 40 CFR152.25(g)) exempts certain "minimum risk pesticides" from the requirements of FIFRA (including registration) if they satisfy all the conditions described in that provision (i.e., 152.25(f)(1)-(3)). Products not meeting all the conditions in the regulation may still be exempt from regulation. Some of the conditions of exemption specifically relate to a product's labeling (see 152.25(f)(3)). For further information, see PRN 2000-6: "Minimum Risk Pesticides Exempted under FIFRA Section 25(b) Clarification of Issues." See also the notice published in the Federal Register, September 28, 1994 (59 Fed. Reg. 49400) for the list of minimum risk inerts (also known as the List 4A inerts).

V. IS THE PRODUCT A DEVICE AND, THEREFORE, NOT A PESTICIDE?

FIFRA defines a device as "any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom." See FIFRA 2(h). FIFRA does not require the registration of pesticidal devices. Devices, however, are subject to a number of FIFRA's provisions including,

labeling requirements and establishment numbers identifying the location where the device was produced. See 40 CFR 152.500 for more information on devices and additional FIFRA requirements.

Chapter 3 **GENERAL LABELING REQUIREMENTS**

I. INTRODUCTION

This chapter addresses "labels and labeling," labeling submission requirements, the sample label format, and guidance concerning specific label requirements versus preferred label language. The sample label format which appears at the end of this chapter is designed to illustrate the typical arrangement of information on a pesticide label.

II. GENERAL INFORMATION

A. DEFINITION OF "LABEL" AND LABELING

1. FIFRA section 2(p) defines the terms as follows:

a. Label. The term "label" is defined as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers."

b. Labeling. The term "labeling" is defined as "all labels and all other written, printed, or graphic matter

(1) **accompanying** the pesticide or device at any time; or

(2) to which reference is made on the label or in literature accompanying the pesticide or device, <u>except</u> to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, and the Department of Health and Human Services; State experiment stations, State agricultural colleges; and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides."

B. CONTAINER LABEL CONTENTS WHEN BOOKLETS ARE USED

Registrants are allowed to provide part of the label text in the form of a booklet or other "pull off" type labeling, when it is not feasible or possible to literally "fit" the entire label on the container. [40 CFR 156.10.] Pursuant to the regulations set out at 40 CFR part 156, Subpart A, the following label information, however, must be on the label which is on or "securely attached" to the container. "Securely attached" means the label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. [40 CFR 156.10(a)(4).]

- Name and address of the producer, registrant, or person for whom produced
- Restricted Use Statement (if required)
- Product Name, Brand or Trademark
- Ingredient Statement
- Signal Word, including Skull & Crossbones, if either are required
- "Keep Out Of Reach Of Children" (KOOROC)

- Precautionary Statements, including Hazards to Humans & Domestic Animals
- EPA Registration Number and EPA Establishment Number
- Storage and Disposal Statements
- Referral Statement to Directions for Use in booklet, if any (supplemental labeling)
- Net weight or measure of contents

Other parts of the label may be placed in a booklet or other "pull off" type labeling.

1. The Agency's regulation requires that words, statements, graphic representations, designs or other information that are legally required to appear on a label be clearly legible,and readily understood by the ordinary individual. In addition, all required label text must appear on a clear contrasting background and not be obscured or crowded. 40 CFR 156.10(a)(1)(2)

C. COLLATERAL LABELING. Bulletins, leaflets, circulars, brochures, data sheets, flyers or other written, printed or graphic matter which are referred to on the label or which are to accompany the product are known in Agency practice as "collateral labeling". Such labeling is subject to applicable requirements of FIFRA and the Agency's regulations, and for example, may not bear claims or representations that substantially differ from those accepted in connection with registration of the product. [FIFRA 12(a)(1)(B).] Collateral labeling must be submitted along with the application for registration and must be accepted by EPA before it can be distributed.

D. MATERIAL SAFETY DATA SHEETS (MSDSs). The Occupational Safety and Health Administration (OSHA), and not the Agency has direct authority over MSDSs. However, when an MSDS is distributed with a pesticide it becomes a part of the pesticide labeling [FIFRA 2 (p)(2)(A).] Because an MSDS becomes part of the labeling, an MSDS could render the pesticide misbranded if the MSDS includes warnings, precautions or any other information that conflict with the FIFRA-approved label. [FIFRA 2(q)] The registrant must ensure that the MSDS which accompanies the product is not inconsistent with the approved labeling. In the event of inconsistency the registrant may need to either seek approval of labeling changes from EPA or change the MSDS (See PR Notice 92-4).

Although an MSDS which accompanies a pesticide product is considered to be labeling, EPA required statements cannot be placed directly on the MSDS instead of the label. For the purpose of labeling the Agency <u>does not review</u> or <u>accept</u> (stamp) MSDSs. The Agency may refer to a product's MSDSs to extract certain information such as the product's physical/chemical properties or composition.

III. MANDATORY AND ADVISORY STATEMENTS

A. MANDATORY STATEMENTS. Mandatory statements generally relate to the actions that are necessary to ensure the proper use of the pesticide and to prevent the occurrence of unreasonable adverse effects on the environment, which is defined by statute. Mandatory statements include directions for use and precautions that direct the user to take or avoid specific actions. The directions and precautions specify where, when and how a pesticide is to be applied. Mandatory statements are generally written in imperative or directive sentences (e.g., "Wash application equipment...," "Do not use ...," "Users must...," "Apply to corn at a maximum rate of one to two pounds per acre 30 days prior to harvest."). Either EPA or the registrant may develop mandatory labeling statements. When writing mandatory statements, both EPA and the registrant need to ensure that such statements meet the criterion above that the statement is <u>necessary</u> to ensure proper use of a pesticide and to prevent unreasonable adverse effects on the environment. The following directions and precautions are examples of mandatory statements:

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

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

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

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

a. A typical label advisory statement as it may have been written prior to PR Notice 2000-5, Guidance for Mandatory and Advisory Labeling Statements.

b. The same advisory statement written using the preferred descriptive terms.

3. **Precautionary Statements**

a. Latex gloves are recommended.

b. Latex gloves provide the best protection.

4. **Physical and Chemical Hazards**

a. It is preferable to open containers of aluminum phosphide products in open air as under certain conditions they may flash upon opening. Containers may also be opened near a fan or other appropriate ventilation which will rapidly exhaust contaminated air.

b. Opening aluminum phosphide containers outdoors or indoors near an exhaust fan or other ventilation ensures that the gas will be rapidly dispersed if the product flashes.

5. **Directions for Use**

Mixing

a. Tank mixtures should be applied immediately after preparation. If for any reason this is not possible, ensure that sufficient agitation has been provided to re-mix all products and check for complete resuspension prior to application.

b. Applying the product immediately after preparation ensures that it is in suspension. If application is delayed, agitation to re-mix the products and checking for resuspension ensures proper blending.

Application

a1. Factors such as depth to the drain system, soil type, and degree of compaction should be taken into account in determining the depth of treatment.

b1. The depth of treatment depends on the depth of the drain system, soil type, and degree of soil compaction.

a2. It may be necessary to treat along one side of interior partition walls if there are cracks in the slab, plumbing entry points, existing termite infestations, or other conditions which would make treatment appropriate.

b2. Treatment along one side of interior partition walls where there are cracks in the slab, plumbing entry points, existing termite infestations, or evidence of other means of access prevents further infestation.

a3. Rotary hoeing is recommended for preemergence applications which do not receive adequate rainfall or sprinkler irrigation to wet the top 2 inches of soil or to the depth of germinating weeds within about 10 days after application.

b3. If rainfall or sprinkler irrigation does not wet the top 2 inches of soil or depth of germinating weeds within 10 days of a preemergence application, rotary hoeing will ensure soil incorporation.

a4. The spray mixture should be directed to the soil around the base of the cotton plants. Care should be taken to prevent the spray from striking the cotton leaves as injury will occur. The use of leaf lifters or shields on application equipment is recommended to avoid spraying the cotton foliage.

b4. Directing the spray mixture around the base of the cotton plants and using leaf lifters and shields on application equipment will help minimize foliage contact and plant injury.

Cleaning

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

b. If an emulsifiable oil, oil concentrate, or other emulsifiable formulation has been used, flushing the sprayer with a detergent solution at the end of the workday will ensure a clean sprayer and trouble-free operation.

IV. MASTER LABEL-SUB-LABEL-SPLIT LABEL-SUPPLEMENTAL DISTRIBUTOR LABEL AND SUPPLEMENTAL LABELING CONCEPTS

A. Types of labels and labeling include a Master Label, Split-Label or Sub-Label, Supplemental Distributor Label and Supplemental Labeling.

1. **Master Label.** A "Master Label" is a label that contains all of the approved uses for a given product and all associated required labeling.

2. **Sub-Label.** A "Sub-Label" or “Split-Label” is a label which bears claims and directions for only a portion of the approved uses under a given product but is a complete label itself, containing all of the required labeling elements. Agency regulations allow a

registrant to distribute or sell a product under a "Sub-Label" or "Split-Label" provided that in limiting the uses identified on the label, no changes would be necessary to the precautionary statements, use classification, or packaging of the product. See 40 CFR. 152.130(b). Since there are no changes being made which would require submission of an amendment to the labeling, split-labels and sub-labels are not required to be submitted to the Agency for approval. If these labels are intended to be distributed under a different product name, the Agency must approve the alternate brand name. [40 CFR 156.10(b)(2)(ii).]

3. **Supplemental Distributor.** Supplemental distributor labels are labels for a product which is registered to one company but distributed by another company. These labels may be the master label or a split/sub-label and may only differ from the approved label by having a different brand name, company name and distributor number. See 40 CFR152.132. The agency must be notified before distribution by submission of a notice of Supplemental Distribution (see chapter 4). Supplemental distributor labels are not submitted to the Agency.

4. **Supplemental labeling**. "Supplemental labeling" is a term used by the Agency to describe labeling which includes uses, use directions, or other instructions which differ from those on the master label. These are partial labels to be distributed with the product and may be distributed by the registrant or the supplemental distributor. Since these are partial labels, they must bear a statement referring the user to the product label for complete directions and a statement that the labeling must be in the possession of the user. Both the product label and the supplemental labeling are required to safely and effectively apply the product. Supplemental labeling is used for state registration of special local needs under section 24c of FIFRA but may also be appropriate for other situations. For labeling requirements for supplemental labeling for State registrations, refer to 40 CFR 162.153(e)(3). Supplemental labeling submitted by the registrant must comply with the same requirements except the specific information relating to the State registration is omitted. Supplemental labeling must be submitted to and be approved by the Agency. At the minimum the Agency always recommend that these labels bear the following information:

- Misuse statement
- The labeling must be in possession of the user at the time of application.
- Read the label affixed to the container for Pesticide X before applying.
- Use of pesticide X according to this labeling is subject to the use precautions and limitations imposed by the label affixed to the container for pesticide X.
- Product Name
- EPA Registration Number
- Restricted Use Statement (if required)

B. Labeling use patterns are captured by the Pesticide Product Information System (PPIS) for registration purposes and the Label Use Information System (LUIS) for reregistration purposes. It is very important that the Agency be able to easily and accurately identify the registered use for any product. LUIS and PPIS capture use sites, application methods (type, timing, and equipment), application rates, frequency of application, maximum number of applications, treatment intervals, and any use limitations (e.g., preharvest intervals,

reentry intervals) from approved Section 3 and Section 24(c) labels. The aggregated use pattern defined by LUIS is the basis for risk assessment in reregistration, while PPIS provides the basis for determining what uses are currently registered. The registrant must submit and maintain a "Master Label" bearing all registered uses for each registered product. The regulations allow the reviewer to request the complete text of the proposed amended label at any time.

C. Over time, registrants may choose to change product labels. These changes are accomplished through the submission of amended labels, by notification, or by "non-notification". [40 CFR 152.44;152.46(a)&(b).] Agency regulations at 40 CFR 152.50(E) allow applicants to submit partial labels reflecting only the proposed amendments or the changes by notification. Partial label submissions speed up the review process because the reviewer does not have to review the entire label, and they cut down on paper work because the entire label does not have to be submitted with every amendment.

1. This process, however, makes it more difficult to determine the scope of registration for a given product. **Therefore, applicants should clearly indicate when their partial labels do not contain the entire use profile for the product and *any specific label sections which are being changed should be clearly marked.* In order to effectively monitor the scope of the registration, Registrants will be asked to indicate at the top of the label whether it is a "Split Label" or "Sub Label or "Master Label." Registrants should also include a reference to the "Master Label" and its last accepted date.** For example:

SPLIT/SUB LABEL (Supplemental) - Revises Master Label dated XXXXX

2. After several of these 'Split-Labels" or "Sub-Labels" or "Supplemental Labels" have been submitted, the registrant will be asked to submit a new "Master Label" containing all the uses currently approved under the product's registration. The reviewer decides how often a "Master Label" should be requested. When the updated "Master Label" is submitted, the registrant should request that it be stamped "accepted" to assure that the Agency's and registrant's records are complete and accurate. Note that there are limitations on how long a registrant can sell a product under old labeling. [40 CFR 152.130(c).]

V. NON-FIFRA LABELING

Some labels submitted to the Agency have information devoted to non- FIFRA issues, e.g., Department of Transportation (DOT) shipping rules, New York City fire code symbols, Hazardous Materials Identification System (HMIS) and National Paints and Coatings Association (NPCA) and National Fire Protection Association (NFPA) hazard codes and rating systems, Food and Drug Administration or State Department of Agriculture numbers, and bar codes. A registrant may choose to place such text on the label but may not replace, obscure, conflict with, or supersede the FIFRA required text.

VI. LABEL SUBMISSION REQUIREMENTS

A. Reviewers should only accept draft labeling for review that meets the regulatory requirements including those set out in [40 CFR 152.50.] Agency preference has been to ask registrants to follow some of the other steps outlined below, that are not required by law.

1. Submissions for new registrations or amendments must include five copies of all draft labeling (typescript or mock-up). [40 CFR 152.50.] For all amendments, the Agency prefers that one copy of the draft proposed label be marked up or annotated in some way, such as Redline/Strikeout, to indicate what has been changed. The other four copies should be "clean" or not annotated in any way, but include all label changes for which the amendment is submitted.

2. All copies must be legible and should be of suitable quality for making legible photocopies. [40 CFR 152.50.] OPP's practice has been to request that draft labeling have print size of at least 12 characters per inch to aid in label review and to ensure that additional photocopies will be legible.

3. Registrants are asked to submit draft labeling on 8½"x11" paper.

B. If the draft labeling submitted by the applicant does not meet the above criteria, the reviewer shall send a letter to the applicant describing the submission deficiencies and request the applicant revise its draft labeling.

VII. LABEL FORMAT

A. INTRODUCTION. Listed below are the various sections of the label in the *approximate* order they should appear on a label. Several sample label formats appear at the end of this chapter. Each section below corresponds to the chapter in this manual which discusses that particular part of the label in more detail. Note that somewhat different formats are used for certain classes of products (e.g., rodenticide baits).

B. FRONT PANEL

1. Restricted Use Pesticide Statement (Chapter 6) if applicable

This section of the label, if applicable, includes the references to "restricted use", which under FIFRA Section 3 (d)(1)(c) describes those pesticides that require "additional regulatory restrictions" to avoid potential unreasonable adverse effects on the environment.

2. Product Name, Brand or Trademark (Chapter 12)

3. Ingredient Statement (Chapter 5)

This section of the label identifies the name and the percentage by weight of each active ingredient and the percentage by weight of other/inert ingredients. If the size or form of the product package makes it impracticable to place the ingredient statement on the front

panel of the label, permission may be granted for the ingredient statement to appear elsewhere. See 40 CFR. 156.10(g)(2).

4. "Keep Out of Reach of Children" (KOOROC) Statement (Chapter 7)

This specific statement, which is commonly referred to as the KOOROC statement ("child hazard warning"), appears on almost all end use pesticide products except those pesticides that are intended for use on children or where it is demonstrated that children will not come in contact with the product. In these cases, a modified statement is allowed.

5. Signal Word (Chapter 7)

Signal words which correspond to the toxicity categories for product hazards (e.g., oral, dermal) appear on the front panel of the label.

6. First Aid (Statement of Practical Treatment) (Chapter 7)

A first aid statement must appear on the front panel of all Toxicity Category I pesticides, but the agency may allow reasonable variations in the placement of the statement. [40 CFR 156.10(h)(1)(iii).] The front panel must include a reference such as "See statement of practical treatment on back panel" near the word "poison" and the skull and crossbones if the Agency allows the first aid information to appear on the back panel. [40 CFR 156.10 (h)(1)(iii).]

7. "Skull & Crossbones" Symbol and the word "POISON" (Chapter 7)

These symbols identify pesticide products which are determined to be in Toxicity Category I based on at least one of the following acute toxicity studies: acute oral, acute dermal or acute inhalation or contains certain inert ingredients. [40 CFR 156.(h)(1)(i)(A); FIFRA 2(q)(2)(d).]

8. Net Contents/Net Weight (Chapter 17)

This section identifies the weight or volume of pesticide in the container.

C. FRONT OR BACK PANEL

1. EPA Registration Number & Establishment Number (Chapter 14)

The EPA Registration Number is the single most important piece of information for tracking pesticide products. **The EPA Registration Number must appear on the label of the product.** 40 CFR156.10(e). The EPA Establishment Number identifies the final physical location where the pesticide product was produced or labeled. The EPA Establishment Number may appear on any suitable location on the label or immediate

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

2. Company Name & Address (Chapter 15)
This section of the label identifies the name and address of the producer, registrant or person for whom the product is produced.

D. BACK PANEL

1. Precautionary Statements

a. Hazards to Humans and Domestic Animals (Chapter 7)

Where a hazard exists to humans or domestic animals precautionary statements that describe the particular hazard, route of exposure and precautions to be taken must appear on the label. See 40 CFR 156.10(h)(2)(i).

b. First Aid (Statement of Practical Treatment) (Chapter 7)

This section of the label provides information to the pesticide user concerning appropriate first aid for the various routes of exposure associated with accidental exposure. [40 CFR 153.10(h)(1)(iii).]

.

c. Environmental Hazards (Chapter 8)

Where a hazard exists to non-target organisms precautionary statements that identify the hazards and necessary precautions must appear on the label. See 40 CFR 156.10(h)(2)(ii).

d. Physical or Chemical Hazards (Chapter 9)

Hazards such as flammability, explosive potential or dielectric breakdown and the various precautions to be taken must be identified, as applicable. [40 CFR 156.10(h)(2)(iii).]

2. Directions for Use (Chapter 11)

This section of the label provides instructions to the user on how to use the product, and identifies the pest(s) to be controlled, the application sites, application rates and any required application equipment. This section may also include certain worker protection issues such as a reentry statement which identifies the specific time period following treatment during which entry into a treated area is restricted. As further described in Chapter 11, other issues must be addressed in the directions for use. [40 CFR 156.10(i).]

3. Storage and Disposal (Chapter 13)

This section of the label provides instructions for storing the pesticide product and for disposing of any unused pesticide and the pesticide container. [40 CFR 156.10(i)(2)(ix).]

4. Warranty Statement (Chapter 12)

This is a disclaimer statement included voluntarily on most pesticide products by the registrant.

5. Worker Protection Labeling (Chapter 10)

All WPS labeling requirements have been consolidated into this chapter. [40 CFR 156 Subpart K.]

VIII. FINAL PRINTED LABELS AND LABELING

A. Final printed labels or labeling must be filed and accepted by the Agency prior to product registration, although applicants need not submit final versions until draft labeling has been provisionally accepted by the Agency. In some cases, reproductions of unusual labels (e.g., silkscreen) are acceptable. See 40 CFR 156.10(a)(6). Agency practice is to request two copies of the final printed labeling that will accompany the pesticide product when distributed or sold. The type size of final printed labels may be checked by using the template on the following page. Make a copy of the template on a transparency sheet (be sure to copy it using a 1:1 ratio or 100% setting on most photocopies-no enlargement or reductions). Overlay the template printed on a transparency on the final printed label and compare the type size of the Signal Word, and the "Keep Out of Reach of Children" statement on the printed label with that of the template. The table at the top of the chart may be used to determine the appropriate type size based on the size of the label.

Label Type Point Chart

Size of Label on Front Panel in Square Inches	SIGNAL WORDS as Required Minimum Type Size [All Capitals]	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 up to 10	10 point	6 point
above 10 up to 15	12 point	8 point
above 15 up to 30	14 point	10 point
over 30	18 point	12 point

NOTE: No type on any label can be less than 6 point.

18 point POISON DANGER WARNING CAUTION
12 point KEEP OUT OF REACH OF CHILDREN
12 point Keep Out of Reach of Children

14 point POISON DANGER WARNING CAUTION
10 point KEEP OUT OF REACH OF CHILDREN
10 point Keep Out of Reach of Children

12 point POISON DANGER WARNING CAUTION
8 point KEEP OUT OF REACH OF CHILDREN
8 point Keep Out of Reach of Children

10 point POISON DANGER WARNING CAUTION
6 point KEEP OUT OF REACH OF CHILDREN
6 point Keep Out of Reach of Children

6 point POISON DANGER WARNING CAUTION
6 point KEEP OUT OF REACH OF CHILDREN
6 point Keep Out of Reach of Children

Consumer Product Sample Label

PRODUCT NAME

[product information: (like what this product is used for)]

CAUTION

KEEP OUT OF REACH OF CHILDREN

First Aid [1]

If Swallowed _____
If Inhaled _____
If on Skin _____
If in Eyes _____
Note to Physician: [2] _____
_____
[Product Name] is an organophosphate pesticide that inhibits cholinesterase.

SEE OTHER PANEL FOR PRECAUTIONARY STATEMENTS

ACTIVE INGREDIENT(S): 90.00%
OTHER INGREDIENTS:[3] 10.00%
TOTAL: 100.00%

This product contains ___ lbs of [A.i.] per gallon.

EPA Registration No.
EPA Establishment No.

[Registrant Name]
[Address]
[Telephone Number]

Net Contents _____

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

_____
_____
PPE _____
_____
_____
_____

ENVIRONMENTAL HAZARDS

_____
_____

PHYSICAL OR CHEMICAL HAZARDS

_____
_____

DIRECTIONS FOR USE

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

GENERAL INSTRUCTIONS AND INFORMATION

_____
_____
_____

GENERAL INFORMATION (non-site-specific):

_____
_____
_____

GENERAL PRECAUTIONS AND RESTRICTIONS (non-site-specific): _____
_____
_____

APPLICATION INSTRUCTIONS
(site-specific)

Use Site: _____
_____
_____

Use Site: _____
_____
_____

Use Site: _____
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Use Site: _____
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Use Site: _____
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Use Site: _____
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Use Site: _____
_____

Use Site: _____
_____
_____
_____

STORAGE AND DISPOSAL

STORAGE _____
_____

DISPOSAL _____
_____

WARRANTY STATEMENT

_____
_____
_____

1. When First Aid statements appear on the front panel they should be grouped together with the other precautionary statements, preferably appearing first, immediately following the general heading “Precautionary Statements”.
2. Content of the Note to Physician is determined, in part, by the Acute Toxicity Review.
3. A complete listing of inert ingredients may be provided below the ingredient statement.

Non-Restricted Use Sample Label

PRODUCT NAME

Product information: (what is product used for)

KEEP OUT OF REACH OF CHILDREN

SIGNAL WORD

First Aid [1]

If Swallowed _____
If Inhaled _____
If on Skin _____
If in Eyes _____
Reminder to have label. Emergency phone number.
Note to Physician: [2] _____

SEE OTHER PANEL FOR PRECAUTIONARY STATEMENTS

ACTIVE INGREDIENT(S): 90.00%
OTHER INGREDIENTS: [3] 10.00%
TOTAL: 100.00%
This product contains ____ lbs of [a.i.] per gallon.

EPA Registration No.
EPA Establishment No.

[Registrant Name]
[Address]
[Telephone Number]

Net Contents _____

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

_____

PPE _____

ENVIRONMENTAL HAZARDS

_____

PHYSICAL OR CHEMICAL HAZARDS

_____

DIRECTIONS FOR USE

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

GENERAL INSTRUCTIONS AND INFORMATION

Chemigation Instructions *or* Prohibition (If required): [4]

_____

SPRAY DRIFT LABELING (If applicable) :

_____

DIRECTIONS for USE
(continued)

~~Non-Crop/Site/Pest:~~ _____

~~Non-Crop/Site/Pest:~~ _____

~~Non-Crop/Site/Pest:~~ _____

~~Non-Crop/Site/Pest:~~ _____

~~Non-Crop/Site/Pest:~~ _____

~~Non-Crop/Site/Pest:~~ _____

~~Non-Crop/Site/Pest:~~ _____

~~Non-Crop/Site/Pest:~~ _____

STORAGE AND DISPOSAL

~~PESTICIDE STORAGE~~ _____

~~PESTICIDE DISPOSAL~~ _____

CONTAINER DISPOSAL

WARRANTY STATEMENT

_____

1. When First Aid statements appear on the front panel they should be grouped together with the other precautionary statements, preferably appearing first, immediately following the general heading "Precautionary Statements".
2. Content of the Note to Physicians is determined in part by the Acute Toxicity Review.
3. A complete listing of inert ingredients may be provided below the ingredient statement.
4. Required except for products intended solely for residential use; direct injection into plants; post harvest application, or application only as a gas or solid (e.g., pellet, tablet, granule, or dust formulations).

Restricted Use Pesticide - Worker Protection Standard Sample Label

RESTRICTED USE PESTICIDE
(If applicable)[1]

Due to (insert reason)
For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

PRODUCT NAME

product information: (what is product used for)

KEEP OUT OF REACH OF CHILDREN

SIGNAL WORD (ENGLISH\SPANISH) **Poison**

[Skull & Crossbones]

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

First Aid [2]

If Swallowed _____
If Inhaled _____
If on Skin _____
If in Eyes _____
Note to Physician: [3] _____

ACTIVE INGREDIENT(S): 90.00%
OTHER INGREDIENTS: [4] 10.00%
TOTAL: 100.00%
This product contains ____ lbs of [a.i.] per gallon.

SEE OTHER PANEL FOR PRECAUTIONARY STATEMENTS

EPA Registration No.
EPA Establishment No.

[Registrant Name]
[Address]
[Telephone Number]

Net Contents _____

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

_____

PPE _____

User Safety Requirements _____

Engineering Controls: _____

ENVIRONMENTAL HAZARDS

_____

PHYSICAL OR CHEMICAL HAZARDS

_____

DIRECTIONS FOR USE

RESTRICTED USE PESTICIDE
(if applicable) [1]

It is a violation of Federal law to use this product in a manner inconsistent with its 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 agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR 170. This Standard contains requirements for the

NON-AGRICULTURAL USE REQUIREMENTS
(If applicable)

Chemigation Instructions *or* Prohibition (If required): [5]

SPRAY DRIFT LABELING (If applicable) :

DIRECTIONS for USE
(continued)

Crop/Site/Pest:

Crop/Site/Pest:

Crop/Site/Pest:

Crop/Site/Pest:

STORAGE AND DISPOSAL

PESTICIDE STORAGE

PESTICIDE DISPOSAL

CONTAINER DISPOSAL

WARRANTY STATEMENT

1. Restricted Use classification as specified in 40 CFR 152.160 - 175.
2. When First Aid statements appear on the front panel they should be grouped together with the other precautionary statements, preferably appearing first, immediately following the general heading "Precautionary Statements"
3. If required content of the Note to Physician is determined, in part, by the Acute Toxicity Review.
4. A complete listing of inert ingredients may be provided below the ingredient statement.
5. Required except for products intended solely for residential use; direct injection into plants; post harvest application, or application only as a gas or solid (e.g. pellet, tablet, granule, or dust formulations).

Chapter 4 **TYPES OF LABEL REVIEWS**

I. INTRODUCTION

A. Label reviews are conducted for many types of submissions. How a reviewer proceeds with a label review depends on the type of action proposed by the registrant and whether the submission is a new submission (first time submitted to the Agency) or a resubmission (follow-up to a previous submission).

B. When a registrant submits information pertaining to several products that are similar in composition or a series of dilutions (products that have the same active ingredient (a.i.) and other ingredients so when diluted they may be considered identical), every effort should be made to route and review these submissions together to ensure consistency of labeling decisions.

II. SUBMISSIONS THAT DO NOT REQUIRE LABEL REVIEW

A. SUPPLEMENTAL DISTRIBUTOR. After a registrant has obtained registration for its pesticide product, a second person or company may then distribute or sell the basic registrant's product under the second person or company's name and address. Such distribution and sale is termed "supplemental distribution" and the product is referred to as a "distributor product." Supplemental distribution requires an agreement between the basic registrant and the second company (usually referred to as the "distributor"). Both companies confirm the distributor arrangement by submitting a completed Notice of Supplemental Distribution of a Registered Pesticide Product form (EPA Form 8570-5) for each distributor product. (See 40 CFR 152.132 for other requirements). The distributor is considered an agent of the registrant for all purposes under FIFRA and both the distributor and the registrant can be held liable for violations pertaining to the distributor product. [40 CFR 152.132.] The basic registrant is requested to notify EPA if it terminates its agreement with a supplemental distributor. Supplemental distributor labels are <u>not</u> submitted to EPA for review. If submitted they will <u>not</u> be stamped "Accepted," or even retained in Agency files (See Chapter 14 for more information on distributor labeling).

B. EXEMPTIONS**.** FIFRA section 25(b) authorizes the Agency to exempt from FIFRA regulation any pesticide which the Agency determines either (1) to be adequately regulated by another Federal agency or (2) to be a character which is unnecessary to be subject to FIFRA In either case, the pesticide labels do not need to be submitted to the Agency. 40 CFR 152.25(g) and PR Notice 2000-6 (for minimum risk pesticides) describe the conditions of exemption and the requirements to meet the exemption. No false or misleading labeling statements under 40 CFR 156.10(a)(5)(i) through (viii) may appear on an exempt pesticide product. Only minimum risk inerts from the current updated List 4A may be used to formulate exempt pesticides. List 4A can be found at http:www.epa.gov/oppbppd1/biopesticides/otherdocs.list4adocs.htm.

C. NOTIFICATION/NON-NOTIFICATION. The Agency's regulations (40 CFR 152.46, and PR Notice 98-10) allow registrants, without Agency approval, to make certain modifications to their label that have no potential to cause unreasonable adverse effects to the environment. Some of these changes can be made simply by "Notification"; which involves an Application for Registration form (EPA Form 8570-1) marked "Notification," a copy of the labeling with changes highlighted, and a Certified Statement of the Notification, submitted to the Document Processing Desk. Notifications are processed separately than amendments and generally within 30 days. If the
"notification" documents raise a concern with the label reviewer, he or she may require the registrant to submit a application for amendment when necessary. [40 CFR 152.46.] The following modifications are some that can be made by notification. Refer to PR Notice 98-10 for specific information on the circumstances under which notification is appropriate and for additional topics that can be modified through notification.

Adding or changing alternate brand names
Changing primary product name
Adding or deleting pests (exceptions include, but are not limited to , pests of public health significance, termites or pests under USDA quarantine)
Adding indoor, nonfood sites to antimicrobial products
Changes in packaging and related labeling statements
Use deletions related to Data Call-Ins
Storage and disposal statements
Use of symbols and graphics (except Skull & Crossbones)
Changes in Warranty Statements

There are changes to labels can be made without notification to the Agency. PR Notice 98-10 identifies those label topics that can be amended through "non-notification." Please note that other PR Notices may permit certain label modifications by notification for specific Agency initiated label changes. Please also be aware that the Antimicrobial's Division notification process is different from other Divisions. See PR Notice 98-10 for details.

III. SUBMISSIONS THAT REQUIRE LABEL REVIEW

A. The following types of submissions require label review:

Old Chemicals and Amendments, without Data
Fast track
Data compensation
Me-Too's
Old Chemical and Amendments, with Data
Products for which Efficacy Data must be Submitted
New Chemical and New Uses
Technical Grade and Manufacturing Use Products
Special Local Needs
Experimental Use Permits

B. OLD CHEMICALS AND AMENDMENTS, WITHOUT DATA. This type of submission involves an application for an "old" chemical (i.e., active ingredient) currently registered for use as a pesticide. Thus, nothing "new" is proposed for the chemical or formulation. These submissions may also include applications for amendments to labels of existing product registrations. An example is an amendment for the addition to the label of a new site or pest which has been previously approved by the Agency for other products containing the same active ingredient. For products composed of multiple active ingredients, the proposed "new site or pest" must be previously approved for all of the a.i.'s.

C. FAST TRACK. An application is considered a fast track action for review if no data or only product chemistry data are submitted. If a registrant chooses to submit acute toxicity data and efficacy data to fulfill the data requirement, the action will not be considered as a fast track action. When label amendments subject to data compensation requirements and procedures are requested (such as when adding a crop), the whole product (not just the added crop) is subject to the data compensation requirements and procedures.

D. DATA COMPENSATION. If no new formula is being proposed, no additional acute toxicity data submissions are required, although data citations may be required (see 40 CFR 152.80 through 152.97). If a crop is added to a label as a me-too submission, data must still be cited because residue data were originally required to register the use on the crop unless the formulator's exemption can be used. Citation of data protects the rights of data submitter(s) by the new registrant's acknowledging the studies and offering to pay the submitter(s) compensation for the cost of generating the original data.

E. ME-TOO'S. For me-too submissions, the pesticide product and the proposed use must be identical or substantially similar to a currently registered pesticide. [FIFRA 3(c)(7)(A).] The applicant must cite the currently registered pesticide product by EPA registration number. The reviewer must ensure that the two products <u>are</u> substantially similar or identical in formulation. To make this determination, refer to the guidance below:

1. If the a.i. in the product is subject to a completed Reregistration Eligibility Decision (RED) Document. If it is, the me-too submission must comply with the terms of that RED document.

2. Acute toxicology data from one product will support another product if:

a. According to the Confidential Statement of Formula (CSF) the proposed product is identical to the cited product.

b. The proposed product is "substantially similar" to the cited product, for example the only difference is that a minor intentionally added component (<1%) is replaced by 2 components with the same function, adding up to the same percentage as the one replaced.

c. The proposed product is essentially a dilution of the cited product with water and the cited product is in Category III or IV for all acute toxicity endpoints.

d. The proposed product is essentially an aqueous dilution of the cited product, is a Category I or II endpoint for one or more acute toxicity endpoints, and a precautionary review shows that the two products are substantially similar.

e. The proposed product has the same active ingredient in the same percentage as the cited product, different intentionally added inert ingredients perform the same functions in approximately the same percentages, and a precautionary review shows that the proposed and current products are substantially similar.

3. The pH's of the two products may provide an indication of whether the products are similar. Sometimes they are widely different. Differences in the pH's can affect irritancy and even oral toxicity. If the products look alike, but have widely different pH's, the application must provide a rationale that would justify treatment of the second product as a "me too". If the pH's are not close to identical, this is a signal that the products are not similar.

4. The label reviewer must also ensure that the new use patterns, including any new or additional public health pests, are the same. In addition, if the label under review is a rodenticide, repellent, or antimicrobial bearing a public health claim, any changes in the other intentionally added ingredients must be cleared by the efficacy reviewers to make certain that these changes will not affect the efficacy of the product (i.e., change of bait color, smell, texture, etc.) No changes to the composition of the rodenticide baits or repellents may be accepted without an efficacy review.

5. The registrant must submit complete product chemistry data for Manufacturing Use Products (MPs) and End-Use Products (EPs) that are produced by integrated systems. The label reviewer should send product chemistry data for product chemistry review. The product chemistry reviewer will compare the concentrations of the active ingredients and their associated impurities to determine substantial similarity in accordance with Standard Operating Procedure 3068.2.

6. For all EPs that are formulated with a registered source product and are found to be toxicologically similar, product chemistry data are required in accordance with 40CFR 158.150-190, and should be reviewed by Product Chemistry for adequacy, completeness and validity of the data.

7. If the proposed me-too product is found to be dissimilar to the cited product, then the label review process is suspended. The reviewer should prepare correspondence to the registrant noting that the Agency has determined that the cited, registered product is not substantially similar to the proposed product and the registrant must submit the required studies or cite another product that is substantially similar.

8. If the me-too product is a "repack" (i.e., the product is simply repackaging from another registered product, with no changes to its composition), check the proposed product's Confidential Statement of Formula (CSF) with the CSF of the cited product to make certain the

formulations are the same. If so, no data are required. Note the CSF should state "Repack of EPA Reg. No."

F. OLD CHEMICALS AND AMENDMENTS WITH DATA. This type of submission involves an old chemical currently registered active ingredient) or a "me-too" where "something new" is being proposed. For example, the proposal may involve a new use, a new application rate, or a change in precautionary statements. Basically, it is an action not previously approved by the Agency, and a review more extensive than a simple me-too comparison is necessary. Supporting data or data citations must accompany the submission. Review of the label will be based upon the conclusions of the data reviews from the product chemists, toxicologists, or efficacy reviewers. Generally, the specific reviews will only affect a small portion of the label; the rest of the text should remain unchanged from the originally accepted label.

G. PRODUCTS FOR WHICH EFFICACY DATA MUST BE SUBMITTED.

1. Efficacy studies document how well pesticide formulations perform as pest control agents. These studies may include tests to determine the lethality of a formulation against a certain pest species, to document effectiveness under actual use situations, and/or to determine whether claims beyond mere control are supported (i.e., length of a residual effect).

2. Although the Agency generally waives the submission of efficacy data for many products (except for the types of products listed below), the applicant or registrant is required to have such data on file for each product. EPA reserves the right to call in such data at any time, either during initial review or subsequent to registration. The team reviewer should be alert to label claims that seem to promise control or performance beyond that of similar products. Examples of products with such claims include herbicides that claim control of weeds in lawns for one full year, and cotton insecticides that claims total season-long elimination of pink bollworm with just one application. When a reviewer identifies questionable or unusual efficacy claims, the PM/team leader should be consulted and, if warranted, the applicant should be told to delete the claims or to submit efficacy data which support the claims. If the reviewer is not sure whether proposed claims are appropriate, the submission should be routed to an efficacy reviewer for assessment.

3. **Some Types of Products Requiring Submission of Efficacy Data**

a. Antimicrobials. All products (excluding those which are recommended for use in or on living humans or animals) intended to control microorganisms infectious to humans.

b. Invertebrate Control. Products intended for use in or on humans (or in or on pets for control of pests which attack humans such as fleas, ticks, mosquitoes, and biting flies) and in premises or in the environment to control pests of sanitary or public health significance such as those above as well as termites, wasps, scorpions, poisonous spiders, fire ants, cockroaches, centipedes, and bedbugs. See PR Notice 96-7 for important information on termiticide labeling and efficacy data requirements for termiticides.

c. Rodenticides and Repellents. Rat and mouse control products; products used to disperse or control birds that pose health threats; products used to control rabies vectors such as bats, skunks, raccoons, foxes, coyotes; products used to control rodents considered to be disease vectors; and products used to control vertebrate animals such as poisonous snakes, dogs, and bears that can injure humans by direct attacks.

d. New Actives Ingredients or New Uses. Formulated products which either contain new active ingredients or have proposed use patterns which differ from any previously accepted for a similar formulation, and which have public health uses.

e. Products to Control Mycotoxin-Producing Organisms. Products intended to control organisms that produce mycotoxins (organic compounds produced by the fungi which may be highly toxic and carcinogenic to mammals). No such products are currently registered.

4. **Product Team Structures/Roles Regarding Efficacy Data**

a. Within the Office of Pesticide Programs, product performance (efficacy) data are specific to and evaluated by the three product Divisions: Antimicrobial Division (AD), Registration Division (RD), and Biopesticides and Pollution Prevention Division (BPPD).

b. For the Antimicrobial Division guidance documents have been developed called DIS/TSS enclosures for the review of antimicrobial pesticides, including determination of health-related and non-health-related issues and label requirements. Efficacy issues including label review are handled by the Efficacy and Science Support Branch in the Antimicrobial Division. The microbiologists within this branch are responsible for determining whether the product claims are supported by the data and that the directions for use are appropriate for the claims.

c. Within the Fungicide and Herbicide Branches in RD, submission of efficacy data are generally not required since the target pests seldom affect human health. Because efficacy data is necessary for registration of certain insecticides and rodenticides, technical reviewers within the Insecticide-Rodenticide Branch review the product performance data submitted with these products.

d. The Biopesticides and Pollution Prevention Division (BPPD), is multi disciplinary, combining both science and regulatory personnel. BPPD has two branches: one handles Biochemical Pesticides and the other handles Microbial and Plant Pesticides. Within each branch there are Regulatory Action Leaders (RALs) and Science Reviewers (SRs). General label review is the responsibility of the RAL, although SRs review certain sections (precautionary labeling, declaration of active ingredients, storage and disposal, etc.) and provide comments to the RAL. Since BPPD is multi-disciplinary, many RALs are scientists who also performs science reviews, and many SRs have regulatory experience that enables them to perform regulatory actions.

H. NEW CHEMICAL AND NEW USES. This type of submission involves a new chemical (a.i.) which is currently not registered by the Agency as a pesticide or a new use. The registrant must propose the labeling for such products. The labeling should, however, follow the general label

format discussed in Chapter 3. The proposed label text may be modified as a result of the science review.

I. TECHNICAL GRADE AND MANUFACTURING USE PRODUCTS. This type of submission involves a product which is used to manufacture or formulate other pesticides. Normally, a technical grade product is registered concurrently with other manufacturing use products or end use products that can be formulated from it. (See description of these types of products below).

1. A MP contains only the a.i. and with intentionally added inert ingredients. See 40 CFR 158.154(k) for more information. MPs are not end use products. (SEE 40 CFR 158.154(h)) An MP contains the technical active ingredient and may contain intentionally added inerts. A technical grade product is considered an MP, but not all MPs are technical grade products. (See 40 CFR 158.154 (h) and (k)).

2. MP registrants are required to identify in their labeling those uses which they are supporting for registration or reregistration. For example, "For formulating only into end-use products for (list the use patterns and sites)." PR Notice 94-1 recommends specific language. OPP requires that registrants identify at a minimum, the relevant sites which are listed in Appendix A, part 158 of the CFR (Use Pattern Index). Some MPs list very specific use patterns including pests and in some cases site limitations to assist their formulators in preparing their application for registration.

3. The labeling of the technical grade or manufacturing use product must fit the basic label format, and will also include a statement such as "For Manufacturing Or Formulating Use Only" and a listing of the use patterns and sites for the EPs to be formulated from the MP. At the registrant's discretion, one of the two statements listed below may be added to an MP label under "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or a user group. Each time a new use is added to the EP label, the technical grade or MP label should be amended to add that same new use.

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 the U.S. EPA data submission requirements regarding the support of such use(s)." (See PRN 94-1).

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 uses."

J. SPECIAL LOCAL NEEDS (SLN) - FIFRA Section 24(c). States have authority under FIFRA Section 24(c) to register additional uses for a federally registered pesticide. The Agency has ninety days to respond to the state as to whether the Special Local Need registration is acceptable. See disapproval process at 490 CFR 162.154(c). Such registrations are for distribution and use only within a particular state to meet a "Special Local Need" ("SLN"). Although SLNs can be approved for many different reasons and application sites, most involve use on crops. A certain

crop grown within a state may be attacked by a new pest not on a current label, or state officials may expect it to be attacked sometime during the growing season, thereby creating a special pest problem. The pesticide (a.i.) must have an established tolerance associated with the crop, or be exempted from the requirement of a tolerance for that crop. Although most 24(c) registrations consist of adding a use to a federally registered product, the state may also register a new end-use product (not federally registered) as a 24(c) registration with a stand-alone label. See 40 CFR 162.152(b)(2) for information on the types of new end-use products for which a state may issue a 24(c) registration.

1. Special Local Need labels are not stamped "Accepted," but are reviewed for the required, pertinent information. EPA sends the State a letter acknowledging receipt of the application. If there is a problem with the SLN (e.g., no established tolerance), a notice of intent to disapprove is sent to the State by the PM/team leader. If something is omitted from the label, the State is informed; however, the SLN is not disapproved. Occasionally, it is necessary to send the SLN to the Health Effects Division (HED) for review (e.g., if there is a question on the associated tolerance). In such cases, HED will review the label and make recommendations.

2. The Section 24(c) review process is described in further detail in OPP's Standard Operating Procedure #4007.1, February 9, 1996.

K. EXPERIMENTAL USE PERMITS. Experimental Use Permits (EUP) authorize extensive field trials (greater than ten acres terrestrial; one acre aquatic) of unregistered or registered pesticides unregistered use. The EUP label follows the standard label format, except that the label must include the EPA Experimental Use Permit No. and the statements: "Not for sale to any person other than a participant or cooperator of the EPA approved Experimental Use program", and "For Experimental Use Only." (Refer to 40 CFR 172.6 for additional requirements.) EUP's are usually issued for a period of one year for a specific number of pounds to be used on a specific acreage, but may be extended for longer periods. (See 40 CFR 172.5).

IV. USE DELETIONS

When a use is deleted from the label, the label is not stamped accepted even if it is found to be acceptable upon reviewing. Registrant that intend to delete uses must submit an application (amendment) form and five copies of revised labeling. See 40 CFR 152.44 and 152.50. Two copies of a marked-up version of the previously approved labeling highlighting the deletions should be included. Use deletions are published in the Federal register according to the requirements of FIFRA 6(f). Any label mistakes not caught in the first review should be addressed during the second and subsequent reviews.

V. RESUBMISSIONS

Resubmissions are follow-up applications from registrants responding to objections the Agency had to their original submissions. The entire label of the subject product should be re-reviewed with particular care to ensure that the registrant has answered all of the concerns identified during the

original review. Any label mistakes not caught in the first review should be addressed during the second and subsequent reviews.

Chapter 5 **INGREDIENT STATEMENT**

I. INTRODUCTION

This chapter covers the ingredient statement and footnotes sections of the label, which must contain, as provided in 40 CFR 156.10(g), the name and percentage by weight of each active ingredient, the total percentages by weight of all "Other Ingredients,"and substatements including, but not limited to: the acid equivalent, elemental equivalent, toxic ingredients, petroleum distillates, sodium nitrite, and corrosivity. If the pesticide contains arsenic, in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. 40CFR 156.10(g)

II. WHAT IS INCLUDED IN AN INGREDIENT STATEMENT

A. FORMAT. The label reviewer must review the proposed label for a clear and prominent ingredient statement which contains the name and the percentage of each active ingredient, and the total percentage of all "inert"or "other" ingredients, in the pesticide and if arsenic is present, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. 40 CFR156.10(g). The ingredient statement must be presented clearly, and be neither obscured nor crowded by surrounding text. 40 CFR 156.10(a)(2) and (ii). Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" must not be used as a heading for the ingredient statement. 40 CFR 156.10(g)

B. ACTIVE INGREDIENT. Under 40 CFR 152.3, active ingredient means any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel, or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant, within the meaning of FIFRA section2(a), except as provided in 40 CFR 174.3.

C. INERT INGREDIENT. Under 40 CFR 152.3, inert ingredient means any substance (or group of structurally similar substances if designated by the Agency) other than an active ingredient which is intentionally included in a pesticide product, except as included in 40 CFR 174.3. Some examples of ingredients that may be inert ingredients include: solvents, stabilizers, spreaders or stickers, preservatives, surfactant, defoamers, etc.

1. PR Notice 97-6 sets forth the Agency's policy concerning the use of "inert" on the label ingredients statement. Under this policy, applicants and registrants are permitted to substitute the heading "Other ingredients" for the heading "Inert ingredients."

D. CONTENTS. The name and nominal concentration expressed as a percentage by weight of each pure active ingredient must be placed under the ACTIVE INGREDIENT heading and the total percentage by weight of all inert/other ingredients must be placed under the heading INERT INGREDIENT or OTHER INGREDIENT (or plural forms of these terms when appropriate).

E. HEADINGS. The headings "ACTIVE INGREDIENT" and "OTHER [INERT] INGREDIENT" (or plural forms of these terms when appropriate), must be the same type size, aligned to the same margin and equally prominent. PR Notice 97-6 recommends "OTHER INGREDIENT" instead of "INERT INGREDIENT," but either may be used. Additionally formatting requirements are set out at 156.10(g)(2)(ii) which provides that the "text of the ingredient statement run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text."

F. PERCENTAGES. The percentages shall be stated in terms of weight-to-weight and the sum of percentages of active and inert ingredients shall be 100. Percentages shall not be expressed by a range of values as 22-25%. 40 CFR 152.10(g)(4). The percentages of active and other ingredients must be aligned by the decimal point.

G. EXPANDED INERT STATEMENTS. Registrants are encouraged to disclose on the label the inert/other ingredients in their pesticide product either by chemical name or functional category with a brief explanatory definition with percentage. For example:

> Other Ingredients.....92.8%
> Purified water, glycerin (to help keep from freezing), surfactant (to keep the active ingredient dispersed in water)

H. It is recommended that the percentage of active and other ingredients be aligned by the decimal point.

III. LOCATION OF INGREDIENT STATEMENT

A. FRONT PANEL. The ingredient statement is normally required to appear on the front panel of the label unless the Agency determines that doing so is impractical. Some examples might be if the pesticide package is extremely small or irregular in shape to the point of making it difficult to place the ingredient statement on the front panel of the label. In such cases, permission may be granted, upon written request (as part of the application), for the ingredient statement to appear on the back or side panel of the label. See 40 CFR 156.10(g)(2)(i).

B. LOCATION ON FRONT PANEL. The preferred location for the ingredient statement is immediately below the product name. (Refer to the sample label formats in chapter 3).

C. OUTSIDE WRAPPERS. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on the outside container or wrapper. See 40 CFR 156.10(g)(2)(i).

IV. NAMES TO BE USED IN THE INGREDIENT STATEMENT

A. FIRST STEPS. The label reviewer must review the names for ingredients used on the proposed label and cross-reference the names in the OPPIN database on the LAN. If none of the

names are included in OPPIN, perhaps the chemical name of the active ingredient is new or the registrant used an inappropriate name. If so, check with your PM/team leader for the correct procedures to follow. Look at each section below to determine the correct names to be used in the ingredient statement.

B. COMMON NAME

1. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. 40 CFR 156.10 (g)(3). Through PR Notice 97-5, the Agency clarified what it considers as acceptable common names. EPA will permit the use of common names approved by the American National Standards Institute (ANSI) in the label ingredients statement without the accompanying scientific chemical names, and will permit the use of other common names listed in PR Notice 97-5 without the accompanying scientific chemical name. When a common name only appears on the label, EPA also recommends the inclusion on labels of Chemical Abstracts Service (CAS) numbers to identify ingredients definitively.

2. The label reviewer should check OPPIN to determine the accepted common name. "(ANSI)" or a "C" in the TYPE column will be shown with the accepted common name in the Chemical Name list. An additional source for this information on older chemicals is the EPA publication, *Acceptable Common Names and Chemical Names for the Ingredient Statement on Pesticide Labels*, 4th edition (December 1979).

3. A list containing some of the common/chemical names may also be found in the Pesticide Tolerance Commodity/Chemical Index section in the back of the CFR volume containing the FIFRA regulations 40 CFR 150-189. Because this list only includes names for chemicals with tolerances, it is only a secondary source. Similarly, a list of some common/chemical names can be found in PR Notice 97-5.

C. CHEMICAL NAME

1. If the active ingredient has a common name, but not one that is considered **"accepted"** the full chemical name must be used in conjunction with a common name 40 CFR 156.10(g)(3). For example:

Acephate (0,S-dimethyl acetylphosphoramidothioate)

2. EPA requests that chemical names be consistent with the nomenclature used in the Chemical Abstracts (CA) Chemical Substance Index, published by the American Chemical Society. OPPIN reflects the correct chemical name: the entry found with the "9CI" (i.e., Ninth Collective Index) designation at the end of the name. [*OPPIN tip for label reviews*: hit the Enter key on the chemical name to see the complete chemical name, which may not appear on the line if the name is too long to fit on the line.]

D. CAS (CHEMICAL ABSTRACTS SERVICE) NUMBER. The CAS number for the active ingredient(s) may be used on the label in connection with the ingredient statement. If the CAS number is used, it should appear as a sub-statement (footnote) to the ingredient statement and not in any way detract from the ingredient statement.

E. MICROBIAL NAME. If the active ingredient is a microbial agent, the Agency requests that the microbial agent be identified by genus and species (and if appropriate also by subspecies and/or isolate number). Again, this name should be identical to the name shown in REFS.

F. DESCRIPTIVE NAME. Descriptive names approved by the Agency may be used in the ingredient statement if there is no accepted common name and no distinctive chemical name. Examples are: "Tobacco dust," "Egg solids," or "Dried blood." Approved descriptive names are listed in REFS, and the name shown on the proposed label must be identical to the name found in REFS.

G. TRADEMARK NAME. A trademark or proprietary name may not be used in the ingredient statement unless it has been accepted as a common name by the Administrator under the authority of FIFRA Section 25(c)(6). See 40 CFR 156.10(g)(3).

V. CRITERIA FOR DETERMINATION OF PESTICIDAL ACTIVITY

A. IS THE INGREDIENT CONSIDERED TO BE ACTIVE

1. The criteria for determination of an ingredient's active or inert status are located in 40 CFR 153.125 and PR Notice 81-4. Generally speaking an ingredient will be considered an active ingredient if, by itself, and when used as directed at the proposed use dilutions, it has the capacity to function as a pesticide or has the ability to elicit or enhance the effect of another compound whose pesticidal activity is substantially increased due to the interaction of the compounds. Ingredients such as stickers and other adjuvants which function simply to enhance or prolong the activity of an active ingredient by physical action are not generally considered to be active ingredients.

2. A chemical may be an active ingredient in one formulation and an inert ingredient in another. Examples are chemicals used as preservatives of a formulation, plant nutrients, or chemicals with some other non-pesticidal use.

B. RELATED COMPOUNDS (ACTIVE). As described in PR Notice 81-4, EPA recommends that related compounds that are now distinguishable from the intended active ingredient(s) due to newer, more discriminating methods of analysis must be accounted for within the pesticide label ingredients statement. If one or more related compounds is isolated and found to have pesticidal activity to the target pest, EPA requests that it be specifically identified and quantified by percentage under the ACTIVE INGREDIENT heading of the label ingredients statement. For example:

ACTIVE INGREDIENTS:
2-Carbomethoxy-1-methylvinyl dimethyl phosphate, α isomer 20.0%
2-Carbomethoxy-1-methylvinyl dimethyl phosphate, β isomer 3.0%
OTHER INGREDIENTS: 77.0%
Total 100.0%

C. RELATED COMPOUNDS (INERT). Related compounds whose active/inert status is not determined by the registrant, must be included (without designation as related compounds or by name) under the total percentage of the INERT INGREDIENT or OTHER INGREDIENT heading (see PR Notice 81-4).

D. EQUIVALENTS: Unless declared as an active ingredient, a related compound must not be included in expressing percent acid or metallic equivalents, nor in the declaration of "pounds active ingredient" or "acid (or metallic) equivalents per gallon" under the ingredient statement. (PR Notice 81-4).

VI. STATEMENT OF CONCENTRATIONS

A. DEFINITION. The percent nominal concentration specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s),as that term is defined in 40 CFR 158.153(i). The nominal concentration is the amount of an ingredient which is expected to be present in a typical sample of a pesticide product at the time the product is produced, expressed as a percentage by weight. The nominal concentration is the only acceptable method for expressing the percentage of active ingredient in the product. **All pesticide ingredient statements must be expressed as nominal concentration.**

B. EXPRESSIONS

1. Reviewers of proposed labels for products subject to deterioration, such as sodium hypochlorite, should note Section IX (Deterioration), below.

2. The percent of the pure active ingredient in a technical grade product is the same as its nominal concentration. This must be indicated in Columns 10 and 13b of the CSF.

3. The nominal concentration in a formulated product is a function of the percentage by weight of the active ingredient in the product (including associated ingredients) and the purity of the source product (its nominal concentration). For example:

> If the purity of the active source is 80%, as declared in column 10 of the CSF, and the percentage by weight of the active ingredient in the formulated product is 20% as indicated in column 13(b) of the CSF, the nominal concentration of the product would be 16% (20% x 0.80), consistent with the label claim. The 16% nominal concentration can be indicated between parentheses in the same column below the 20%w/w.

4. If wider limits for active and inert ingredients were justified as per the regulations 40 CFR 158.175 (c) which case the proposed upper and lower certified limits must be indicated on the Confidential Statement of Formula (CSF) and the guarantee of each active ingredient in percent must be indicated on the label. The guarantee is the label claim nominal concentration, a value between the upper and lower certified limits, not equal to either value.

5. The sum of the percentage by weight of the active ingredient and intentionally added inert/other ingredients in a formulated product must be equal 100%. In a technical grade of active ingredient, the total of all nominal concentrations of the pure ingredient plus associated ingredients, including impurities, must be ≥98%.

6. For ingredient statements which reflect the fact that the active ingredient is the only component of the product, the inert ingredients header is not necessary. For example, for a product which is 100% pure chlorine gas, the following ingredient statement is acceptable:

ACTIVE INGREDIENT:
Chlorine.....100.0%

Assuming that the chlorine gas is only 99% pure, then the following ingredient statement would be required:

ACTIVE INGREDIENT:
Chlorine.....99.0%
OTHER INGREDIENTS..... 1.0 %

7. If the proposed label is for a liquid formulation, the label reviewer must check the Directions For Use section. If any of the use directions of the pesticide product are expressed as a certain weight of active ingredient per unit area (such as pounds per acre), a statement of the weight of the active ingredient per unit volume of the pesticide formulation must also appear at the end of the ingredient statement. See 40 CFR 156.10(g)(4). This is very important when calculating the use rates. An example of this would be, "One gallon contains 4 pounds of the active ingredient (chemical)." If dosage rates in the directions for use are expressed as weight of product/unit area, the weight of the product/gallon must be stated.

VII. SUBSTATEMENTS (FOOTNOTES)

Based on historical practice, EPA requests the following footnotes appear on the label, as applicable:

A. PETROLEUM DISTILLATES. Products containing petroleum distillates, xylene or xylene range aromatic solvents at ≥10% should be indicated on the label immediately below the ingredient statement as a footnote below the term “Inert ingredients” or “Other Ingredients” as follows:

“Contains petroleum distillates, xylene or xylene range aromatic solvents.”

B. INGREDIENTS OF TOXICOLOGICAL CONCERN. Products containing ingredients of toxicological concern should be indicated on the label immediately below the ingredient statement as a footnote below the term “Inert Ingredients or “Other Ingredients” as follows:

> “This product contains the toxic ingredient (name of ingredient), at ...% (indicate the upper certified limit of the toxic component in percent).

C. SODIUM NITRITE. Products containing sodium nitrite at >0.1% should indicate in the ingredient statement as a footnote below the term “Inert Ingredients”(or “Other Ingredients”) as follows:

> “This product contains sodium nitrite.”

VIII. DETERIORATION

A. GENERAL LABELING. In cases where it is determined that a pesticide formulation changes chemical composition significantly over time, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]." (40 CFR 156.10(g)(6)(i)) Note the product must meet all label claims up to the expiration time indicated on the label.

B. SODIUM HYPOCHLORITE. For sodium hypochlorite products containing 5.25 - 12.5% active ingredient, the Agency historic practice has been that instead of an expiration date on the label, the following labeling statement is necessary to ensure the product is effective (because of its rapid degradation).

> "Degrades with age and exposure to sunlight and heat. Use a test kit and increase dosage as necessary to obtain the required level of available chlorine."

IX. SPECIFIC DESIGNATIONS FOR SOME INGREDIENT STATEMENTS

A. Some pesticide ingredients require specific designations on the ingredient statement for proper clarification and identification. Examples of some of these specific designations are shown below:

1. **Microbial Pesticides**. Biopesticides are generally subject to the same labeling provisions as conventional pesticides. They are viewed essentially the same as chemical pesticides with respect to label requirements, except for differences with the ingredient statement.

a. Products containing live microorganisms the agency has historically required that the label indicate the equivalent number of viable units (spores, cells, colony forming units, etc.) per unit weight or volume of product.

b. For Bacillus thuringiensis (Bt) products, the Agency has historically required the following labeling information. The active ingredient declaration must be based upon percent by weight of insecticidal toxin(s) present. Strain variety, as well as percent active ingredient declared for each order of insects affected, must appear on the label. (PR Notice 72-6). The use of potency units expressed in terms of International Units (IU) per milligram of product is required unless the percent toxin has been shown to predict field activity. If used, it should appear on the label below the ingredient statement and should be followed by the statement "Potency units should not be used to adjust use rates beyond those specified in the Direction for Use section." For example:

ACTIVE INGREDIENTS:
Bacillus thuringiensis subspecies kurstaki

Lepidopteran active toxin	3.0%
Dipteran active toxin(s)	2.0%
OTHER INGREDIENTS:	95.0%
Total	100.0%

Potency: 40,000 International Units per milligram of this product. Potency units should not be used to adjust rates beyond those specified in the Directions for Use section.

Because the reregistration data on percentage of active ingredients have not been reviewed for Bt products, labels for many Bt products still list the percentage a.i. based on potency. For potency based ingredient statements for lepidopteran active Bt products, would indicate 500,000 International Units (IU)/mg product = 100% active ingredient. Percent active ingredient is calculated on the product potency compared to the 100% active ingredient assumption of 500,000 IU/mg. Thus, a 16,000 IU/mg product would be (16,000/mg) x (100%/500,000 IU/mg) = 3.2.%.

(1) Subdivision M (Pesticide Testing Guidelines) *Microbial and Biochemical Pest Control Agents* (July 1989) addresses this topic. Certified limits can be expressed as:

(a) Microbial Pest Control Agents (MPCA) units/unit weight or volume
(b) International Units of Potency per unit weight
(c) Weight percent of product

Items (a) and (b) may be expressed using biological, genetic, biochemical, serological or other appropriate data. For example:

ACTIVE INGREDIENT:

Pseudomonas cepacia type Wisconsin	3.8% (by wt.)
OTHER INGREDIENTS:	96.2% (by wt.)
Total	100.0% (by wt.)

Contains at least 50 million viable cells/lb (10^5 cells/gram).

ACTIVE INGREDIENTS:	
Trichoderma harzianum (ATCC 20476)	16.6% W/W
Trichoderma polysporum (ATCC 20475)	16.6% W/W
OTHER INGREDIENTS:	66.8.% W/W
Total	100.0% W/W

Minimum 4.5 million colony forming units (CFU) per pound (454 grams)

2. **Biochemical Pesticides**. The ingredients statement for a product for which the active ingredient is a naturally occurring plant regulator, (such as cytokinins, auxins, or gibberellins) and for which quantitative chemical methods and units are not available, must be stated in an acceptable and generally recognized bioassay unit. For example:

ACTIVE INGREDIENT:	
Cytokinin (equivalent to 200 ppm kinetin activity)	3.0%
OTHER INGREDIENTS:	97.0%
Total	100.0%

3. **Pheromone Products**. The ingredient statement for pheromone dispenser labels shows the pheromone in mg. per dispenser as a footnote. This must be as reflected in the CSF.

ACTIVE INGREDIENT:	
Pheromone*	1.0%
OTHER INGREDIENTS:	99.0%
Total	100.0%

*x mg per dispenser

4. **Insect Virus-based Insecticides**. Pesticide products containing an insect virus as the active pesticide ingredient must indicate the number of activity units (polyhedral inclusion bodies for nuclear polyhedrosis viruses or capsules for granulosis viruses) per gram (10^6 PIBS/gm) or percentages (%). For example:

BIOCONTROL-1

Biological Insecticide for the Control of Douglas Fir Tussock Moth

ACTIVE INGREDIENT*:
Polyhedral Inclusion Bodies of Douglas Fir
Tussock Moth Nuclear Polyhedrosis Virus. 13.5%
OTHER INGREDIENTS 86.5%
Total. 100.0%
*Contains at least 70 million activity units per gram.

Often the active ingredient statement will include "... and insect body parts..." whether the baculovirus is propagated in vivo or in vitro. For example:

SPECIFIC-T-1

ACTIVE INGREDIENT:	
Granulosis Virus of Cydia Pomonella (Coddling Moth)	
(at least 5 x 108 GIBS/ml)	0.005%
OTHER INGREDIENTS:	99.995%
Insect parts/water/inert solids	99.985%
Aureomycin (5.5%)	0.015%
Total	100.000%

5. **Salts, Amine or Ester of Acids**. If the active ingredient is a salt, amine or ester of an acid, the label must declare in a substatement under the ingredient statement the percentage equivalent of the acid. For example:

ACTIVE INGREDIENTS:
Isooctyl ester of 2,4-Dichlorophenoxyacetic acid* 12.0%
Isooctyl ester of 2-(2,4-Dichlorophenoxy) propionic acid** 10.0%
OTHER INGREDIENTS: 78.0%
Total 100.0%
*2,4-Dichlorophenoxyacetic acid equivalent, 9.5%
**2-(2,4-Dichlorophenoxy)propionic acid equivalent, 9%

6. **Copper and Zinc Salts or Complexes**. Pesticide products for which the active ingredients are copper salts or complexes must declare the chemical name of the copper complex as active ingredient and the equivalent metallic copper declared in a substatement. For example:

ACTIVE INGREDIENT:
Copper naphthenate* 93.2%
OTHER INGREDIENTS: 6.8%
Total 100.0%
*Metallic copper equivalent, 22%

This type ingredient statement declaration is also applicable to zinc. For example, zinc naphthenate must be expressed as percent metallic zinc equivalent.

7. **Brominated and/or Chlorinated Compounds**. Certain brominated or chlorinated compounds may require a reference in the ingredient statement to the available chlorine or bromine. For example:

ACTIVE INGREDIENT:
1-Bromo-3-chloro-5, 5-dimethylhydantoin 86.4%
1-3dibromo-5, 5-dimethylhydantoin 8.6%
OTHER INGREDIENTS: 5.0%
Total 100.0%
Provides: 66.8% Available Bromine
25.4% Available Chlorine

8. **Metal Ion Exchange Resins**: Any metal (e.g., Ag or Cu) used as pesticide, when bound to an ion exchange resin, must be declared on the label as the percent metallic equivalent with a footnote immediately below the ingredient statement specifying the identity and amount of the ion exchange resin which was used.

9. **Sodium Chlorate Products**: Because sodium chlorate is extremely flammable, all pesticide products containing sodium chlorate must include a fire retardant in the formulation. These labels must bear in the vicinity of the ingredient statement, a statement indicating that the product contains a fire retardant. If the proposed label is a sodium chlorate product, check the CSF to verify that the product contains a fire retardant (column 15, Purpose in Formulation).

10. **Arsenic Containing Products**: Pesticide products which contain arsenic in any form must include a substatement of the percentages of total arsenic and water-soluble arsenic calculated as elemental arsenic. See 40 CFR 156.10(g)(1). For example:

"Total arsenic, all in water soluble form, expressed as elemental = xx%"

11. **Products with Petroleum Distillates**: Formulations containing greater than or equal to 10% petroleum distillates, xylene, or xylene range aromatic solvent must reflect the statement "Contains petroleum distillates, xylene, or xylene range aromatic solvent" immediately below the ingredient statement as a footnote to the inert ingredients.

12. **Fertilizer-pesticide Combinations**: Pesticides that are formulated in combination with fertilizers must bear an ingredient statement the same as any other pesticides. The fertilizer composition must be separate from the pesticide ingredient statement and must not detract from or obscure the required pesticide labeling statements.

13. **Complexing Agents**: In products containing an active ingredient bound with other agents as a complex, the active ingredient, must be declared in the ingredient statement with a footnote immediately below the active ingredient statement listing the complex formed. In the case of complexed iodine, for example, the active ingredient is titratable iodine.

ACTIVE INGREDIENT:
Iodine* 15.0%
OTHER INGREDIENTS: 85.0%
Total 100.0%
*from (name of complexing agent)

X. INERT INGREDIENTS

A. SPECIAL LABELING REQUIREMENTS FOR INERTS OF TOXICOLOGICAL CONCERN (LIST 1). Products containing one or more other/inert ingredients on List 1 (inert ingredients of toxicological concern) have historically been required to include on the label the statement: "This product contains the toxic inert ingredient (name of inert)." See Inert Ingredients in Pesticide Products; Policy Statement OPP-36140;FRL-3190; 40 CFR 156(g)(7). This statement must be placed in close proximity to the ingredient statement in a type size comparable to other front

panel text. (Refer to chapter 13 also) For enforcement purposes applicants have been asked to indicate on the label the "maximum" percent of ingredients of toxicological concern characterized in the product. PR Notice 90-1, issued May 1, 1990, revised and modified previous published lists

of inert ingredients in pesticide products that are of toxicological concern and require priority testing. In general, after the PR Notice was issued EPA did not register any new products containing a List 1 inert. The most current inert list is available on the
Web: http://www.epa.gov/opprd001/inerts. The list of seven inert ingredients is as follows:

LIST 1. -- INERTS OF TOXICOLOGICAL CONCERN

CAS No.	Chemical Name
50-00-0	Formaldehyde
78-59-1	Isophorone
81-88-9	Rhodamine B
108-95-2	Phenol
117-84-0	Diocytl phthalate
123-31-9	1,4-benzendiol
25154-52-3	Nonylphenol

B. IDENTIFICATION OF INERT/OTHER INGREDIENTS. Inert ingredients are not required to be identified individually in the ingredient statement except when EPA determines that such inert ingredient may pose a hazard to man or the environment. See 40 CFR 156.10(g)(7). In such a situation, EPA may require that the name of the inert be listed in the ingredient statement. However, if a registrant wants to list a particular inert ingredient in the ingredient statement the registrant must list **all** inert ingredients directly below the ingredient statement.

XI. ALTERNATE FORMULATIONS

A. EPA may approve a basic formulation and one or more alternate formulations for a single product. An alternate formulation must meet the criteria listed in 40 CFR 152.43(b)(1) through (4). The Agency may require the submission of data to determine whether the criteria have been met. Registrants are encouraged to keep their alternate formulas, if any, up-to-date. The label text of the alternate formulation product must be identical to that of the basic formulation. The Agency will not approve an alternate formulation if the alternate formulation requires a change in the label text.

B. The alternate formulation must have the same certified limits for each active ingredient as the basic formulation. 40 CFR 152.43(b)(1)

C. If the alternate formulation contains an inert ingredient or impurity of toxicological significance, the formulation must have the same upper certified limit for that substance as the basic formulation.

D. The analytical method required under 40 CFR 158.180 must be suitable for use on both the basic formulation and the alternate formulation.

E. Alternate formulas, should be clearly marked "Alternate Formula A," "Alternate B," etc. Further, indication that an alternate formula is replacing "alternate formula x" or "is in addition to "alternate formula y" would reduce confusion.

F. Except for approved dye substitutions, EPA does not accept alternate formulations for rodenticides.

Chapter 6 **USE CLASSIFICATION**

I. INTRODUCTION

End -use pesticide products (as opposed to products solely for further formulation into other pesticides (See 40 CFR 152.166)) may be classified as Restricted Use Pesticides (RUP), or general use, or may be unclassified. 40 CFR 152.160(a). The Agency does not normally classify products for general use; products that are not restricted remain unclassified. See 40 CFR 152.160(a). If the Agency determines that the pesticide, when applied in accordance with the label's directions for use, warning and cautions may generally cause, without additional regulatory restrictions, unreasonable adverse effects, the Agency will classify the pesticide as an RUP. See FIFRA 3(D)(1)(c). The policy that drives this classification is that when labeling cannot sufficiently mitigate the risk, special training in handling and applying the pesticide product is necessary to ensure the safe use of the product. The sale and distribution of RUPs must be conducted pursuant to the regulations set out at 40 CFR 152.167, or is subject to restrictions promulgated through Agency regulation. FIFRA 3(d)(1)(C)(i)&(ii). The use of RUPs is limited to certified applicators or persons under their direct supervision. Use of unclassified products is not limited in any manner unless the labeling limits use to a specific definable group, (e.g., veterinarians).

II. UNCLASSIFIED PRODUCTS

A. CRITERIA. While there are no specific criteria for determining if a product is unclassified, the following issues can help a label reviewer perform that assessment:

1. **Me-too**. The product under review is a me-too registration, and the product cited as substantially similar is unclassified.

2. **Data Supported**. The product under review is a new product for which data were submitted and none of the following data reviews indicates that the product should be considered for restricted use classification.

a. Environmental Effects, Fate and Groundwater reviews assess the toxicity to fish, birds and mammals, and endangered species and assess the possibility of groundwater contamination and persistence in soil.

b. Chemistry and Exposure reviews assess the degree of human health exposure.

c. Toxicity reviews assess the acute and chronic toxicity of the product, and the acute and chronic human health hazards.

3. **MPs**. The product under review is a manufacturing use product (MP). MPs are not subject to the 40 CFR 152.166 restricted use labeling requirements.

4. **AI's not previously restricted use.** The product under review contains no active ingredient(s) or use(s) which have been previously classified as restricted use. To check: Refer to 40 CFR 152.175. Another reference source for this information is the Webpage: www.epa.gov/opppmsd1/RestProd/. Note that under 40 CFR 152.170(d), there may be other evidence such as field studies or monitoring data that would result in the Agency determining that a pesticide should be restricted use.

If the label under review meets any of the above criteria, then the product is unclassified. If the label under review does not meet one of the above criteria, then the product may be classified as an RUP.

III. RESTRICTED USE PESTICIDES (RUP)

A. DETERMINATION OF CLASSIFICATION. Review the criteria below to determine whether the product should be classified as an RUP.

1. If the product under review is a me-too registration and the cited product is classified as an RUP, then the product label under review must bear the Restricted Use classification. Go to section B below on "Labeling Requirements for an RUP."

2. Based on a review of the data that support the product registration, the pesticide may be classified as RUP if its toxicity exceeds the specific hazard criteria set out at 40CFR 152.170. Even if the RUP criteria are triggered, the label reviewer should check with the Product Manager/team leader to determine if the potential risk can be adequately mitigated through additional labeling restrictions. See 40 CFR 152.170(e). If not, the product must be classified as an RUP. Go to Section 3 below on "Labeling Requirements for RUPs." If the PM/team leader determines that the product should not be classified as an RUP because additional label language can mitigate the risk, then the label reviewer must include a memo to the file noting this decision. The memo must specify the basis for the decision under 40 CFR 152.170(e), including the alternative labeling language required. The label reviewer must sign and date the memo and place it in the registration jacket. The label reviewer should make sure the product label under review does not bear any use classification.

B. LABELING REQUIREMENTS FOR RUPS. Restricted use pesticides are subject to the labeling requirements specified of 40 CFR 156, including the requirements set out at 40 CFR 156.10(j)(2) described further in PR Notice 93-1. The product may have both general and restricted uses. If there is a restricted use, the labeling requirements for restricted use must be followed. Check the label under review to make certain that the label meets the RUP labeling requirements listed below:

1. The statement "Restricted Use Pesticide" must appear at the very top of the label's front panel, 40 CFR 156.10(j)(2)(i). No other wording or symbols should appear above the RUP statement. PR Notice 93-1.

2. The Agency requests that the RUP statement be followed by the reason for RUP classification. (40 CFR 156.10(j)(2)(i)). (See the next section below for examples of chemical-specific RUP statements and reasons for RUP classification).

4. The RUP statement should be enclosed in a box to enhance its visibility on the label. PR Notice 93-1.

5. The RUP statement must appear with sufficient prominence in relation to other label text and graphics so as not to be overlooked. (40 CFR 156.10(j)(2)(i)(A)).

6. The label must bear the phrase "Restricted Use Pesticide" under the heading "Directions for Use" See 40 CFR 156.10 (i)(2)(i).

7. 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). If type size is too small, the label reviewer must notify the registrant in writing of the type size requirements specified in the Code of Federal Regulations at 40 CFR 156.10(h)(1)(iv) for the signal word.

8. The label must not bear any designation indicating that certain uses are restricted and other uses are not restricted. If the registrant wants to include unrestricted uses on a product with restricted uses then the entire product must be labeled restricted. This is to avoid the general public obtaining access to products with restricted uses. If the registrant desires to market uses as unrestricted, then the registrant must seek a separate label only for those unrestricted uses. [40 CFR 156.10(j)(2)(i).]

C. WORDING OF THE RUP TERMS OF RESTRICTION. The label must bear the general summary statement of the terms of restriction at top of the front panel (40 CFR 156.10(j)(2)(i)(B)). See Chapter 3 for correct formats.

1. If use is restricted to certified applicators, the general RUP statement listed at 40 CFR 156.10(j)(2)(i)(B) must appear as follows: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification."

2. Some pesticides require a specific RUP statement, based on specific case-by-case risk management decisions. The Agency in some cases has determined that particular RUP statements are applicable to specific products or to the active ingredient(s). Check the appropriate science review, and consult your Product Manager or Team Leader to determine if a specific RUP statement has been applied to particular products or active ingredients. Then evaluate whether the particular product at issue requires that same or similar language based on risk management issues and the FIFRA statutory standard of unreasonable adverse effects. Also, check in OPPIN or the Chemical Review Manager/Team Leader for the status of the Reregistration Eligibility Decision (RED) document for the chemical. If a RED document has been issued, check it for any specific guidance for Restricted Use Pesticide classification and/or associated labeling. NOTE: Additional specific

RUP statements will be added to the manual as they are identified. Following are some examples of RUP statements. The format for specific RUP statements and examples of chemical-specific statements that the Agency has historically used are set out below:

"Restricted Use Pesticide [Same minimum type size as signal word]"

"Due to [reason for restricted use]"

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification.

a. Acetochlor

"Due to Oncogenicity. For retail sale to and use only by Certified Applicators, or persons under their direct supervision, and only for those uses covered by the Certified Applicator's certification."

b. Acrolein

"Due to high toxicity. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification."

c. Alachlor

"Due to Oncogenicity. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification."

d. Aldicarb (Temik® brand)

"Acute Oral Toxicity and Ground Water Contamination. For retail sale to and use only by Certified Applicators or persons under their direct supervision, and only for those uses covered by the Certified Applicator's certification."

e. Azinphos-Methyl (Guthion™)

"Due to acute toxicity. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification."

f. Creosote

"Due to carcinogenicity. For retail sale to and use only by Certified Applicators or persons under their direct supervision, and only for those uses covered by the Certified Applicator's certification."

g. Diclofop-methyl

“Due to oncogenicity in laboratory mice. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator’s certification.”

h. Diazinon

“Due to Avian and Aquatic Toxicity. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification."

i. Fortress™

"Due to Acute Human, Avian and Aquatic Invertebrate Toxicity. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

j. Hydrogen Cyanamide

"Due to corrosive effects to eyes and skin. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

k Hydrogen Phosphide

"Due to acute inhalation. Toxicity of highly toxic hydrogen phosphide (phosphine, PH_3) gas. For retail sale to and use only by Certified Applicators for those uses covered by the applicator's certification or persons trained in accordance with the accompanying product manual working under the direct supervision and in the physical presence of the certified applicator. Physical presence means on site or on the premises. Read and follow the label and the (manufacturer’s, name of SPECIFIC MANUFACTURER) product manual which contains complete instructions for the safe use of this pesticide."

l. Isoxaflutole

"May injure (phytotoxic) susceptible non-target plants. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification. Commercial and Certified Applicators must ensure that all persons involved in these activities are informed of the precautionary statements."

m. Oxamyl

"Due to acute toxicity and toxicity to birds and mammals. For retail sale to and use only by Certified Applicators or persons under their direct supervision, and only for those uses covered by the Certified Applicator's certification."

p. Methomyl

"Due to high acute toxicity to humans. For retail sale to and use only by Certified Applicators or persons under their direct supervision, and only for those uses covered by the Certified Applicator's certification. Direct supervision for this product requires the Certified Applicator to review federal and supplemental label instructions with all personnel prior to application, mixing, loading, or repair or cleaning of application equipment."

q. Methyl Parathion (except encapsulated formulation)

"For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those used covered by the Certified Applicator's certification. Direct supervision for this product is defined as the Certified Applicator being present during application, mixing, loading, repair and cleaning of application equipment. Commercial Certified Applicators must also ensure that all persons involved in these activities are informed of the precautionary statements."

r. Sulfuric Acid Desiccant

"Due to severe tissue corrosive action. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

Chapter 7 **PRECAUTIONARY STATEMENTS**

I. INTRODUCTION

A. CONTENTS. This chapter addresses label requirements and recommendations for those parts of the Precautionary Statements related to human health and is organized into the following sections:

- Introduction
- Background
  - Documents Used to Determine Labeling
  - Acute Toxicity Data
- Determining the Precautionary Labeling
- The Signal Word, Poison, Skull and Crossbones, and Child Hazard Warning
- The Hazards to Humans and Domestic Animals Statements
- Personal Protective Equipment (PPE)
- The First Aid Statements
- Labeling Options
  - Use Dilutions
  - Other Deviations

B. PURPOSE OF STATEMENTS. The precautionary statements are designed to provide the pesticide user with information regarding the toxicity, irritation and sensitization hazards associated with the use of a pesticide, as well as treatment instructions and information to reduce exposure potential. While the Precautionary Statements include Personal Protective Equipment (for uses that trigger worker protection standards), User Safety Requirements, Engineering Controls, User Safety Recommendations, Environmental Hazards, and Physical or Chemical Hazards, for the purposes of this manual, those topics are addressed in other chapters. The remaining sections (Signal Word, Child Hazard Warning, Hazards to Humans and Domestic Animals, First Aid and Personal Protective Equipment [Non-Worker Protection Standard (WPS)] are fully addressed in this chapter. Label reviewers should consult the mandatory/advisory PR Notice 2000-5 for guidance in recommended language for precautionary statements.

II. BACKGROUND INFORMATION

A. DOCUMENTS USED TO DETERMINE CONTENTS OF PRECAUTIONARY STATEMENTS ON LABELS. The Code of Federal Regulations specifies both the acute toxicity category endpoints [40 CFR 156.62] and the Hazards to Humans and Domestic Animals statements associated with each toxicity category [40 CFR 156.70]. These toxicity categories and labeling statements, however are not currently being used by the Agency, because they are less detailed and provide less protection for pesticide users than other guidance. The 40 CFR 156.70(c) states that specific statements pertaining to the hazards of the product and its uses must be approved by the Agency. The labeling statements provided in the Federal Register Notice issued on 9/26/84, entitled Proposed Rule on Labeling Requirements (Volume 49, Number 188) have been used by the Agency for the past twenty years. The acute toxicity categories listed in the Proposed Rule are also being

used with one exception. The acute inhalation toxicity category endpoints currently used are from a 2/1/94 Health Effects Division paper entitled "Interim Policy for Particle Size and Limit Concentration Issues in Inhalation Toxicity Studies."

B. ACUTE TOXICITY DATA. The Signal Word, Hazards to Humans and Domestic Animals, Personal Protective Equipment (non-WPS) and First Aid statements are typically determined by the results of the six acute toxicity studies performed with the product formulation. The acute oral, acute dermal and acute inhalation studies evaluate systemic toxicity via the designated routes of exposure. The primary eye irritation and primary skin irritation studies measure irritation or corrosion, while the dermal sensitization study evaluates the potential for allergic contact dermatitis. With the exception of dermal sensitization, each acute study is assigned to a toxicity category based on the study results (See Table 1 below). The results of these six acute toxicity studies must be known in order for the appropriate labeling language to be determined.

Table 1 - Toxicity Categories

Study	Category I	Category II	Category III	Category IV
Acute Oral	Up to and including 50 mg/kg	> 50 thru 500 mg/kg	> 500 thru 5000 mg/kg	> 5000 mg/kg
Acute Dermal	Up to and including 200 mg/kg	> 200 thru 2000 mg/kg	> 2000 thru 5000 mg/kg	> 5000 mg/kg
Acute Inhalation[1]	Up to and including 0.05 mg/liter	> 0.05 thru 0.5 mg/liter	> 0.5 thru 2 mg/liter	> 2 mg/liter
Primary Eye Irritation	Corrosive (irreversible destruction of ocular tissue) or corneal involvement or irritation persisting for more than 21 days	Corneal involvement or other eye irritation clearing in 8-21 days	Corneal involvement or other eye irritation clearing in 7 days or less	Minimal effects clearing in less than 24 hours
Primary Skin Irritation	Corrosive (tissue destruction into the dermis and/or scarring)	Severe irritation at 72 hours (severe erythema or edema)	Moderate irritation at 72 hours (moderate erythema)	Mild or slight irritation at 72 hours (no irritation or slight erythema)

[1] 4 hr exposure

C. USE OF REDs. During Reregistration, the Reregistration Eligibility Decision (RED) document may also specify personal protective equipment, engineering controls and user safety recommendations. In cases where RED specifications differ from those determined by the acute toxicity categories, the most protective statements must be employed. The regulations allow use of a higher signal word for human hazard when necessary to prevent unreasonable adverse effects on man and the environment. 40 CFR 155.10(1)(i)(E).

III. DETERMINING THE PRECAUTIONARY LABELING

A. THE SIGNAL WORD

1. **When Required**. A Signal Word is required for all registered pesticide products unless the pesticide product meets the criteria of Toxicity Category IV by all routes of exposure. If a signal word is used in this case, it must be "Caution."

2. **Determining the Signal Word**. The Signal Word is determined by the most severe toxicity category assigned to the five acute toxicity studies (see table 1) or by the presence of methanol in concentrations of 4% or more. Refer to the acute toxicity data review to determine the most severe toxicity category. Also check the Confidential Statement of Formula to determine if methanol is present. The Signal Words and associated toxicity categories are as follows:

Toxicity Category I ..... DANGER
Toxicity Category II ..... WARNING
Toxicity Category III ..... CAUTION
Toxicity Category IV..... None Required

3. **Location and Prominence**. The Signal Word is required to appear on the front panel of the label, and the Agency requests that it appear on a separate line from the required Child Hazard Warning statement (Keep Out of Reach of Children). It is preferred that it appear below the KOROC statement. The Signal Word is also required on any supplemental labeling intended to accompany the product in distribution or sale. The Agency also requests that it appear in the Precautionary Statements section immediately below the subheading "Hazards to Humans and Domestic Animals". In cases where the "First Aid" and "Hazards to Humans and Domestic Animals" statement appear on the front panel, the Agency requests that the Signal Word be placed directly below the Child Hazard Warning statement, but it does not have to be repeated after the "Hazards to Humans and Domestic Animals" statement. All required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to assure that they will not be overlooked under customary conditions of purchase and use [See 40 CFR 156.60(b)]. See Chapter 3 for the Minimum Type Size requirements for the Signal Word and the Child Hazard Warning statement. The Agency requests that the Signal Word appear in all capital letters and be oriented in the same direction as other label text.

4. **Related Information**. Because of the potential for confusion, the Agency historically has not approved labels containing the terms "caution," "warning", or "danger," except as the Signal Word for that label (e.g., "CAUTION: Wash hands before eating, or smoking" on a label with the signal of "Caution"). Another example is the statement required by California's Proposition 65 which normally requires the term "warning." Registrants should use the term "notice" or "attention" instead, so that it does not conflict with the EPA required Signal Word.

B. POISON - SKULL AND CROSSBONES SYMBOL

1. **When Required**. The word "POISON" and the skull and crossbones symbol are required for products classified as toxicity category I for acute oral, acute dermal, or acute inhalation toxicity studies [40 CFR 156.64(a)(1). It is recommended if the inert, methanol, is present at 4% or more in the subject product.

2. **Location and Prominence**. If required, the word "POISON" and the skull and crossbones symbol must appear in immediate proximity to each other. The word "POISON" must appear in red on a background of a distinctly contrasting color. If the proposed label does not indicate these display requirements, include this requirement in your response to the registrant. In addition, the Agency requests that the "Poison" and the skull and crossbones symbol appear near the Tox.1 signal word "Danger".

Table 2 - Signal Word and Associated Labeling Determination

Type of Study	Product A	Product B	Product C	Product D	Product E
Acute Oral	III	IV	I*	III	II*
Acute Dermal	IV	III	III	IV	II
Acute Inhalation	III	IV	III	III	II
Primary Eye	III	II	I	I	II
Primary Skin	IV	IV	II	IV	II
Special Inert, e.g., methanol	No	No	No	No	Yes*
CORRECT SIGNAL WORD	**CAUTION**	**WARNING**	**DANGER**	**DANGER**	**DANGER**

*Product C and Product E must also bear additional labeling (Skull & Crossbones symbol in close proximity to the word "POISON" which must appear in red on a contrasting background). Product C must bear the additional labeling as a result of the toxicity category I classification for the acute oral toxicity study. Product E should bear the additional labeling because it contains a special inert (methanol) at greater than 4%, which as described in paragraph B1. above.

C. CHILD HAZARD WARNING STATEMENT

1. **When Required**. The Child Hazard Warning statement ("Keep Out Of Reach Of Children") is required on all product labels, unless the requirement is waived. The warning statement requirement may be waived when the registrant adequately demonstrates that the likelihood of contact with children during distribution, storage or use (e.g., an MUP in some situations) is extremely remote or if the pesticide is approved for use on infants or small children.

2. **Location and Prominence**. The Child Hazard Warning statement must appear on the front panel [40 CFR 156.66]. It is preferred that the Child Hazard Warning appear on a separate line above the Signal Word. If the Signal Word and Child Hazard Warning were to appear on the same line, a pesticide user could incorrectly assume that the Signal Word is intended primarily for children rather than as a general precaution for all persons. If the label under review has the signal word and Child Hazard Warning on the same line, request that the registrant revise the label. Also make sure that the Child Hazard Warning statement is oriented in the same direction as other label text.

3. **Additional Information**

a. Based on the FIFRA unreasonable adverse effects standard, the Agency has not allowed the Precautionary Statements or the Directions for Use to contain any statement which implies that the product may be used by children. For example, draft labels of products intended to repel insects should not contain instructions such as "Do not allow use by small children without close adult supervision." Such labeling creates unacceptable risk issues, as it implies that a child can apply the product as long as an adult watches.

b. A modified Child Hazard Warning statement may be used for products where child contact is expected during normal use. For products requiring a modified statement, make sure that the statement is appropriate for the use pattern. Examples of appropriate statements are as follows: "Do not allow children to apply product" or "Do not allow children to play with pet collar."

D. THE HAZARDS TO HUMANS AND DOMESTIC ANIMALS STATEMENTS

1. **When Required**. Hazards to Humans and Domestic Animals statements are required when any acute toxicity study results in a product classification of toxicity category I, II, or III and/or when the dermal sensitization study result is positive. Hazards to Humans and Domestic Animals statements may specify both mandatory actions and advisory information.

2. **Required Header**. The Hazards to Humans and Domestic Animals statements must appear under the section heading "Precautionary Statements" and below the subheading "Hazard to Humans and Domestic Animals." The Signal Word must appear before the precautionary paragraph. [40 CFR 156.10.]

3. **Location and Prominence**. The Hazards to Humans and Domestic Animals section may appear on any panel. Please note, however, that these statements should not be included within the Directions For Use section. These statements should be organized so that the routes of exposure of most concern (severe routes of exposure) as supported by the toxicity category classification are listed first.

4. **Determining the Hazards to Humans and Domestic Animals Statements for Fumigant Products**. Refer to PR Notice 84-5, Registration Standards or Reregistration Eligibility Decision Documents (REDs) suggested Hazards to Humans and Domestic Animals statements.

5. **Determining the Hazards to Humans and Domestic Animals Statements for Non-Fumigant Products**. Select statements from the tables below based on the toxicity category assigned to each study. Statements from these tables should be combined to form a concise paragraph. Repetitious sentences should be omitted. Products in the scope of the WPS should only use the statements in Tables 3 through 8 of this chapter. However, refer to Chapter 10 of this manual to determine the appropriate Personal Protective Equipment. In cases where the toxicity categories are not known, the precautionary labeling must be consistent with the signal word.

6. **Related Information**. Hazards to Humans and Domestic Animals statements must be appropriate for all uses on the label. These statements must be consistent with each use pattern listed on the label. No statement should be used that is reasonably beyond the control of the typical applicator. Hazards to Humans and Domestic Animals statements must not require use of specialized equipment which would not be readily available to the typical user of the product.

Table 3 - Typical Statements for Acute Oral Toxicity

Toxicity Category	Signal Word	Statements
I	DANGER-POISON Skull & Crossbones required*	Fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.
II	WARNING	May be fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.
III	CAUTION	Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.
IV	CAUTION (optional)	No statements are required. However, the registrant may choose to use category III labeling.

* For products containing 4% or more of methanol, the Agency believes that in order to mitigate potential risk the following statement should be added to the label: "Methanol may cause blindness."

Table 4 - Typical Statements for Acute Dermal Toxicity

Toxicity Category	Signal Word	Statements
I	DANGER-POISON Skull & Crossbones required	Fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Wear [specify appropriate protective clothing]. Remove and wash contaminated clothing before reuse.
II	WARNING	May be fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Wear [specify appropriate protective clothing]. Remove and wash contaminated clothing before reuse.
III	CAUTION	Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Wear [specify any appropriate protective clothing, if appropriate].
IV	CAUTION (optional)	No statements are required. However, the registrant may choose to use category III labeling.

Table 5 - Typical Statements for Acute Inhalation Toxicity

Toxicity Category	Signal Word	Statements
I	DANGER-POISON Skull & Crossbones required	Fatal if inhaled. Do not breathe (dust, vapor, or spray mist).* Wear [specify appropriate respiratory protection from Table 4, Chapter 10]. Remove and wash contaminated clothing before reuse.
II	WARNING	May be fatal if inhaled. Do not breathe (dust, vapor or spray mist).* Wear [specify appropriate respiratory protection from Table 4, Chapter 10]. Remove and wash contaminated clothing before reuse.
III	CAUTION	Harmful if inhaled. Avoid breathing (dust, vapor or spray mist).* Remove and wash contaminated clothing before reuse.
IV	CAUTION (optional)	No statements are required. However, the registrant may choose to use category III labeling.

* Choose the word which appropriately describes the product during use.

Table 6 - Typical Statements for Primary Eye Irritation

Toxicity Category	Signal Word	Statements
I	DANGER	Corrosive.* Causes irreversible eye damage. Do not get in eyes or on clothing. Wear [specify appropriate protective eyewear such as goggles, face shield, or safety glasses]. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.
II	WARNING	Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear [specify appropriate protective eyewear such as goggles, face shield, or safety glasses]. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.
III	CAUTION	Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear [specify protective eyewear, if appropriate]. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.
IV	CAUTION (optional)	No statements are required. However, the registrant may choose to use category III labeling.

* The term "corrosive" is not required if corrosive effects were not observed during the study.

Table 7 - Typical Statements for Primary Skin Irritation

Toxicity Category	Signal Word	Statements
I	DANGER	Corrosive. Causes skin burns. Do not get in eyes, on skin, or on clothing. Wear [specify appropriate protective clothing and gloves]. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.
II	WARNING	Causes skin irritation. Do not get on skin or on clothing. Wear [specify appropriate protective clothing and gloves]. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.
III	CAUTION	Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Wear [specify protective clothing and gloves, if appropriate].
IV	CAUTION (optional)	No statements are required. However, the registrant may choose to use category III labeling.

Table 8 - Typical Statements for Dermal Sensitization

Study Results	Statement
Product is a sensitizer or is positive for sensitization	Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
Product is not a sensitizer or is negative for sensitization	No labeling is required for this result.

E. PERSONAL PROTECTIVE EQUIPMENT

Personal protective equipment requirements are specified for uses covered under the Worker Protection Standard (WPS), but there are no regulatory requirements for non-WPS products, products used by residents, or products intended only for manufacturing use. However, to protect human health, the following guidance is offered.

1. **For Non-WPS (Commercial Applicators) Uses**

While there are no regulatory requirements that demand PPE for non-WPS products, applicators are tested on their comprehension regarding what types of PPE are used and how to use them correctly. This testing implies that PPE is expected to be worn by commercial applicators. In order to protect human health, label reviewers are encouraged to review the toxicity data and the potential exposures from the product's uses to determine whether PPE would be protective and should be recommended. In cases where the reviewers determine PPE would be beneficial, the various PPE tables in Chapter 10 provide information about which PPE is protective in specific circumstances. However, if there is an applicable RED document which specifies PPE requirements based on concerns specific to the active ingredient then those PPE requirements should be placed on the label.

2. **For Products used by Residents/Consumers**

While there are no regulatory requirements that demand PPE for resident/consumer use products, in order to protect human health, label reviewers are encouraged to review the toxicity data and the product's uses to determine whether PPE would be protective and should be recommended. In cases where the reviewers determine PPE would be beneficial, the PPE tables in Chapter 10 provide information about which PPE is protective in specific circumstances. In some cases, the PPE indicated in these tables may need to be modified; for example, to fit the consumer's ability to acquire it. For example, "shoes" may need to be substituted for "chemical resistant footwear" or "safety glasses" may need to be substituted for "protective eyewear." If there is an applicable RED document which specifies PPE requirements based on concerns specific to the active ingredient then those PPE requirements should be placed on the label.

F. FIRST AID STATEMENTS

1. **When Required**. A First Aid statement is required when any acute toxicity study result is classified as category I, II, or III. It is acceptable for the registrant to include First Aid statements for studies that are classified as category IV.

2. **Required Header**. The Agency recommends that the first aid statements appear under either of the following headings: "First Aid" or "Statements of Practical Treatment." See PR Notice 2001-1. The heading "Statements of Practical Treatment" is not recommended by the Agency for residential/household-use products. In addition, the Agency historically has not allowed the heading "Antidote" in conjunction with the first aid statements unless a specific antidote is recommended.

3. **Location and Prominence**. First Aid statements shall appear on the front panel of the label for all products classified as toxicity category I [40 CFR 156.68]. The Agency may, however, permit reasonable variations in the placement of the statement of First Aid as long as the reference statement "See First Aid (or Statement of Practical Treatment) on [identify appropriate panel]" appears on the front panel, preferably near "Poison" and the skull and crossbones. First Aid statements for toxicity categories II and III classification may appear on any panel of the label. However, any time First Aid statements appear other than on the front panel, a referral statement such as "see side/back panel for first aid" should appear on the front panel in close proximity to the Signal Word. Furthermore, First Aid statements on the side or back panel should be grouped near the other precautionary labeling text, yet set apart or distinguishable from the other label text, for example placed in a box below the Hazards to Humans and Domestic Animals section. First Aid statements should be organized so that the most severe routes of exposure, as demonstrated by the toxicity classification, are listed first.

4. **Determining the First Aid Statements for Fumigant Products**: Refer to PR Notice 84-5 and Registration Standards/REDs.

5. **Determining the First Aid Statements for Non-Fumigant Products**. Review Table 9 to determine the preferred First Aid statements for each route of exposure. Registrants should support alternative First Aid statements with medical evaluations of the product. Approval of alternative First Aid statements is guided by considerations such as those set out in the "Content and Clarity" section below. The Agency has not approved the use of salt water for emesis as a first aid technique. (See PR Notice 80-2) .

a. Content and Clarity. First Aid statements must be brief, clear, simple and in straightforward language so that the average person can easily and quickly understand the instructions. First Aid statements should apply to all ages or when necessary, should include distinctions between the treatments for different ages (e.g., children vs. adults). Any reasonably competent individual should be able to perform the First Aid statements. These statements should not include procedures which must be performed by medical personnel or require specialized equipment. Such procedures belong under the Note to Physician heading (see section G below).

b. Acute Dermal and Primary Skin Irritation. Because both of these studies focus on the dermal route of exposure, any first aid statements required by the results of these two studies can be combined. Use the first aid statement required for the acute dermal toxicity study if the results of both studies place the product in the same acute toxicity category. Use the statements for the more severe acute toxicity category if the results of the studies would place the product in different acute toxicity categories.

c. Eye and Skin Irritation. If the product is corrosive and is in toxicity category I or II for eye or dermal irritation, then a first aid statement for ingestion may also be included.

6. **If the product contains an organophosphate** (i.e., an organophosphorus ester that inhibits cholinesterase) or an N-methyl carbamate (i.e., an N-methyl carbamic acid ester that inhibits cholinesterase), the following phrase is recommended for the First Aid statement See PRN 200-1:

CONTAINS AN _____ (either organophosphate or N-methyl carbamate)
THAT INHIBITS CHOLINESTERASE.

7. **If the product contains zinc phosphide**, the following First Aid statement is recommended (See PRN 2000-1):

> "If swallowed: Immediately call a Poison Control Center or doctor or transport the person to the nearest hospital. DO NOT DRINK WATER. Do not administer anything by mouth or make the person vomit unless advised to do so by a doctor."

TABLE 9 - FIRST AID STATEMENTS

Route of Exposure and Toxicity Category	First Aid Statement
Ingestion treatment for acute oral toxicity categories 1, 2, and 3	If swallowed: -Call a poison control center or doctor immediately for treatment advice. -Have person sip a glass of water if able to swallow. -Do not induce vomiting unless told to by a poison control center or doctor. -Do not give anything to an unconscious person.
Acute oral toxicity category 4	Statement is not required. Registrants may use toxicity category 1-3 statements if they choose.
Skin exposure treatment for acute dermal toxicity, and irritation categories 1, 2, and 3	If on skin: -Take off contaminated clothing. -Rinse skin immediately with plenty of water for 15-20 minutes. -Call a poison control center or doctor for treatment advice.
Dermal and skin irritation toxicity category 4	Statement is not required. Registrants may use toxicity category 1-3 statements if they choose.
Inhalation treatment for acute toxicity categories 1, 2, and 3	If inhaled: -Move person to fresh air. -If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. -Call a poison control center or doctor for further treatment advice.
Inhalation toxicity category 4	Statement is not required. Registrants may use toxicity category 1-3 statements if they choose.
Eye exposure treatment for eye irritation categories 1, 2, and 3	If in eyes: -Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. -Call a poison control center or doctor for treatment advice.
Eye irritation toxicity category 4	Statement is not required. Registrants may use toxicity category 1-3 statements if they choose.
General information to include either near the first aid statement or emergency phone number	-Have the product container or label with you when calling a poison control center or doctor or going for treatment.

G. NOTE TO PHYSICIANS

1. **When Used**. The Note to Physician is not required nor mentioned in the 40 CFR. If the label under review is for a product which is a fumigant, refer to PR Notice 84-5 or relevant Registration Standards or REDS for the appropriate Note to Physician. For all other products, EPA currently uses a Note to Physician as specified in the 1984 proposed rule for the following types of products:

a. All products that are classified as toxicity category I.

b. Products which are corrosive or classified as toxicity category I for eye or skin . These products must include the following Note to Physician: "Probable mucosal damage may contraindicate the use of gastric lavage."

c. Products which contain $\geq$ 10% petroleum distillate should include the following Note to Physician: "Contains petroleum distillate. Vomiting may cause aspiration pneumonia."

d. Products which produce physiological effects requiring specific antidotal or medical treatment such as: Cholinesterase Inhibitors (e.g., carbamates and phosphorothioates, and organophosphates); Metabolic Stimulants (e.g., dichlorphenols); Anticoagulants (e.g., warfarin).

2. **Location and Prominence**. The Note to Physician should be located in close proximity to the First Aid statement, but should be clearly distinguished from it. In other words, it should not be placed within the First Aid statement, but should appear below the last First Aid statement.

3. **Contents of Note**. The Agency does not provide specific Notes to Physicians except for toxicity category I eye and skin irritants. However, the Agency does provide the following guidance concerning the content of Notes to Physicians. Check the label under review to make certain that it addresses the following information:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

IV. LABELING OPTIONS

A. USE DILUTIONS (Aqueous Solutions only)

1. **When Used.** Additional Hazards to Humans and Domestic Animals and First Aid statements which correspond with the toxicity categories associated with a product's use dilution, may be allowed on product labels provided the conditions below are satisfactorily addressed. Following is guidance for the submission and review of such data and for the content and placement of associated labeling.

2. **Data Requirements**. All data and draft labeling for use dilution Hazards to Humans and Domestic Animals statements should be sent to the appropriate Product Manager with a request for pesticide amendment. In some cases, use dilution labeling statements triggered by systemic toxicity (acute oral, dermal or inhalation toxicity) may be supported by extrapolation from the LD50/LC50 for the concentrate. At a minimum the following is required to even consider extrapolating toxicity categories. This information must be submitted by the Registrant with the extrapolation request.

a. a slope calculated from at least three, and preferably more, dose levels having partial responses (i.e., a well characterized dose-response);

b. dose groups sufficiently large (>5 per group) to allow for the calculation of confidence limits that fall within the defined Toxicity Category boundaries;

c. Extrapolation to a higher toxicity categories will only be applied to water dilutions. It should also be determined that there are no other factors affecting the toxicity of the EP (e.g., inerts that enhance the absorption of the active ingredient, promote the active ingredient's toxicity, etc.). Other types of extrapolations will be done on a case by case basis.

d. Use dilution Hazards to Humans and Domestic Animals statements triggered by skin or eye irritation must be supported by new or cited studies. If another registered diluted product (such as a ready-to-use formulation) has acceptable data and is found similar to the concentrated product after it has been diluted, those data may also be used to support revised labeling.

3. **Labeling Requirements**. It is not EPA's intent to allow dual sets of Hazards to Humans and Domestic Animals statements and/or First Aid statements on the label. Rather, EPA will allow certain modified statements to be added that are applicable to the most concentrated use dilution only. [See 40 CFR 156.68(b)] These additional statements (triggered by the toxicity category of the most concentrated use dilution) must be placed directly after the required statements for the concentrate. Following are some examples (in italics) of how use dilution labeling must appear on product labeling:

Hazards to Humans and Domestic Animals:

> "Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear goggles or face shield. *After product is diluted in accordance with the directions for use, goggles or face shield are not required."*

First Aid:

> "If on skin: Wash with plenty of soap and water. Get medical attention. *If product, diluted in accordance with the directions for use, gets on skin, medical attention is not required.*"

B. OTHER DEVIATIONS

1. **Optional Hazards to Humans and Domestic Animals Statements**. Registrants may submit Hazards to Humans and Domestic Animals statements which reflect specific hazards. 40 CFR 156.10(i)(B). Such requests must be supported by data (or substantive justification), and should be routed to label reviewers or the Chemistry and Exposure Branch (for PPE). For example, the statements "Do not remove contact lenses, if worn. Get immediate medical attention." would not be approved by the Agency without supporting data or rationale.

2. **Toxicity Category IV Precautionary Labeling**. If the product is all toxicity category IV (non-sensitizer), precautionary labeling statements are normally not required. However, if registrants desire to place precautionary labeling on such a product they may do so. To promote labeling consistency it is recommended that the registrant use precautionary statements triggered by toxicity category III. Registrants may propose alternate labeling which should be reviewed by precautionary labeling reviewers.

3. **Me-Too Deviations**. If a me-too product is citing a product that has optional statements on the label, such as IV. A. above, those statements are not required on the me-too if the acute toxicity data results are available. Questions about the availability of the acute studies should be referred to the precautionary labeling reviewers.

Chapter 8 **ENVIRONMENTAL HAZARDS**

I. INTRODUCTION

A. The Environmental Hazards statement provides the precautionary language advising of the potential hazards to the environment from transport, use, storage, or spill of the product. The hazards may be to water, soil, air, beneficial insects, plants, and/or wildlife. Generally, the information contained in this section is based upon the results of seven basic acute toxicity studies performed on the technical grade of the active ingredient(s) in the formulation. These seven studies are: (1) avian oral LD_{50} (with mallard or bobwhite quail), (2) avian dietary LC_{50} (mallards), (3) avian dietary LC_{50} (bobwhite quail), (4) freshwater fish LC_{50} (rainbow trout), (5) freshwater fish LC_{50} (bluegill sunfish), (6) acute LC_{50} freshwater invertebrates (Daphnia magna or water flea) and (7) honeybee contact $LD_{50.}$ For specific data requirements see Part 158.

B. In addition, data concerning a chemical's potential to contaminate groundwater or surface water, to drift, to adversely affect non-target plants and bees provide important information. These studies are hydrolysis, batch equilibrium, aerobic soil metabolism, field dissipation, and the prospective groundwater study.

C. The data generated from all of these studies support the language used for the Environmental Hazards statements. Review of the data is performed by the Environmental Fate and Effects Division (EFED) or other science reviewers who may also evaluate any label text proposed by the registrant to determine what statements are required.

II. REVIEWING THE STATEMENTS

A. DOES THE PRODUCT REQUIRE AN ENVIRONMENTAL HAZARDS STATEMENT? The label reviewer must first determine whether the use patterns on the label require any Environmental Hazards statement. The use pattern of a pesticide helps determine the need for and the specific text of the Environmental Hazards section. The label reviewer may conclude that all pesticides used outdoors must have the statement. However, the reviewer should also look at the proposed statement with a critical eye towards its applicability. Does it makes sense for the product? For example, a granular herbicide would not generally need a statement warning of potential spray drift problems since granular formulations are not "sprayed" and are seldom associated with any "drift."

1. Products which are intended for use exclusively indoors may omit the Environmental Hazards statement. Products applied to domestic animals, such as flea collars or ear tags may generally omit the statement. However, the statement may be required for a domestic use product such as a dog dip due to the potential for contamination of water by the use of a such a product. Thus it is important for reviewers to carefully evaluate the use of the product to determine whether potential risk from the transport, use, storage or disposal of the product should be mitigated by the Environmental Hazards statement.

2. Manufacturing use products (MPs), although used indoors to formulate other products, require some Environmental Hazards text because MPs still are generally highly concentrated and could pose a serious hazard if a spill occurred. A discharged statement is also required see section F.1. below for recommended language.

3. The Agency historically has required products labeled for use outdoors to have Environmental Hazards statements on their labels.

4. If the reviewer determines that the use pattern triggers the need for Environmental Hazards labeling, the proposed draft labeling must be reviewed according to the requirements outlined in the regulations and the policy described in the remainder of this chapter.

B. STATEMENT LOCATION. The Environmental Hazards section of the label should be located under the general heading "Precautionary Statements." It <u>must</u> have the heading "Environmental Hazards" (not "Environmental Precautions," "Environmental Protections," or anything similar). [40 CFR 156.10(h)(2)].

C. SUPPORT FOR STATEMENTS. The text of the statements is then reviewed according to the type of action:

1. If the action represents a submission <u>accompanied by data</u>, the environmental science reviewer will evaluate the environmental hazards statements and recommend any necessary label changes as part of the data review. The label reviewer must specify all requested changes in the response to the registrant. The necessary language must be in accordance with mandatory/advisory guidance. See Chapter 3 and PR Notice 2000-5.

2. The environmental reviewer is responsible for reviewing data on all technical products and may also review data associated with end-use formulations. Data requirements are governed by FIFRA and the implementing regulation set out in Part 158. Generally speaking data are required when an end-use formulation is likely harmful to non-target organisms (for example, micro encapsulated insecticides which are used on crops are potentially harmful to pollinators). If the Reregistration Eligibility Decision (RED) Document has been issued, it may contain appropriate Environmental Hazards statements, but the reviewer should evaluate whether the RED specifically addresses the use at issue and make necessary variations in the label statement. If the reviewer is working on a me-too application for registration (where another identical or substantially similar formulation is already registered), the Environmental Hazards statements of the similar formulation should be compared with those in the RED. If the similar registered product label language is consistent with the RED, the me-too Environment Hazard language should be the same as the currently registered product. If there are no similar products, the application should be routed to EFED or the science reviewers. Additionally, if a registrant wishes to amend the Environmental Hazards statements, environmental reviewers may need to see the amendment application.

a. Since the cited label may have some statements that are outdated and/or missing (required or recommended since the label was accepted), it is important to check the regulations and the statements outlined in the rest of this chapter to make sure that both the cited label and the draft label reflect current Agency requirements and policy.

b. If an error is discovered in the Environmental Hazards section of the cited me-too label, the reviewer should write a letter informing the registrant of the error(s) and request an application for amendment be submitted within a reasonable time, such as 30 days.

D. GENERAL STATEMENTS

1. Generally, all products with directions for outdoor, terrestrial uses should have the following statements in the Environmental Hazards section:

> "For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate."

a. These statements are preceded by **"For terrestrial uses,"** to make it clear that the statements **do not** apply to the other general use patterns -- e.g., mosquito adulticides, aquatic uses such as mosquito larvicides, aquatic herbicides, piscicides, etc., greenhouse and indoor uses.

b. Note that some Bt products do not require the above statements. Based on the fact some Bt products are applied to terrestrial agricultural fields to control mosquitoes in periodic standing water.

c. If a pesticide product is aerially applied to forests, the above statements should be preceded with the phrase: "Except under the forest canopy" There are many creeks and streams under forest canopies. The statement as written allows spraying the forest canopy, but requires spray valves to be shut off when passing over ponds, streams, etc. not under the forest canopy.

2. For outdoor residential consumer products (except for lawn care which requires the same statement as outdoor terrestrial uses), the statements generally required by the Agency to meet risk/benefit concerns are as follows:

> "Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate."

a. The reviewer must keep in mind the use pattern of the product undergoing a label review. If the product is actually intended for application to water to control algal growth, for example the above two statements would be inappropriate. Or, if the product is a residential aerosol spray in a can for application to wasp or hornet nests, no equipment would be used, and the statement regarding cleaning of equipment may be omitted.

3. Products with directions for outdoor terrestrial uses requiring a fish or aquatic invertebrate toxicity statement usually contain a statement warning of hazard from drift and or runoff. The word drift should be omitted if the product is a "Granular" or if it is applied "in furrows"or injected into the soil. The Agency has historically required that the following statement appear in the Environmental Hazards section:

> "Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas."

4. **Groundwater Advisories**

a. If the environmental reviewers determine that the chemical (or major degradates) has laboratory-derived mobility (Kd less than 5) and persistence characteristics (e.g., hydrolysis half-life at any pH greater than 30 days or aerobic soil metabolism half-life greater than 2 weeks) similar to other pesticides found in ground water as a result of normal label uses, and no detections are reported in ground water (for example, for a new chemical), the Agency has generally required the following label language:

Ground Water Advisory

"This chemical has properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."

b. If the environmental reviewers determine that the chemical (or major degradates) has laboratory derived mobility and persistence characteristics similar to other chemicals found in ground water as a result of normal label uses, **AND**:

(1) Detections are reported in ground water in a prospective ground water study or other monitoring study conducted for registration, or other reliable monitoring data in the publicly available literature, or

(2) Field dissipation results confirm the chemical leaches, then the Agency has historically required the following label language:

Ground Water Advisory

"[Name of chemical] [A degradate of (name of chemical)] is known to leach through soil into ground water under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."

5. **Surface Water Label Advisories**

The Agency has historically required the following statement to be added to all household and agricultural labels modified for the specific pesticide characteristics and targeted audience.

"This product may contaminate water through runoff. This product has a [insert phrase a.1, a.2, or a.3, according to the pesticide's "mean" soil partition coefficient (Kd)] for [insert phrase b.1, b.2, or b.3, according to the pesticide's aerobic soil metabolism half-life] after application. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product. [insert phrase c.1 or c.2 depending on whether the product is intended for the householder or farmer].

a. Soil Partition Coefficient Phrases.

1. Kd less than 15 - “high potential for runoff”
2. Kd between 15-300 - “a potential for runoff”
3. Kd greater than 300 - “a potential for runoff”

b. Aerobic Soil Metabolism Half-Life Phrases.

1. T½ less than 8 days - ‘several days after application”
2. T½ between 8 and 30 days - “several weeks after application”
3. T½ greater than 30 days - “several months or more after application”

c. Targeted User Community.

(1) *Household Label*. Avoid applying this product to ditches, swales, and drainage ways. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours.

(2) *Agricultural Label*. A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours. [For pesticides with a soil partition coefficient of “C” add the following, “ Sound erosion control practices will reduce this product’s contribution to surface water contamination].”

E. NON-TARGET ORGANISM STATEMENTS

1. The following statement has historically been required when a pesticide intended for outdoor use contains an active ingredient which has a mammalian acute oral $LD_{50} \leq 100$ mg/kg, an avian acute oral $LD_{50} \leq 100$ mg/kg, or a subacute dietary $LC_{50} \leq 500$ ppm[1]:

"This pesticide is toxic to [birds] [mammals] or [birds and mammals]."

2. The following statement has historically been required when a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} or aquatic invertebrate (including estuarine species such as oyster and mysid shrimp) $EC_{50} \leq 1$ ppm:

"This pesticide is toxic to [fish] [fish and aquatic invertebrates] [oysters/shrimp] or [fish, aquatic invertebrates, oysters and shrimp].”

[1]This information will be found in submitted data, the RED document, or the Registration Standard. It may not necessarily be available to the label reviewer, but helps you to understand the origin of the statements.

3. If field studies or accident history, such as the FIFRA § 6(a)(2) reports, indicate that use of the pesticide may result in fatality to birds, fish or mammals, the following statement has historically been required:

> "This pesticide is extremely toxic to [birds], [mammals], [fish], or [birds and mammals and fish]."

4. If a pesticide is used outdoors as a foliar application, especially to crops, and is toxic to pollinating insects, a "Bee Hazard" warning must be included in the Environmental Hazards. 40 CFR56.10(h)(2)(ii)(E). The following table sets out the toxicity groupings and required label statements for honey bees:

Honey Bee Toxicity Groups and Cautions

Toxicity Group	Precautionary Statement if Extended Residual Toxicity is Displayed	Precautionary Statement if Extended Residual Toxicity is not Displayed
I Product contains any active ingredient with acute LD_{50} of 2 micrograms/bee or less	This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.	This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.
II Product contains any active ingredient(s) with acute LD_{50} of greater than 2 micrograms/bee but less than 11 micrograms/bee.	This product is toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product if bees are visiting the treatment area.	This product is toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visiting the treatment area.
III All others.	No bee caution required.	No bee caution required.

5. If a pesticide product is used to control aquatic weeds, the Environmental Hazards section must normally contain the following statement:

> "Treatment of aquatic weeds can result in oxygen loss from decomposition of dead weeds. This loss can cause fish suffocation. Therefore, to minimize this hazard, treat 1/3 to ½ of the water area in a single operation and wait at least 10 to 14 days between treatments. Begin treatment along the shore and proceed outwards in bands to allow fish to move into untreated areas. Consult with the State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is needed."

6. Pesticide products that include directions for mosquito control may require one of the following statements in the Environmental Hazards section, although the aquatic toxicity of the specific product may lead to more or less stringent statements. For example, certain bacterial larvicides, such as some Bt products, are considered non-toxic to aquatic organisms and would not require any statement. Some pyrethroids registered as mosquito adulticides are highly toxic to aquatic organisms and may require stronger precautions than those listed below, tailored to the specific products, in order to prevent water contamination. Products with aquatic toxicity concerns between these extremes should have one of the following recommended statements:

Larvicides--- "Aquatic organisms may be killed in waters where this pesticide is used. Consult with the State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is needed."

Adulticides--- "Do not apply over water, except where mosquitoes are emerging or swarming, or to treat vegetation where mosquitoes may rest. Drift and washoff from vegetation may be hazardous to aquatic organisms [and wildlife] in or adjacent to treated areas. Do not contaminate water when disposing of equipment wash waters or rinsate. Before making the first mosquito control application in a season, consult with the State agency with primary responsibility for regulating pesticides to determine if permits are required."

NOTE: As this edition of the Label Review Manual is being issued, revisions to label language concerning products for adult mosquito control are being considered by the Agency.

7. If a pesticide product is applied to irrigation water and contains an ingredient requiring an aquatic organism toxicity statement, the Environmental Hazards section must contain the following statement:

"Irrigation water treated with this product may be hazardous to aquatic organisms. Treated water must either be held on the irrigated field until absorbed by the soil or not released for (number) days."

F. MISCELLANEOUS STATEMENTS

1. For certain registered end-use products, technical grade products and other manufacturing use products (i.e., those used to formulate other products), a "point source discharge" is a possibility because effluent from the manufacturing plant may contain pesticides. This does not include those products used to control roaches or other pests in the facilities, but applies to those chemicals used in the formulation processes.

a. The Agency recommends that the following National Pollutant Discharge Elimination System (NPDES) statement (as outlined in PR Notice 93-10) should appear on such products, in addition to any other required statements.

> "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

b. PR Notice 95-1 exempts certain end-use products [i.e., products in containers of less than 5 gallons (liquid), less than 50 pounds (solid, dry weight) and in aerosol containers of any size] from bearing effluent discharge statements specified by PR Notice 93-10. PR Notice 93-10 still applies to the following kinds of pesticide products that may result in discharges to the waters of the United States or to municipal sewer systems, including but not limited to: (A) all technical grade and manufacturing use products; and (B) end-use products packaged in containers equal to or greater than 5 gallons (liquid) or 50 pounds (solid, dry weight), and registered for industrial preservative, water treatment, other industrial processing uses (such as cooling tower water systems, pulp and paper mill water systems, secondary oil recovery injection water systems, food processing operations, leather tanning, wood protection and textile treatment), and commercial and institutional uses (including, but not limited to, hospitals, hotels/motels, office buildings, and prisons).

c. The exemption of certain containers from the labeling requirements of PR Notice 95-1 does not relieve a producer or user of such products from the requirements of the Clean Water Act or state or local requirements, if applicable.

2. If a pesticide product contains directions for use in treating seed or is formulated as a granule, pellet, or treated bait, the Agency has historically required the following Environmental Hazards statements:

> "Treated _____ [seed], [granules], [pellets], [baits] exposed on soil surface may be hazardous to _____ [birds], [wildlife], [fish and aquatic invertebrates] or [birds, other wildlife, and fish]. Cover or collect _____ [seeds], [granules], [pellets], [baits] spilled during loading."

3. When the label bears a reference to mixing with other products, the Agency recommends that the registrant add a statement such as the following:

"Observe the most restrictive of the labeling limitations and precautions of all products use in mixtures."

NOTE: Chemical specific statements, such as groundwater/surface water, spray drift/runoff, or endangered species statements will be added to the manual as they are identified. The label reviewer should consult with the product manager/team leader and EFED or environmental reviewer.

Chapter 9 **PHYSICAL OR CHEMICAL HAZARDS**

I. INTRODUCTION

This chapter covers the Physical or Chemical Hazards statements that are required for certain pesticide products by the regulations of 40 CFR156.78. Such hazard statements address flammability, explosive potential and precautions. In addition, special hazard statements are required for certain fumigants. The reviewer should look through the regulations and through the guidance set out in the following sections to evaluate labels..

II. PLACEMENT OF THE "PHYSICAL OR CHEMICAL HAZARDS" STATEMENT

A. Placement of the Physical or Chemical Hazards section should be immediately below the Hazards to Humans & Domestic Animals statements and Environmental Hazards statements in the Precautionary Statements section of the label.

B. The physical or chemical hazards section must bear the subheading "Physical or Chemical Hazards."

III. LABELING FOR FLAMMABLE PRODUCTS

A. Precautionary statements relating to product flammability are required if the product meets the criteria set out in the regulations and described below. Review Table 1 to determine the appropriate flammability statements.

B. Data requirements for flammability are covered in the regulations at 40 CFR 158.190. OPPTS Harmonized Test Guidelines Series 830, Product Properties (830-6315), covers the **flash point** and **flame extension** of a product. The flash point is the lowest temperature at which a liquid product containing a combustible ingredient that gives off a flammable vapor will ignite. The flame extension test is required for aerosol products. The flame extension test is conducted by holding the aerosol can 6 inches from a flame and discharging the product across the flame. The extension of any flame from the flame source (typically a candle) in inches is noted and recorded. Any flame extension more than 18 inches or any flashback of flame to the valve at any degree of valve opening would then dictate the proper labeling of the product as either being flammable or extremely flammable. Flashback occurs when the flame is drawn back toward the aerosol can by the stream of propellant. This would indicate an extremely flammable product.

C. The product's flash point is shown on the Confidential Statement of Formula (CSF) and should be expressed in degrees Fahrenheit (°F) and the equivalent in degrees Celsius (°C). For aerosol products, the registrant is required to report the results of the flame extension test and any positive flashbacks. This requirement does not apply to liquid products that are typically incombustible, as well as solid products not containing combustible ingredients such as most dust or granular formulations, pellets/tablets (baits), impregnated materials, etc. If the CSF indicates "not applicable or N/A for flammability," you may skip this section.

TABLE 1 - FLAMMABILITY STATEMENTS

Flash Point	Required Text
(A) Pressurized Containers	
Flash point at or below 20°F or if there is a flashback at any valve opening	**Extremely flammable**. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 inches long at a distance of 6 inches from the flame.	**Flammable**. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	**Contents under pressure**. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) Nonpressurized Containers	
At or below 20°F	**Extremely flammable**. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	**Flammable**. Keep away from heat and open flame.
Above 80°F and not over 150°F	**Combustible**. Do not use or store near heat or open flame.

[40 CFR 156.78)]

D. In order to avoid confusion with the signal word, the terms, CAUTION, WARNING, and DANGER (human hazard signal words) are **NOT** to be used with the flammability statements. These words are only to be used as the human hazard signal word on the product. [40 CFR 156.64(b)(3)].

E. If the product is a total release fogger containing a propellent with a flash point at or below 20°F, the following label statement must be included in the "Physical or Chemical Hazard" section:

> "This product contains a highly flammable ingredient. It may cause a fire or explosion if not used properly. Follow the Directions for Use on this label very carefully."

In addition to this required language, a graphic symbol such as that illustrated below or an equivalent symbol, must be displayed adjoining the "Physical or Chemical Hazard" statement. The graphic symbol must be no smaller than twice the size of the first character of the human hazard signal word. Also, the two phrases shown below must be presented near the graphic symbol. PR Notice 98-6 and [40 CFR 156.78(d)(3)].

Highly Flammable Ingredient
Ingrediente Altamente Inflamable

IV. DECLARATION OF NON-FLAMMABILITY

A. NON-FLAMMABILITY CLAIM. Certain products may bear a claim of non-flammability, with terms like "non-flammable" or "non-flammable (gas, liquid, etc.)." If the draft label has no claim of non-flammability, skip this section. However, if the proposed draft label has such a claim, the reviewer must check to see if the terms "Extremely Flammable" or "Flammable" do not appear in the *Physical or Chemical Hazards* section of the proposed label. Obviously, if either of these terms appear in the *Physical or Chemical Hazards* section, the claim of non-flammability CAN NOT be used.

B. CRITERIA FOR DECLARING NON-FLAMMABILITY

1. If the proposed label bears a claim of non-flammability, the Agency has historically required it to meet the following criteria:

a. If a gas or mixture of gases: the product must not ignite when a lighted match is placed against the open cylinder valve.

b. If a liquid: the product must have a flash point greater than 350°F (177°C). Refer to the CSF for the flash point.

2. If you are unsure of whether the product meets the criteria for declaring non-flammability, submit the label package for product chemistry review to determine the validity of the non-flammability claim.

C. NON-FLAMMABILITY LABELING STATEMENT AND PLACEMENT

The phrases "non-flammable", "non-flammable gas" or "non-flammable liquid," may appear as a sub-statement to the ingredients statement, or on a back or side panel. The phrase should not be highlighted or emphasized such (as through use of inordinately large type size, or sharply contrasting color, etc.) so as to constitute a misleading safety claim.

V. LABELING FOR LIQUID PRODUCTS USED NEAR ELECTRICAL EQUIPMENT *(Dielectric Breakdown Voltage)*

A. If the proposed draft label is not for a liquid, skip this section. Some liquid products may pose a shock hazard when used near electrical equipment or outlets. The dielectric breakdown voltage is a measure of a liquid's capacity to conduct electricity and is required if the end use product is a liquid and is to be used near electrical equipment. [See 40 CFR 158.190(a)]. If the proposed label **is** for a liquid product, review the criteria below:

1. **Criteria for Determining the Requirement of the Shock Hazard Statement**

a. The use directions permit use of the product near electrical equipment or electrical outlets (transformers, cable TV pedestals, conduits, etc.); **and**

b. the data matrix does not provide a dielectric breakdown voltage; or

c. the dielectric breakdown voltage is less than 5,000 volts.

2. **Shock Hazard Labeling Statement and Placement.** The Agency has historically taken the position that if the product meets the criteria above, the following statement must be shown under the heading "Physical or Chemical Hazards."

> "Do not apply this product around electrical equipment due to the possibility of shock hazard."
> (OPPTS Test Guidelines Series 830, Product Properties, #830-6321)

VI. LABELING FOR EXPLOSIVE POTENTIAL

A. WHEN REQUIRED. When data submitted in accordance with 40 CFR Part 158 demonstrate hazards of a physical or chemical nature other than flammability (such as explosive potential), appropriate statements of hazard must be included on the label. Such statements must address the potential explosion hazard.

B. CHEMICALS WITH POTENTIAL EXPLOSION HAZARD. Chemicals that the Agency recommends have specific statements for potential explosion hazard include but are not limited to: sulfur dust, carbon dust, potassium nitrate, sodium nitrate, and potassium chlorate. If the CSF indicates that the product might require labeling for potential explosion hazard, submit the label package for product chemistry review for a determination.

VII. ADDITIONAL LABEL STATEMENTS FOR CERTAIN FUMIGANTS

For some fumigant chemicals, statements of flammability or other physical or chemical hazards may be required. Several fumigants are highly flammable in the liquid or vapor form. The statements of flammability listed below for the following chemicals should be located on the side panel under the heading "Physical or Chemical Hazards." (Reference: PR Notices 84-5 and 85-6)

Sodium and Calcium Cyanides
"In the presence of moisture, highly poisonous gas (hydrogen cyanide) is formed."

VIII. WARNING STATEMENTS ABOUT MIXING CERTAIN PRODUCTS

Some products react with certain surfaces such as galvanized steel to form highly combustible gases. Therefore, under the Directions for Use section, some product labels prohibit mixing, storing, or applying the product in galvanized steel or unlined steel containers. This is acceptable. However, no human hazard signal word (Caution, Warning, or Danger) may be used with this information. [40 CFR 156.64(b)(3)]. The registrant may use "Attention," "Notice" or a similar word or phrase to alert the user. (Refer to chapter 11, Directions for Use, for more information on this issue.)

IX. REQUIREMENT FOR USE OF FIRE RETARDANT

Because of its combustion capability, the Agency has historically required all formulations of **sodium chlorate** to include an appropriate fire retardant chemical. Refer to Chapter 5, Ingredients Statement, for placement instructions for the required statement.

X. OTHER PHYSICAL/CHEMICAL HAZARD STATEMENTS

When data submitted in accordance with the requirements set forth in 40 CFR 158.190 demonstrate hazards of a physical or chemical nature other than flammability or explosive potential, appropriate statements of hazard must be included on the label. Such statements may address hazards of oxidizing or reducing capability, reactivity, or corrosivity. These decisions are made on case-by-case basis.

Chapter 10 **WORKER PROTECTION LABELING**

I. INTRODUCTION

This chapter provides guidance for reviewing statements required for the protection of agricultural workers and handlers. Although much of this chapter focuses on the requirements of the Worker Protection Standard ("WPS"), it goes beyond the WPS to include protections required for non-WPS occupational users of pesticides as well. Portions of the label that are focused on in this chapter include the signal word, certain Precautionary Statements (Personal Protective Equipment (PPE), Engineering Controls, User Safety Requirements, User Safety Recommendations) and certain Directions for Use (Agricultural Use Requirements, Restricted Entry Intervals, Early Entry PPE, Notification Statements and Non-Agricultural Use Requirements).

II. BACKGROUND

A. THE WORKER PROTECTION STANDARD. The Worker Protection Standard (WPS) [40 CFR 170 and 40 CFR 156, Subpart K (156.200 - 212)] was published in the *Federal Register* on August 21, 1992. These regulations establish standards and labeling requirements for worker protection. Further, PR Notices 93-7, 93-11 (provides supplemental guidance to PRN 93-7) provide Agency guidance for complying with the WPS. The correct product specific WPS labeling can be found in the Acute Toxicity Data Evaluation Record (DER) for any given product.

B. PESTICIDE REREGISTRATION. All pesticides sold or distributed in the United States and first registered before November 1984 must be reregistered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. The results of those reviews are published in a Reregistration Eligibility Decision (RED) Document. As part of the pesticide reregistration process, a comprehensive worker risk assessment is performed. The worker risk assessment is based on toxicological criteria and potential for dermal, oral or inhalation exposure. Based on that risk assessment, worker protection labeling specific to the active ingredient is established. When necessary to address risk to non-WPS workers, the RED Document goes beyond the WPS to provide labeling protection for those workers not subject to the WPS. Chemical specific worker protection labeling requirements can be found in the RED Documents.

C. EVALUATING THE RED DOCUMENT AND THE WPS. To determine the correct worker protection labeling for a given product, the label reviewer must consider both the chemical specific worker protection labeling defined by the RED Document and the product specific labeling defined in the acute toxicity review and/or guidance contained in this chapter. In most cases, the correct worker protection labeling is determined by taking the most restrictive statements from each source.

III. DETERMINATION OF PRODUCTS SUBJECT TO THE WORKER PROTECTION STANDARD (WPS)

A. SCOPE OF WPS. Review this section to determine whether the label under review involves a product that is subject to the WPS. The WPS does not apply to manufacturing use products, or to unregistered pesticides used under an experimental use permit issued under FIFRA section 5, or under an exemption issued under FIFRA section 18. This determination is important because WPS products have unique labeling requirements.

B. CRITERIA. Does the product bear directions for use involving the production of an agricultural plant [defined at 40 CFR 170.3 as any plant grown or maintained for commercial or research purposes and includes, but not limited to, food, feed, and fiber plants; trees; turfgrass; flowers, shrubs; ornamentals; and seedlings]. Or does the product bear labeling that could reasonably permit such a use?

NO: The product is not subject to the WPS. The requirements in this chapter do not apply.

YES: Does the product meet any of the exceptions listed below?

EXCEPTIONS: The WPS set out in Subpart B (40 CFR 170.102 et seq) does not apply when any pesticide is applied on an agricultural establishment (farm, forest, nursery or greenhouse) in the following circumstances:

- For mosquito abatement, Mediterranean fruit fly eradication, or similar area wide public pest control programs sponsored by governmental entities.

- On livestock or other animals, or in or around animal premises.

- On plants grown for other than commercial or research purposes, which may include plants in habitations, home fruit, and vegetable gardens, and home greenhouses.

- On plants that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds, and that are intended only for aesthetic purposes or climatic modification.

- By injection directly into agricultural plants. Direct injection does not include “hack and squirt,” “frill and spray,” “chemigation,” soil-incorporation, or soil injection.

- In a manner not directly related to the production of agricultural plants, including, but not limited to, structural pest control, control of vegetation along rights-of-way and in other non-crop areas, and pasture and rangeland use. Note if the registrant wants to include directions for cutting hay in pastures or rangelands then the product must bear WPS requirements.

- For control of vertebrate pests.

- As attractants or repellents in traps.

- Post harvest treatments on the harvested portions of agricultural plants or harvested timbers.

- For research uses of unregistered pesticides.

NO: The product IS subject to the WPS. Keep reading.

YES: The product is NOT subject to the WPS. The requirements in this chapter do not apply.

1. Remember, in some cases it is not clear whether or not a product is "in-scope" of the WPS. If the intention is to remove the product from the scope of the WPS, language should be used that limits **where** this product can be applied, rather than **who** may apply it. This can be done by using exclusionary statements such as the following:

> "Not for use on turf being grown for sale or other commercial use as sod, or for commercial seed production, or for research purposes."
> or
> "For use only on home lawns."

2. For further details, see PR Notice 93-11, Supplement F.

IV. SIGNAL WORD

Products subject to the WPS that are classified as toxicity category I or II must also bear the corresponding Spanish signal word and the Spanish statement provided below. The Spanish signal word and statement below must appear in close proximity to the English signal word. The Spanish signal word for toxicity category I is "PELIGRO" and the Spanish signal word for toxicity category II is "AVISO." The statement that must appear on toxicity category I and II WPS products is as follows:

> **"Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)"**

V. SPLIT LABELING FOR WPS AND OCCUPATIONAL USE PRODUCTS

A. If a registered product contains uses that are both subject to WPS and not subject to WPS, the registrant should be encouraged to have separate registrations for each use type. However, the registrant is allowed to register the product with both use types on one label and /or choose to market the product with two sub-labels (under one registration) featuring only one of the use types on each sub-label. The registrant may market the product under two distinctly different product labels, using additional brand names for the WPS labeling and non-WPS labeling. If the registrant chooses to market the product with both WPS and non-WPS uses, a Non-Agricultural Use Requirements box must be used to contain all non-WPS worker related restrictions. In either case, the registrant must submit a master label that clearly distinguishes between the two separate sub-labels. However, it

is not permissible to provide the WPS labeling merely as a supplemental label to a non-WPS product.

B. Many pesticide products also contain residential consumer uses along with WPS and non-WPS occupational uses. Because the personal protective equipment and other worker protection statements may be significantly different for occupational and residential consumer products, the registrant should be strongly encouraged to submit separate registrations with one containing the WPS and Non-WPS Occupational uses, and the other containing the residential consumer uses.

VI. PRECAUTIONARY STATEMENTS

There are four types of worker protection statements that appear in the Precautionary Statements of a label. They are as follows: A) Handler Personal Protective Equipment (PPE); B) User Safety Requirements; C) Engineering Controls; and D) User Safety Recommendations. These statements may be required by the WPS on in-scope products and also on non-WPS occupational products if required by a RED Document. The reviewer should also refer to Chapter 7 for additional, non-WPS, information on determining the correct toxicity category and other appropriate precautionary language.

A. HANDLER PERSONAL PROTECTIVE EQUIPMENT (PPE)

The correct handler PPE is determined by comparing the product specific handler PPE specified in the acute toxicity review for a product with the chemical specific handler PPE requirements specified in the RED Document. In most cases, the reviewer uses a combination of the most protective statements given in the RED Document and the Acute Toxicity Review to determine the correct handler PPE labeling. The correct product specific handler PPE can be derived from the Acute Toxicity Review for a given product or refer to sections 1 through 4 below to determine the correct product specific PPE. Once the correct product specific Handler PPE has been determined, the reviewer should compare this labeling with worker protection labeling required by the RED Document and use the table in this section to select the most protective PPE.

1. **Identifying the Correct Product Specific Handler Protective Clothing.** Once the correct toxicity category has been established, the product specific handler PPE can be identified. Reviewers may obtain the correct product specific handler protective clothing from the Acute Toxicity Review. Table 1 below shows how the correct product specific handler protective clothing is derived in the Acute Toxicity Review based on the toxicity category for a given product.

TABLE 1 - HANDLER PPE FOR WPS PRODUCTS

Route of Exposure	Toxicity Category by Route of Exposure of End-Use Product			
	I DANGER	II WARNING	III CAUTION	IV CAUTION
Dermal Toxicity or Skin Irritation Potential[1]	Coveralls worn over long-sleeved shirt and long pants Socks Chemical-resistant footwear Chemical-resistant Gloves[2]	Coveralls worn over short-sleeved shirt and short pants Socks Chemical-resistant footwear Chemical-resistant Gloves[2]	Long-sleeved shirt and long pants Socks Shoes Chemical-resistant Gloves[2]	Long-sleeved shirt and long pants Socks Shoes No minimum[4]
Inhalation Toxicity	Respiratory protection device[3]	Respiratory protection device[3]	No minimum[4]	No minimum[4]
Eye Irritation Potential	Protective eyewear[5]	Protective eyewear[5]	No minimum[4]	No minimum[4]

[1] If dermal toxicity and skin irritation toxicity categories are different, PPE shall be determined by the more severe toxicity category of the two. If dermal toxicity or skin irritation is category I or II, refer to Section 3 below to determine if additional PPE is required beyond that specified in Table

[2] Refer to Section 3, Table 3 to determine the specific type of chemical-resistant glove.

[3] Refer to Section 4 to determine the specific type of respiratory protection.

[4] Although no minimum PPE is required for these toxicity categories and routes of exposure, the Agency may require PPE on a product-specific basis.

[5] "Protective eyewear" is to be used instead of "goggles" and/or "face shield" and/or "shielded safety glasses" and similar terms to describe eye protection.

2. **Identifying Additional Product Specific Handler Protective Clothing (Apron and Headgear)** Additional PPE is required for products that are classified as toxicity category I or II for acute dermal toxicity or skin irritation. If the label under review does not involve a category I or II classification for either of these studies, skip this section. If the label under review does involve a category I or II classification for either the acute dermal toxicity or skin irritation, review Table 2 below to determine the additional product specific PPE.

TABLE 2 - ADDITIONAL DERMAL TOXICITY AND/OR SKIN IRRITATION PPE FOR TOXICITY CATEGORY I OR II

Conditions Requiring Additional PPE and Labeling	Required PPE and Labeling
All products that are not ready to use and do not require a chemical resistant suit must bear the corresponding statement:	"When mixing and loading wear a chemical resistant apron."
All products labeled for application procedures that might involve overhead exposure must bear the corresponding statement:	"For overhead exposure wear chemical-resistant headgear."
All products labeled for use of equipment other than the product container to mix, load or apply the product must bear the corresponding statement:	"When cleaning equipment wear a chemical-resistant apron."

3. **Product Specific Glove Selection for Handlers**. Chemical-resistant gloves are required for all products classified as toxicity category I, II, or III for acute dermal toxicity or primary skin irritation. Review the types of chemical-resistant gloves below, and determine if the label lists the appropriate glove type based on the product formulation. The registrant can specify a chemical-resistant glove type other than those specified in Table 3 if information is available that indicates that another glove type is more appropriate or provides greater protection. The registrant must verify why the alternative glove should be used. The label must indicate the specific type of chemical-resistant glove(s) (such as nitrile, butyl, etc. for the appropriate category of solvent). See the solvent list in PR Notice 93-7, pp. 13-15. For those solvents not listed contact the Health Effects Division's Chemistry and Exposure Branch (CEB-I). Listed below are the standard glove types required by the WPS.

a. Solid Formulations: applied as solids or formulations containing only water as the solvent or contain solvents other than water at less than 5%, the glove statement shall specify "chemical-resistant" gloves. (Reference: Supplement III, Main Labeling Guidance, Page 11, of PR Notice 93-7.

b. Aqueous-Based Formulations: applied as formulated or diluted solely with water for application, the glove statement shall specify "chemical-resistant" gloves.

c. Other Liquid Formulations which are formulated or diluted with liquids other than water: (constitutes more than 5% of the end-use product), the glove statement shall specify "chemical-resistant (such as nitrile or butyl) gloves."

d. Gaseous Formulations or Formulations applied as Gases: may retain any existing glove statement established before 10/20/92 including any glove prohibition statement. If no glove statement or glove prohibition currently exists on the label, then the glove statement shall be "chemical-resistant (such as nitrile or butyl) gloves."

TABLE 3 - EPA CHEMICAL RESISTANCE CATEGORY SELECTION CHART
(For use when PPE section on pesticide label lists a chemical resistance category)

SELECTION CATEGORY LISTED ON PESTICIDE LABEL	**TYPE OF PERSONAL PROTECTIVE MATERIAL**							
	Barrier Laminate	**Butyl Rubber ≥ 14 mils**	**Nitrile Rubber ≥ 14 mils**	**Neo-prene Rubber ≥ 14 mils**	**Natural Rubber* ≥ 14 mils**	**Poly-ethylene**	**Polyvinyl Chloride (PVC) ≥ 14 mils**	**Viton ≥ 14 mils**
A (dry and water-based formulations)	NA	NA	NA	NA	high	NA	NA	NA
B	high	high	slight	slight	none	slight	slight	slight
C	high	high	high	high	moderate	moderate	high	high
D	high	high	moderate	moderate	none	none	none	slight
E	high	slight	high	high	slight	none	moderate	high
F	high	high	high	moderate	slight	none	slight	high
G	high	slight	slight	slight	none	none	none	high
H	high	slight	slight	slight	none	none	none	high

**includes natural rubber blends and laminates*

HIGH: Highly chemical-resistant. Clean or replace PPE at end of each day's work period. Rinse off pesticides at rest breaks.
MODERATE: Moderately chemical-resistant. Clean or replace PPE within an hour or two of contact.
SLIGHT: Slightly chemical-resistant. Clean or replace PPE within ten minutes of contact.
NONE: No chemical-resistance. Do not wear this type of material as PPE when contact is possible.
NA: Not Applicable. Provides high resistance but exceeds level of protection required for these formulations.

4. **Product Specific Respiratory Protection Device (RPD) Selection for Handlers**: RPD(s) are required for all products classified as toxicity category I or II for acute inhalation. Review the RPD types in Table 4 and determine if the label lists the appropriate type based on the product description and toxicity category. If the registrant has submitted information showing that a more protective RPD should be selected, allow the registrant to retain that RPD requirement on the label under review. Information that could support an alternate RPD could be the submission of the product vapor pressure data indicating that the RPD specified in Table 4 would not provide adequate protection or could pose an increased risk to the user.

a. In June 1995, the National Institute for Occupational Safety and Health (NIOSH) revised the certification criteria and definitions for nonpowered, air-purifying particulate respirators. 42 CFR Part 84 replaced the outdated certification standards in 30 CFR Part 11 regulations. The new Part 84 regulation creates a total of nine classes of particulate filters; these classes apply only to nonpowered, air-purifying, particulate filter respirators. Since NIOSH allowed manufacturers of respirators to continue selling and shipping Part 11 particulate filters as NIOSH-certified until July 10, 1998, changes in label language were phased in as described below.

b. New and Old Respirator Language Schedule

(1) April 1, 2000: New language must be present on all labels.

(2) Between April 1, 2000 and March 31, 2001: registrants must include both old language and new language on labels.

(3) After April 1, 2001: registrants may begin removing old language from labels.

(4) After April 1, 2004: Registrants must have new language and old language must be gone.

c. Oil definition. NIOSH defines oil as a high boiling-point, liquid hydrocarbon that will accumulate on a respirator's particulate filter with minimal evaporation. This includes any of a large class of substances which are viscous, combustible, liquid at ordinary temperatures, and soluble in ether or alcohol but not in water. Some examples of oil-type products or products that contain oil are: mineral oils (e.g., petroleum/hydrocarbons lubricating oils), as well as certain adjuvants such as crop oils and surfactants added when a pesticide product is mixed with water or with other pesticides in tank mixes. If an oil is present at any level in the pesticide itself or in the mixture of pesticide with water, solvent, fertilizer, adjuvants, etc. added to the crop, and if a respirator is required (i.e. if the product is in toxicity category I or II for inhalation toxicity), then only an R- or P-series respirator may be used; an N-series respirator may only be used when there is no oil involved.

d. In determining whether a pesticide product label should require the use of non-oil resistant N-series, oil-resistant R-series, or oil-proof P-series respirators the reviewer should first examine the CSF for the presence of oil compounds in the product formulation at any concentration. Generally, N-series are only used for non-oil based aerosols. R-series may be used for oil based aerosols with a time limitation of 8 hours, and P-series for periods of time longer than 8 hours with considerations of resistance, soiling, or damage. The reviewer should then examine the Directions

for Use section of the label for instructions calling for the addition of crop oils, surfactants and other organic substances that may be oils as defined by NIOSH. If the reviewer has any question whether a substance listed in either the CSF or the Directions for Use is actually an oil, this question should be referred to the Chemistry group of the Registration Division's Technical Review Branch or a Chemist in the appropriate Division.

TABLE 4 – NEW AND OLD RESPIRATOR LANGUAGE		
Pesticide Type	If Old Language Said:	New Language (per PR Notice 98-9) must say:
Gases Applied Outdoors: Products that are formulated or applied as a gas (space and soil fumigants) and that may be applied outdoors must bear labeling specifying the following RPD requirements and statement:	"...a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) OR a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)".	**Pesticide Mixtures with Oil:** "...respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P or HE prefilter." **Pesticide Mixtures without Oil:** "...respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or HE prefilter."

TABLE 4 – NEW AND OLD RESPIRATOR LANGUAGE		
Pesticide Type	If Old Language Said:	New Language (per PR Notice 98-9) must say:
Gaseous Products Used in Enclosed Areas: Products that are formulated or applied as a gas (space and soil fumigants) and that may be used in greenhouses or other enclosed areas must bear labeling specifying the following RPD requirements and statement:	"...For handling activities in enclosed areas, use either a supplied-air respirator with MSHA/NIOSH approval number prefix TC-19C, OR a self-contained breathing apparatus (SCBA) with MSHA/NIOSH approval number TC-13F." The designations for the TC-19C and TC-13F respirators did not change with the latest NIOSH regulations.	**Pesticide Mixtures with Oil: language did not change except that the references to MSHA should be deleted.** **Pesticide Mixtures without Oil - language did not change except that the references to MSHA should be deleted.**
Solid Products: Products that are formulated and applied as solids.	"...dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."	**Pesticide Mixtures with Oil:** "...dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any R, P, or HE filter. **Pesticide Mixtures without Oil:** "...dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any N, R, P or HE filter."

TABLE 4 – NEW AND OLD RESPIRATOR LANGUAGE		
Pesticide Type	If Old Language Said:	New Language (per PR Notice 98-9) must say:
Liquid Products in Toxicity Category I: Products that are formulated and applied as liquids must bear labeling specifying the following RPD requirements and statement:	"...a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), OR a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)".	**Pesticide Mixtures with Oil**: "... respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P or HE prefilter." **Pesticide Mixtures without Oil**: "...respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or HE prefilter."

TABLE 4 – NEW AND OLD RESPIRATOR LANGUAGE		
Pesticide Type	If Old Language Said:	New Language (per PR Notice 98-9) must say:
Liquid Products in Toxicity Category II: Products that are formulated or applied as liquids:	"For handling activities during [insert applicable terms based on directions for use, such as: air blast, mist blower, pressure greater than 40 p.s.i. with fine droplets, smoke, mist, fog, aerosol or direct overhead], use either a respirator with an organic vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), **OR** a canister approved for pesticides (MSHA/NIOSH approval number prefix 14G). For all other exposures, use a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."	**Pesticide Mixtures with Oil**: "...respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P or HE prefilter." **Pesticide Mixtures without Oil**: "...respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or HE prefilter."

e. Respirator types for which label language changes are not required at this time.

(1) powered air purifying respirator equipped with a high efficiency particulate air (HEPA) filter (MSHA/NIOSH approval number prefix TC-21C).

(2) powered air purifying respirator equipped with an organic-vapor (OV) removing cartridge plus a high efficiency (HE) filter (MSHA/NIOSH approval number prefix TC-23C).

(3) powered air purifying canister-type respirator (gas-mask) equipped with an organic vapor canister that uses HE filters (MSHA/NIOSH approval number prefix TC-14G).

f. In reviewing the NIOSH certification changes, EPA has concluded that all 42 CFR 84 (Part 84) respirators meet or exceed all 30 CFR 11 (Part 11) requirements and that a respirator certified under Part 84 is an acceptable substitute for a respirator certified under Part 11.

	TABLE 5 - Oil Resistance & Efficiency of Filters		
Filter Efficiency	**N-series particulate filters** **Not resistant to oil.**	**R-series particulate filters** **Oil-resistant**.	**P-series filters** **Oil-proof.**
95%, 99%, and 99.97%	N95/ N99/ N100 Not resistant to oil. May be used for solid & liquid particulate hazards. *Time limitations*: Use and reuse of N-series filters would be subject only to considerations of hygiene, damage and increased breathing resistance. (See manufacturer's recommendations, and the Use Limitation section within PR Notice 98-9 for guidance on determining whether a respirator filter can still function after a particular exposure).	R95/ R99/ R100 Oil-resistant. May be used for solid & liquid particulate hazards. *Time limitations*: The R-series filters should be used only for a single shift (or for 8 hours of continuous or intermittent use) when oil is present. (See manufacturer's recommendations, and the Use Limitation section within PR Notice 98-9 for guidance on determining whether a respirator filter can still function after a particular exposure).	P95/ P99/ P100 Oil-proof May be used for solid & liquid particulate hazards. *Time limitations*: Use and reuse of the P-series filters would be subject to the manufacturer's recommendation Repeated exposures may degrade the filter below its rated efficiency. (See manufacturer's recommendation and the Use Limitation section within PR Notice 98-9 for guidance on determining whether a respirator filter can still function after a particular exposure).

5. **Compare Product Specific PPE with PPE Required by the RED Document.** After completing steps 1 through 4 and identifying the handler PPE based on the product specific acute toxicity data, the reviewer must now consider the PPE required by the RED Document, if one has been published. A combination of the most protective PPE specified in the Acute Toxicity Review (or derived from steps 1 through 4 above) and the RED Document must be used to determine the appropriate product labeling. For guidance on which PPE is considered more protective, consult Table 6.

Note: All end-use occupational use products (WPS or non-WPS) must have the minimum baseline Handler PPE of long-sleeved shirt, long pants and socks and shoes.

Table 6 - Guide to Selecting the Most Protective Handler PPE Level of Protection				
Type of PPE	Minimum Required	Next Highest Level of Protection	Next Highest Level of Protection	Highest Level of Protection
Protective Clothing	Long-sleeved shirt and long pants	Coveralls over short-sleeved shirt and short pants	Coveralls over long-sleeved shirt and long pants	Chemical Resistant Suit
Protective Footwear	Socks and Shoes	Chemical -resistant footwear	Chemical-resistant boots	NA
Gloves	None	Chemical-resistant gloves	NA	NA
Protective Headwear	None	Chemical-resistant headgear	NA	NA
Chemical resistant Apron	None	Chemical-resistant apron worn over long-sleeved shirt and long pants	Chemical-resistant apron worn over coveralls over long-sleeved shirt and long pants	NA
Respiratory Protection Device	None	Dust/mist filtering respirator	Organic Vapor (OV) removing respirator	Air Supplying Respirator

6. **Required Location for Handler PPE**. Handler PPE statements for applicators and other handlers must appear in the "PRECAUTIONARY STATEMENTS" section of the labeling. The preferred location is directly below the Hazards to Humans and Domestic Animals Statements.

7. **States may require the use of additional WPS PPE**. The Agency will approve additional state-required language if it is clear that it applies only in that state.

B. PESTICIDE USER SAFETY REQUIREMENTS

1. **Statements for Contaminated Personal Protective Equipment**

a. All occupational use products must bear the following statements:

"Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

b. If the product is a concentrate (diluted before use, or is an ultra-low-volume or low-volume concentrate, or contains more than 50% active ingredient) and is in Toxicity Category I or II, its label must include the following statement before the previous statement:

> "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

Note: The RED Document may also require the above statement.

2. User Safety Requirements must appear in the "PRECAUTIONARY STATEMENTS" section of the labeling. The preferred location is directly below the Personal Protective Equipment. NOTE: If a RED has not been done "User Safety Requirements" identified as such may not exist.

C. ENGINEERING CONTROL STATEMENTS

1. **PPE for Engineering Control Systems**. Engineering Controls may be required by the RED Document or by the Acute Toxicity profile of a given product.

a. Engineering Controls for Toxicity I and II Products. Unless it is supplemented or superseded by the RED Document, if product is Toxicity Category I or II for either acute dermal toxicity or skin irritation potential, or if either of these data are not available, use the end-use product signal word as a surrogate, then the following statements shall appear on the label.

> "When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."
>
> (*For products packaged in water-soluble packages*)
> "Water-soluble packets, when used correctly, qualify as a closed loading system under the WPS. Handlers handling this product while it is enclosed in intact water-soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks, a chemical-resistant apron, and chemical-resistant gloves."
>
> "IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down."

b. Engineering Controls for Toxicity III and IV Products. Unless it is supplemented or superseded by the RED Document, if the product is Toxicity Category III or IV for acute dermal toxicity and skin irritation potential, or if either of these data are not available, and signal word is CAUTION, then the following statements must appear on the label.

> "When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides

(40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

(*For products packaged in water soluble packages*)
"Water-soluble packets, when used correctly qualify as a closed loading system under the WPS. Handlers handling this product while it is enclosed in intact water-soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, and socks instead of listed PPE."

"IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down."

2. Engineering Controls must appear in the "PRECAUTIONARY STATEMENTS" section of the labeling.

D. USER SAFETY RECOMMENDATIONS

1. **When Required.** If the product falls within the scope of WPS, then a User Safety Recommendations box, as indicated in PR Notice 93-7, Supplement Three, must also appear in a separate box on the label containing appropriate user safety information. Many RED Documents also require User Safety Recommendations for Non-WPS occupational use products. Although the registrant may include any appropriate user safety recommendations on their label, below are some typical statements required by the RED Documents or found on many products.

2. **Example of a User Safety Recommendations Box**

"User Safety Recommendations"

"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

VII. DIRECTIONS FOR USE

A. PRODUCTS SUBJECT TO THE WPS. For products subject to the WPS, there are four types of worker protection statements that appear in the Directions for Use of a label. They are as follows: 1) General Statements; 2) Brief Agricultural Use Requirements Referral Statement; 3) Agricultural Use Requirements; and 4) Non-Agricultural Use Requirements.

1. **General Statements**. 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. See the sample at the end of this chapter.

a. "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)

b. "For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation."

2. **Brief Agricultural Use Requirements Referral Statement**

"Agricultural Use Requirements
Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. Refer to supplemental labeling under "AGRICULTURAL USE REQUIREMENTS" in the DIRECTIONS FOR USE section for information about this standard."

a. This statement should be used if you put the Agricultural Use Requirements Box in Supplemental Labeling.

b. This statement must appear on the product label near the statement referring users to the supplemental labeling. This statement must be IN A BOX under the heading "AGRICULTURAL USE REQUIREMENTS."

3. **Agricultural Use Requirements Box Statements.** The following statements must also appear on all WPS labels. These statements must appear after the heading "Directions for Use" and **IN** the AGRICULTURAL USE REQUIREMENTS box. (See example AGRICULTURAL USE REQUIREMENTS box at the end of this chapter.)

a. "Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170."

b. "This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on the label about personal protective equipment, restricted-entry interval, and notification to workers (as applicable)."

c. Do the use directions of the end-use product permit area wide treatment in residential or public areas through fog, aerial, or other broadcast application where contact with workers or other persons, either directly or through drift cannot reasonably be avoided? Examples: applications for control of mosquitoes, gypsy moths, or Mediterranean fruit flies. If the product permits those types of area wide treatment, then the statement, "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," should appear **IN** the "AGRICULTURAL USE REQUIREMENTS" Box.

d. Restricted Entry Statements. All WPS products must have a Restricted Entry Interval (REI). An REI is the time period immediately following a pesticide application during which entry into the treated area is restricted. REIs are set by Supplement Three-A of PR Notice 93-7, the RED Document or by using the guidelines listed below. If the REI established by the RED Document is different from the guidance below, the REI established by the RED must be required on the label. Some labels may have several different REIs for different crops. The REI must appear in the following format:

> "Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) (include single REI here, see below for multiple REIs)."
>
> * **Single REI:** If a product has only one REI, then the REI shall appear as a continuation of the above required sentence in one of the following formats: "of X hours"; "of X days" or "until the acceptable exposure level of X ppm or mg/m^3 is reached."
>
> * **Multiple REI(s):** If different REI's exist for certain crops or uses, then the REI must appear in the directions for use for that crop or use. The REI must be immediately preceded or followed by the word "Restricted Entry Interval" or the letters "REI."
>
> * **72 hr REI** for organophosphorous ester in arid areas: If the active ingredient is an organophosphorous ester that may be applied outdoors in an area where the average annual rainfall for the application site is less than 25 inches per year, the following statement shall be added to the restricted-entry statement: 72 hours in outdoor areas where average annual rainfall is less than 25 inches a year.

e. Early Entry PPE

(1) All products subject to the WPS must bear the following statements for workers who reenter the treated area prior to the expiration of the restricted entry interval:

> "For early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, wear:" (Insert all Early Entry PPE specified by the RED document. If there is no RED document follow the guidelines below to select the correct early entry PPE)

(2) If a RED document has not yet been issued for a chemical, consider the following when selecting the correct early entry PPE: a) start with the Handler PPE; b) omit any respiratory protective devices; c) if the handler body clothing requirement is a long-sleeved shirt and long pants, then the early-entry worker requirement shall be "coveralls"; and d) if there is no handler requirement for gloves, then the early-entry requirement shall be "chemical resistant gloves (made of any waterproof material)."

f. Notification-to-Workers Statements. Notification to workers statement is required if the product meets the criteria below:

(1) *Fumigants*: Fumigants that are registered for use in greenhouses or whose labeling allows use in greenhouses must bear the following statement:

> "For greenhouse applications, notify workers of the application by warning them orally and by posting warning signs outside all entrances to the greenhouse."

(2) *All Other Products*: Products which contain any active ingredient classified as toxicity category I based either on acute dermal toxicity data, skin irritation data, or the criteria below shall bear the following notification statement:

> "Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas."

(a) To identify the toxicity category follow the steps below:

(i) Step 1: Examine available data for toxicity category determination. Since acute dermal and skin irritation data may not always be available, use the following list in selecting which data/signal word should be used for determining the acute toxicity category:

a. Consider acute dermal and skin irritation data on all a.i.(s) in the product;

b. If acute dermal data are missing for any a.i., consider acute oral data on that a.i. in addition to the primary skin irritation data on the a.i.

c. If acute oral and acute dermal data are missing for any a.i., consider the skin irritation data on the a.i.;

d. If the acute oral, acute dermal, and skin irritation data are missing for any a.i., consider the signal word of the registered manufacturing use product for the a.i.;

e. If none of the above data is available on any a.i. in the product, consider the signal word of the end-use product.

(ii) Step 2: If any data used in Step 1, items a-e are toxicity category I or otherwise require use of the equivalent signal word of "DANGER", then a notification statement is required.

(3) *Location of Statement*

(a) All notification statements must be located in the DIRECTIONS FOR USE section in the box with the heading AGRICULTURAL USE REQUIREMENTS.

(b) If notification is not required. The reviewer should make sure that the statement about notification to workers is dropped from the General statement in the Agricultural Use Requirements box. For example:

> "... It also contains specific instructions and statements pertaining to statements on this label about personal protective equipment (PPE), and the restricted-entry interval."

g. Non-Agricultural Use Requirements

(1) If the label contains only uses within the scope of the WPS, skip this section.

(2) If the label contains or the RED requires entry restrictions, notification requirements, or other instructions similar to WPS requirements that apply to uses NOT within the scope of the WPS (non-agricultural uses), there should be a second box on the label called: "Non-Agricultural Use Requirements."

(3) This box may be placed anywhere in the Directions for Use section of the label **after** the Agricultural Use Requirements box.

(4) The following statements must be contained in the Non-Agricultural Use Requirements box:

(a) "Non-Agricultural Use Requirements"
"The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses."

(b) In addition, place into the Non-Agricultural Use Requirements box all the entry restrictions, notification requirements, or other statements and instructions (except personal protective equipment requirements) that apply to the non-WPS uses on the label. Examples: "Keep children and pets out of the treated area until sprays have dried"; or, "Keep unprotected persons out of treated areas until sprays have dried."

VIII. DETERMINING THE CORRECT REI

The correct REI may be specified in the RED Document. If a RED Document is not available, refer to Supplement Three-A of PR Notice 93-7, or use the following guidance to determine the correct REI.

A. REI(s) FOR FUMIGANTS. Current REI(s) will be retained or at the time of registration, an REI will be determined on a case-by-case basis.

B. REI(s) DETERMINED BY SUBDIVISION D DATA (158.390). REI(s) will be retained.

C. ALL OTHER REI(s). Follow the steps below to determine the correct REI(s).

1. **Step 1: Identify Acute Toxicity Data to Be Used in Determining REI(s)**

a. REI(s) are based on the most severe acute toxicity category assigned to the acute dermal, eye irritation and skin irritation data for all of the active ingredients (a.i.) in a product. In many instances, these data are not always available. The following list indicates the preferred order for selecting data on which to determine the toxicity category for each a.i.:

(1) Use the acute dermal, eye irritation and skin irritation data for the technical product for each active ingredient;

(2) Use the acute oral and eye irritation and/or skin irritation data for any active ingredient missing acute dermal data;

(3) Use the eye irritation and/or skin irritation data for any active ingredient missing the acute oral and acute dermal data;

(4) Use the signal word of the registered manufacturing use product that is the source of the active ingredient which does not have any acute oral, acute dermal, eye irritation, or skin irritation data;*

(5) Use the signal word of the product under review if none of the above data is available on the active ingredient and if the active ingredient without data is not a registered manufacturing use product.*

b. The following chart provides examples of how the acute toxicity category is determined for purposes of determining the REI.

TABLE 7 - DETERMINING ACUTE TOXICITY CATEGORY FOR REI PURPOSES

Product A	Variable Acute Tox Data for Each Active Ingredient	Tox Cat.	Tox Cat. Used to Determine REI
single a.i.	Acute dermal tox data Eye irritation data	III II	II[1]
Product B	**Available Acute Tox Data for Each Active Ingredient**	**Tox Cat.**	**Tox Cat. Used to Determine REI**
a.i. #1	Acute dermal tox data Eye irritation data Skin irritation data	III II III	II
a.i. #2	Acute oral tox data	III	III
a.i. #3	Signal word of registered MP (source of a.i.)	I	I[2]

[1] The appropriate REI for Product A would be 24 hours.
[2] The appropriate REI for Product B would be 48 hours.

2. **Step 2: Determine appropriate REI(s) using the chart below and note exceptions***:

TABLE 8 - DETERMINING THE REI

Most Severe Tox Category Used to Determine the REI	Length of Required REI
When the most severe tox category is III or IV	The REI is 12 hours
When the most severe tox category is II	The REI is 24 hours
When the most severe tox category is I	The REI is 48 hours
In addition: If the product is an organophosphate ester that inhibits cholinesterase and may be applied outdoors in an area where the average rainfall for the application site is less than 25 inches per year,	The REI is 72 hours.

*Exceptions:

1. If any existing interim REI, established prior to 10/20/92, is longer than the REI(s) shown in the table above, the existing interim REI should be retained.
2. If a product bears REI(s) for uses not subject to the WPS, those REI(s) should be retained and included in the "Non-Agricultural Use Requirements" box. If multiple REI's exist, follow instructions for multiple REI's below.

3. **Reduced Risk Restricted Entry Intervals to 4 Hours**. To qualify for a reduction in the REI to 4 hours products must meet the following criteria:

a. The active ingredient is in Toxicity Category III or IV based upon data for acute dermal toxicity, acute inhalation toxicity, primary skin irritation, and primary eye irritation. Acute oral toxicity data are used if no acute dermal data are available. If EPA lacks data on primary skin irritation, acute inhalation, or primary eye irritation of the active ingredient, the Agency can review data on that end-point for similar active ingredients (analogs), as long as it excludes such active ingredients from consideration for the reduced REI, if the analog is in Toxicity Category I or II for that endpoint.

b. The active ingredient is not a dermal sensitizer (or in the case of biochemical and microbial active ingredients, no known reports of hypersensitivity exist).

c. The active ingredient is not a cholinesterase inhibitor (N-methyl carbamate and organophosphate) as these chemicals are known to cause large numbers of pesticide poisonings and have the potential for serious neurological effects.

d. No known reproductive, developmental, carcinogenic, or neurotoxic effects have been associated with the active ingredient. If the active ingredient does not have data available for these chronic health effects, EPA considers data on appropriate chemical and biological analogs. Active ingredients that have been classified as carcinogenic in Group B (probable human carcinogen) or Group C (possible human carcinogen) chemicals for which quantification of potential risk (Q1*) is appropriate, as well as those scheduled for the Health Effects Division's Cancer Peer Review process, are omitted from consideration.

e. EPA does not possess incident information (illness or injury reports) that are"definitely" or "probably"' related to post-application exposures to the active ingredient.

f. Some active ingredients are not included in PR Notice 95-3 because they have been the subject of a Reregistration Eligibility Decision (RED) document which concluded that a 12 hour or longer REI was necessary to protect workers. Active ingredients with REIs established during reregistration activities are NOT eligible for reduced REIs. It should also be noted that WPS does not apply to pheromones used in insect traps.

IX. LABELING STATEMENTS FOR SPECIAL SITUATIONS

A. CHEMIGATION STATEMENT (from PR Notice 93-7, Supplement 3, page 39)

1. Does the current labeling for an end-use product contain instructions for posting a warning sign about chemigation?

a. NO: No action is necessary.

b. YES: Find those statements in your revised labeling and add the following statement:

"This sign is in addition to any sign posted to comply with the Worker Protection Standard."

B. SOIL INCORPORATION/INJECTION/SEED TREATMENT (from PR Notice 93-7, Supplement 3, page 39)

1. Does the current labeling for an end-use product contain instructions for incorporating or injecting the product into the soil or planting medium?

a. NO: No action is necessary.

b. YES: Include the following statement in the Agricultural Use Requirements box under Item 4 which gives the restricted entry interval instructions:

> "Exception: if the product is soil-injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated."

C. ENGINEERING CONTROL STATEMENTS (from PR Notice 93-7, Supplement 3, page 50)

1. Does the current product labeling contain any requirements or recommendations for the use of closed systems, enclosed cabs, or open or enclosed cockpits?

a. NO: Do the following:

(1) Choose to add the following paragraph to the labeling:

> "When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS."

(2) To add this statement to your labeling, include it in the Precautionary Statements section of the label under the heading "Engineering controls."

D. ULV AND LV USES (from PR Notice 93-7, Supplement 3, page 40)

1. If the product contains directions for use as a ULV or LV concentrate, do the following:

a. If the product does not have any PPE requirements, do nothing.

b. If the product does have PPE requirements and the product contains directions for use ONLY as a concentrate, do the following:

In the Precautionary Statements section, change the standard heading of "Mixers and Loaders must wear:" to "Mixers, loaders, applicators, and other handlers who may be exposed to the concentrate must wear:" This heading will also replace the standard heading "Applicators and other handlers (other than mixers and loaders) must wear:"

c. If the product does have PPE requirements but does not contain directions for use solely as a concentrate, do the following:

In the Precautionary Statements section, change the standard heading of: "Applicators and other handlers (other than mixers and loaders) must wear:" to "Handlers who may be exposed to the dilute through application or other tasks must wear:" AND also change the standard heading "Mixers and Loaders must wear:" to "Handlers who may be exposed to the concentrate through mixing, loading, application, or other tasks must wear:"

X. SAMPLE AGRICULTURAL USE REQUIREMENTS BOX

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its 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 requirement specific to your State and Tribe, consult the State/Tribal agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this `label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of __ hours. The REI is 72 hours in outdoor areas where average annual rainfall is less than 25 inches a year.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water), is:
- coveralls over long-sleeved shirt and long pants
- chemical-resistant gloves such as barrier laminate or viton
- chemical-resistant footwear plus socks
- protective eyewear
- chemical-resistant headgear

Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas.

Chapter 11 **DIRECTIONS FOR USE**

I. INTRODUCTION

A. 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. Label writers and reviewers should keep in mind the distinction between mandatory statements and advisory/recommended information, and try to write the label statements accordingly. See PR Notice 2000-5

B. PURPOSE OF DIRECTIONS FOR USE. The "Directions for Use" section of a pesticide label describes how the product may legally be used and how the product must not be used. The requirements for the directions for use section are found in the regulations at 40 CFR 156.10(i), but generally speaking the information necessary is as follows:

- the pest(s) that the product may be used to control;
- the sites where the product may be used;
- the application methods that are required or preferred;
- how much pesticide should 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 may be applied;
- all restricted entry intervals (REIs) pertaining to existing uses, as applicable;
- maximum application rates (per treatment and per year);
- preharvest intervals (PHIs); and
- any other requirements as necessary

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 mentioned are required, prohibited, encouraged, or discouraged. Other sentences in the use directions may be used only to convey background information.

C. FORMAT. Charts, tables, and graphics may be used in the Directions for Use section as long as they do not contain or imply false or misleading information and they provide accurate information in a clear, concise and complete manner. Instructions may be numbered if a true sequence of actions is required.

D. CLARITY. The text in the Directions for Use section should be expressed in complete sentences. 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 and /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 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.

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

> "Mix 1½ 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 1½ 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.

F. APPLICATION RATE. The actual application rate, (e.g., <u>how</u> <u>much product</u> 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.

Labels for residential/household 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.

II. REVIEW STRATEGY FOR DIRECTIONS FOR USE

A. This section presents recommended strategies for reviewing the Directions For Use section of pesticide labels. It also presents two different methods for reviewing the label and 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.

Some draft labels may contain statements or information not acceptable according to FIFRA, or the implementing regulations. Such statements must be corrected. In addition, 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.

B. TYPE OF LABEL REVIEWS FOR DIRECTIONS FOR USE

1. **Me-too Application**. If the application is a me-too submission (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 me-too application.

Target pests or use sites found on the registered product's label may be omitted from the me-too product's labeling. For example, a me-too application is made for an insecticide formulation to add structural perimeter treatments for crickets, ants, and sowbugs. The registered product referenced in the me-too 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 or new public health pests may appear on the label for the pending me-too product. The format for the presentation of use information on the me-too 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 me-too product meets applicable legal requirements on labeling.

a. A major pitfall in side-by-side label comparisons is the possible presence of an unacceptable use or other error on the label of the cited registered product.

(1) If an error is discovered in the Directions for Use section 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. Upon the Agency's approval of the corrected label the registrant generally is provided with 18 months to sell or distribute existing stocks of the "old" label. 40 CFR 152.130(c). If there are risk issues associated with 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. If a Reregistration Eligibility Decision (RED) Document has been issued for the active ingredient in the product undergoing review, the reviewer must ensure that:

(1) all of the use sites on the label are in Appendix A of the RED;

(2) the site(s)/pest(s) are all eligible for Reregistration;

(3) if any one of the use sites is not in Appendix A, it may be a new use (see B.2. below) or an old use that (i) has been subsequently modified by the RED or deleted from labels as a risk mitigation measure or (ii) was not supported in reregistration. Products whose labels contain such uses may not be reregistered;

(4) if any of the uses have been declared ineligible for reregistration, the use may not be reregistered; and,

(5) if a favorable Reregistration Eligibility Decision document could not be made for any of the uses due to a lack of adequate relevant data, the product labels may be accepted as amendments to the registration if they are otherwise in compliance with the terms of the RED document.

Further, if the product contains more than one active ingredient, <u>all uses</u> on the label must be acceptable for <u>all</u> of the active ingredients. For example, an ethyl parathion/methyl parathion product may only be used on the nine crops registered for ethyl parathion applications, even though methyl parathion is registered for use on additional crops. 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.

2. **Non Me-Too Applications**. When a registrants's application is not for a me-too product such as when a registrant proposes a new use, new application rate, preharvest interval (PHI) change, or a other action not previously approved by the Agency, a more extensive review than the simple me-too 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..

C. ANALYSIS OF DIRECTIONS FOR USE. Once the type of review has been determined for the submitted action, the label reviewer may proceed with an actual analysis of the Directions for Use section. 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 necessary because:

- some labels may be very old,
- previously accepted uses and language may no longer be recommended based on Agency guidance such as PR Notices
- some changes may be unannounced.

Therefore, it is critical that the entire Directions for Use section be reviewed very carefully before accepting the label.

D. KEY QUESTIONS TO BE ANSWERED WHEN REVIEWING THE DIRECTIONS FOR USE SECTION.

The questions contained in the *Label Reviewer's Checklist* (Section IX of this chapter) should be addressed when reviewing the Directions for Use section of the label. When answering these questions the reviewer should refer, as appropriate, to:

- labels of substantially similar products for me-too applications,
- to the RED (if there is one),
- to the Registration Standard (if there is one not superseded by a RED), and
- for new or revised uses, to any science/technical reviews, or the efficacy reviewer.
- Current PR Notices must also be considered when using the Checklist. In addition, the CFR 40, Part 180 should be consulted for published tolerances, or use the Tolerance Index System (TIS) on the LAN.

The "Directions for Use" section can become very complex depending on the sites and pests claimed. Individual Branches may have their own perspective on specific aspects of the "Directions For Use" section. PM/team leaders, efficacy reviewer and fellow reviewers are the best sources of such specific information to understand the contours of 40 CFR 156.10 and general policy statements.

III. CONTENT

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)(c)(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)."

In order not to confuse the user, products meant for manufacturing processes cannot also have directions for use as an end use product, as the regulations states that manufacturing use products must not get into the hands of the public except after incorporation into divided products. Note, in some cases an MP may be labeled for specific end uses as well as for manufacturing uses; generally, such products tend to be industrial-use products which may either be reformulated into EPs or incorporated into various materials to produce treated articles (e.g.,wood preservatives, in-can paint preservatives, etc). EPs may be used as an active ingredient source for other EP's, but the label for such a source product may not include directions for its use as a MP and the label must bear the same sites as the EP formulated from it. Pesticide products used for manufacturing products which are not required to be registered (treated articles or substances, etc.) are considered to be end-use products. Labels for such source products must bear complete Directions for Use sections.

B. 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 classed 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).

C. 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, [see 40 CFR 156.10(i)] and as long as the reviewer has determined that it is not necessary for such directions to appear on the container label and the label bears such as "See directions for use on enclosed brochure."

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 EP is the regulations.

For typical end-use products, the Directions for Use section will cover the following subsets of information:

- standard requirements, such as the misuse statement, Worker Protection Standard boxes, etc.
- lists of target pests for which control is claimed;
- lists of permitted use sites;
- restrictions and other limitations on use;
- general information about the product and its use
- specific application instructions
- "Storage and Disposal" instructions

IV. STANDARD REQUIREMENTS

Special Reminder to Reviewers

Not only should the Directions for Use section provide basic application information, its contents must also make sense. Any applicator, and especially the general consumer, who is a nontechnical and occasional applicator, should be able to easily understand and be expected to follow the directions for use.

A. 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 in FIFRA or the applicable regulations. These elements should always be presented on the label, in the following order:

- "Directions For Use Heading"
- Use Classification Statement
- Misuse and Related Statements
- Worker Protection Standard (WPS) Requirements (if applicable)

B. 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.

C. USE CLASSIFICATION STATEMENT

D. MISUSE STATEMENT. 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."

1. Other statements relating to misuse, such as the following, are acceptable for residential/ household use products, and can be used in <u>addition</u> to and following the 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."

2. The general misuse statement to be used for experimental Use permits (EUPs), read as follows:

"For Experimental Use Only" (40 CFR 172.6(a)(1)).

E. WORKER PROTECTION STANDARD. 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. 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.

V. APPLICATION INFORMATION

A. CONTENT. 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 subsets of the sites and pests combination 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 indicate 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.

B. 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). PR Notice 87-1 states that subject labels (as specified above) must either include

the statement, "Do not apply this product through any type of irrigation system" or include labeling statements regarding chemigation contained in PR Notice 87-1.

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.

C. SPRAY DRIFT LABELING. As this edition of the Label Review Manual is being issued, revisions to label language for Spray Drift are under way.

VI. GUIDANCE FOR WORDING APPLICATION INFORMATION. What goes in this subsection will vary considerably according to the type of pesticide product and the intended user.

A. 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.

1. 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:

"This product may only be used by veterinarians/physicians." 40 CFR 156.10(i)(1)(iii)(B).

2. 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 for marketing purposes, however, neither FIFRA nor the applicable regulations provide for labeling statements such as for "professional 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. Such statements are also not likely to be enforceable under FIFRA.

Note: The Agency can designate pesticides for "restricted use" if the Agency determines that the product may cause unreasonable adverse effects without additional regulatory restrictions. See FIFRA 3(d), see also 40 CFR Part 152 Subpart I. In that case, a restricted use product can only be used by a certified applicator. (The regulations at 40 CFR Part 171 set out the requirements for certification of applicators.)

3. If the product is a termiticide, 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 pesticide products. A State may have more restrictive requirements regarding qualifications of persons using this product. To find out how to legally use this product in your State, consult with your State's Pest Control regulatory agency."

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

B. THE PESTS BEING CLAIMED. The term pest is defined by statue 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. 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.

1. **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.

2. **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.

3. **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.

4. **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.

C. WHERE THE PRODUCT IS USED. 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 which presents specific application directions.

1. **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.

2. **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, kitchens, etc. 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".

3. **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.

4. **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.

5. **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.

D. USE-RELATED INFORMATION. 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.

1. **Liquid Spray Instructions**. Labels for liquid formulations generally refer to "spraying" the product as the method of application. Labels which 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:

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 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 general use patterns on the label.

2. **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.

3. **Aerial Applications**. For aerial applications, spray volumes **must** be stated.

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

E. 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 by 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").

1. **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 also must 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.

2. **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.

3. **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.

F. USE RESTRICTIONS. General, or 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 also may 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...
- PHIs or Rotational Crop Restrictions (unless site-specific)

1. **Appropriateness of Precautions and Restrictions**.

a.. 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.

b. 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 other products," or other similar restrictions). Unless there is some risk based reason for such use restrictions, such statements are <u>not generally acceptable</u> on product labels

because they are false and/or misleading. Labels may prohibit use of the product on certain crop varieties.

When used in reference to the response of crops and weeds to the proposed pesticide product (e.g., a 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. **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, preferably with the general information:

> "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."

3. **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. EPA will NOT accept a label prohibition against the use of one product with another which is not necessary to protect human health or the environment. When compatibility with other pesticides or liquid fertilizers is being addressed, the label should include specific instructions or recommend a jar test.

VII. ADDITIONAL APPLICATION INFORMATION

This subsection of the Directions For Use may be given any of several headings, including "Application directions", "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 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., 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).

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. Additional information that may be included in these instructions, by site/crop and/or target pests, includes:

A. PREHARVEST INTERVAL (PHI). If required to meet the FIFRA standard, the PHI should be indicated as numbers of weeks or days. 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 the Special Directions Column. Preslaughter interval (PSI's) should be expressed similar to the PHIs.

B. NET CONTENTS AND APPLICATION RATE. The directions for use may 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.]

C. 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 maximim 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.

VIII. STORAGE AND DISPOSAL INSTRUCTIONS

Labels for pesticide products are required to bear labeling instructions for the storage and disposal of pesticides and pesticide containers. 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. Also, please refer to PR Notice 2001-6 for further guidance.

APPENDIX A - LABEL REVIEWER'S CHECKLIST

1. Does the label have the correct heading "Directions for Use"? Is the heading given sufficient prominence so that it is clear to the reader that the entire intended "Directions for Use" section falls under it?
2. Does the product have the required Misuse Statement? If the product has additional misuse statements are they acceptable?
3. 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?
4. Is the product subject to the 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?
5. Is there appropriate Storage and Disposal information on the label?
6. Should there be a General Instructions and Information sub-heading and section on the label?
7. 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?
8. Does the label contain adequate spray drift labeling?
9. Should there be a Use Restrictions sub-heading and section?
10. Are the sites and pests identified? Are they identified consistently throughout the entire label?
11. Is the formulation acceptable for this site/pest combination?
12. If a RED has been issued, is the site eligible for Reregistration?
13. Is all equipment (e.g. for mixing, loading or application) identified/specified and is the equipment practical for the user?
14. Are adequate preparation and handling instructions included?
15. Is the timing of the applications appropriate?
16. Are all methods of application appropriate?
17. Are General Precautions and Restrictions clearly presented as a group? Should they be?
18. Are the application rates indicated? Are they appropriate and calculated correctly? Do they deviate from a standard use pattern?
19. Are there appropriate tolerances or exemptions from tolerance to cover all food uses?
20. Is the Pre-harvest Interval or Pre-slaughter Interval correct?
21. Is the application frequency acceptable?
22. Is the rate of application consistent with the packaging of the product?
23. Are site specific precautions and restrictions clearly listed with each site/pest combination?
24. If the product contains more than one active ingredient, are all the uses acceptable for all the active ingredients?
25. Is there any unclear or ambiguous or contradictory language on the label?
26. 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?
27. Has the appropriate RED(s) been checked for any required labeling?
28. Are there any PR Notices that provide useful guidance?
29. Are label statements worded appropriately as mandatory or advisory?
30. Check 40 CFR 156.10 for further guidance.

Chapter 12 **LABELING CLAIMS**

I. INTRODUCTION

This chapter provides guidance for reviewing claims made on proposed labels. For purposes of this chapter there are three types of claims: 1) general claims, 2) claims associated with the product name, and 3) efficacy related claims. This chapter also provides guidance on Warranty and Disclaimer statements on labels and claims made in advertising.

II. GENERAL CLAIMS

A. Every pesticide must have labeling which is accepted by EPA before the pesticide can be sold or distributed. Labeling is defined in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 2(p)(2) as meaning labels and all other written, printed, or graphic material accompanying a pesticide or device at any time or to which reference is made on the label or in accompanying literature. As defined in FIFRA Section 2(q)(1)(A), a pesticide is misbranded if its labeling bears any statement, design or graphic representation which is false or misleading. FIFRA Section 12(a)(1)(E) provides that it is unlawful for any person to distribute or sell any pesticide which is misbranded. EPA's regulation, at 40 CFR 156.10(a)(5), provides examples of statements that are considered to be misbranded; such as:

1. A false or misleading statement concerning the composition of the product;

2. A false or misleading statement concerning the effectiveness of the product as a pesticide or device (EPA may review and approve or disapprove non-pesticidal claims appearing on a pesticide label);

3. A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

4. A false or misleading comparison with other pesticides or devices;

5. Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by an agency of the Federal Government;

6. The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

7. A true statement used in such a way to give a false or misleading impression to the purchaser;

8. Label disclaimers or warranty statements which negate or detract from labeling statements required under FIFRA and EPA's regulations;

9. Safety claims of the pesticide, or its ingredients, including statements such as "trusted," "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed."

10. Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

    a. "Contains all natural ingredients"
    b. "Among the least toxic chemicals known"
    c. "Pollution approved"

B. For certain aquatic use products, claims to reduce sludge and unpleasant odors in water or to clean, clarify or deodorize ponds and lakes are not considered pesticidal claims; nor are claims regarding the reduction of nutrients and organic matter in water, provided no claim is directly made or implied that the reductions will result in reduced pest populations. The claims "Reduces critical nutrients for cleaner, clearer ponds", "Ponds with algae need to reduce nutrients", and "Bacterial Product to Control Excess Nutrients for Clear, Clean Ponds" imply pesticidal use and therefore require registration.

C. Slime and odor control agents and other products expressly claiming control of microorganisms of economic or aesthetic significance are **not** considered to be public health related, but should bear accurate pesticide labeling claims. Registrants are still responsible for ensuring that these products perform as intended by developing efficacy data which must be kept on file by the registrant.

D. EPA's policy does <u>not</u> permit the use of the terms "natural", or "naturally" in the labeling of any products, including biopesticide products, both microbials and biochemicals. These terms cannot be well defined, and may possibly be misconstrued by consumers as a safety claim.

E. If a label reviewer is in doubt as to whether a claim or statement is false or misleading, he or she should consult their divisions "Ombudsperson", or "OGC" before allowing the claim. PR Notices 98-10 and 93-6 also provide guidance on claims, however, the statute and applicable regulation control.

III. SOME EXAMPLES OF <u>UNACCEPTABLE</u> CLAIMS

A. Statements that imply or suggest that the product can or will prevent or control disease or offer health protection.

B. "Commercial Line," "Commercial Size," "Institutional Size," "Garden Center Size": The use of these terms for products clearly intended for consumer household use is misleading.

C. "Kills Numerous Insects," "Kills Many Insects," "Kills All Insects": These claims imply a greater range of effectiveness than labeled. If however, these claims are limited to those pests

listed on the label, i.e., "Kills many insects as listed below (or as listed on the label)," it may be acceptable.

D. Claims about the Absence of an Ingredient: Statements or claims that express the absence of certain ingredients are misleading statements prohibited by 40 CFR 156.10 (a)(5)(i) and/or 40 CFR 156.10(a)(5)(viii). These claims are examples of a true statement used in such a way as to give a false and misleading impression to the purchaser. Even though a claim expressing the absence of an ingredient is true, it would generally be considered to be misleading because if it falsely suggests to the purchaser that the product is less risky, better, or more desirable than a product containing the ingredient in question. Further, a product must not claim that it does not contain an ingredient if it never contained the substance in the first place.

E. "Child Resistant Package" or Other CRP Related Claims: If a pesticide product requires child-resistant packaging (CRP), and has complied with the CRP regulations in 40 CFR 157 then the claim to that effect on the label is acceptable. Whether CRP is mandatory or voluntary the label may indicate the use of CRP and the proper use instructions for the CRP. However, in no circumstances may any safety claims beyond the statement "in CRP" be made due to the use of CRP.

F. Biodegradable: The term "biodegradable" is generally unacceptable for any pesticide product. Except the term may be used only in reference to the package or packaging and then only if the registrant certifies that the package breaks down and they provide information to support it. Otherwise "biodegradable" may not be used on a pesticide label in any context.

G. Claims Such as "Prevents Infection," "Controls Infection", or "Prevents Cross Infection" or that the product will control or mitigate any disease, infection or pathological conditions constitute public health claims and are not acceptable.

H. The term "steri-" implies sterilant activity and is not acceptable as a product name or on a product label unless it is a sterilant.

I. Statements that imply indefinite or all encompassing protection against bacteria, fungi or algae such as "germ-free",or "algae-free" are not acceptable.

IV. PRODUCT NAMES

A. The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label. See 40 CFR 156.10(b). No name, brand, or trademark may appear on the label which is false or misleading, or has not been approved by the Administrator through registration, or that the Agency has been notified of a name via supplemental registration, as an additional name pursuant to 40 CFR 152.132, or by notification as allowed by PR Notice 98-10.

B. Product names cannot constitute false and misleading claims. Although a company has the discretion to name its product, the company is still governed by the false and misleading standard. An example of a misleading product name is, *"Fresh Squeezed Disinfectant."* The phrase "Fresh

Squeezed" in the name is misleading because it could convey that the product is meant to be consumed. The Agency plans to issue a draft PR Notice which articulates a clarified position concerning false or misleading product names. Until that notice is issued in final form, the following is the Agency's current guidance:

1. Product names, claims or statements that express or imply a higher level antimicrobial activity than demonstrated by testing are not acceptable.

2. General superlative terms such as "super," "superior," and "ultra" no longer need to be qualified by the term "brand" in a product name. However, this determination still does not allow terms or claims like those which clearly imply heightened efficacy (e.g., "hospital strength," "professional strength," etc.) (see PR Notice 93-6).

3. The Office of Pesticide Programs is under no obligation to ensure registrants use the correct trademark™ and copyright© symbols on labels. Registrants are encouraged to use the correct symbols.

4. If a product falls within the scope of the Worker Protection Standard and contains an organophosphate (i.e., an N-organophosphorus ester that inhibits cholinesterase) or an N-methyl carbamate (i.e., an N-methyl carbamic acid ester that inhibits cholinesterase), the label shall indicate the term directly under the Product Name or in the first aid statement. 40 CFR 156.206(c)(1).

C. The exact same name cannot be used for different products registered by any one registrant. The product name must be sufficiently different to clearly distinguish one product from another. However, a supplemental distributor may use the same product name as the parent product.

V. EFFICACY RELATED CLAIMS

A. Even though registrants/applicants must conduct efficacy studies, the Agency only routinely requires the submission of these studies for certain types of products. EPA reviews efficacy data (also referred to as product performance data) when a pesticide product bears a claim to control pest organisms that pose a threat to human health. Such pests include, but are not limited to, (a) microorganisms which are infectious to man in any area of the inanimate environment, (b) vertebrates (e.g., rodents, birds, bats, dogs, and skunks) that may directly or indirectly transmit diseases to or injure humans, and (c) insects that carry human diseases (e.g., mosquitoes, ticks, etc.). (40 CFR 158.640). EPA also requires submission of efficacy data to support claims for the control of termites. On a case-by-case basis, the Agency may require substantiation of an efficacy claim.

B. The following points should be kept in mind when reviewing labels bearing public health efficacy claims:

1. The terms "microbiocide", "microbicide", and "microbiostat" generally are not acceptable on a public health product. If used on a nonpublic health product, the claim must be qualified to indicate that the product does not provide public health protection.

2. The term “biocide” generally is unacceptable on a public health product because it implies that the product can kill all living organisms. It may be used on a non-public health product provided it is qualified by directions for use or other statements that make clear the types of organisms to be controlled.

3. True, non-misleading claims regarding the effectiveness of a product against target pests, e.g., "kills roaches," "controls target pests," and "kills pests on contact” are acceptable. However, such claims may not be exaggerated or used in a way that would make them misleading. EPA may require additional efficacy data to substantiate claims which go beyond mere control of claimed pests.

4. Terms which describe a specific level of efficacy and which are standard EPA-accepted claims such as "bacteriostatic," "sanitizer," "disinfectant" and "sterilant" are acceptable.

5. Implied claims (e.g., any statement, design, graphic representation or brand name) of heightened efficacy of a pesticide product by itself or as compared with another product or device are false and misleading. Examples of such claims include, but are not limited to: "professional strength," "extermination strength," "hospital strength," "industrial strength," "institutional strength," "super strength," "ultra strength," "maximum strength," "maximum efficacy," "extra strength," "double-strength," "triple-strength," "hospital grade," "high potency," and "high-powered" (Reference: PR Notice 93-6).

a. Terms which function only to define a use site and which are not themselves claims of heightened efficacy, provided that such terms are not used in a manner that is misleading, are acceptable. For example, "hospital use" may be acceptable as long as it doesn’t imply “hospital strength”, is not used in the product name and is not highlighted on the label to the exclusion of other acceptable use sites.

6. Words or phrases that imply a product possesses unique characteristics because of its composition are not acceptable. See 40 CFR 156.10(a)(5)(i). Examples of such terminology are, “unique formula,” or “strongest on the market.” The claim “new” may be used on the labeling of a product of new composition for a period of 6 months following approval of the labeling; however, the word “new” may not be a part of the product name of record.

7. Claims that are inconsistent with efficacy established by testing are unacceptable. For example, a claim of 30 second efficacy is not acceptable if testing and/or use directions require 2 minute contact time for efficacy.

8. Claims of efficacy based on an unsubstantiated, or improbable site/pest relationship are unacceptable. A claim for control of Legionnaire’s disease in cooling tower water is unacceptable.

C. INSTRUCTIONS TO LABEL REVIEWERS

1. Check with the efficacy reviewers if the label makes unusual claims, deviates from a standard use pattern, or if the formulation changes (minor formulation changes in an antimicrobial

product can alter the efficacy of the product; alternate formulations are not acceptable for rodenticides). Request a formal efficacy review for all claims which differ significantly from existing claims.

2. As mentioned earlier, do not allow any claim that would render the product misbranded under FIFRA and 40 CFR part 156.10(a)(5).

VI. WARRANTY AND DISCLAIMER STATEMENTS

A. Warranty and Disclaimer statements containing language intended to limit liability of the registrant or act as disclaimers or warranties for the product are generally covered by state law or may fall under the jurisdiction of the Federal Trade Commission. The Agency will evaluate these statements to assess to the extent that the statements impact FIFRA label standards or the Agency's implementing regulations. There are four types of label language associated with disclaimers, warranties and limitations of liability that the Agency has found to be unacceptable under statutory and regulatory standards. It is important to recognize that these statements must be assessed on a case by case basis. They are as follows:

1. Overly broad statements negating or detracting from the Directions for Use or other label language (including precautionary statements and directions for use). For instance, the warranty statement, that the product would not work would negate Direction for Use which explained how the product was to be used.

2. Label language asserting that the buyer has accepted the manufacturer's statement of his/her respective rights. (e.g., manufacturer states buyer's rights are extremely limited; "all of these conditions are beyond the control of registrant X"). Because these statements are almost always incomplete (in terms of fully explaining a buyer's rights in the jurisdiction (state) of purchaser and because they can mislead buyers into thinking that they have no legal remedy, they may constitute "misbranding" under FIFRA.

3. Overly broad language implying buyer has no legal right to recover damages from manufacturer (e.g., "all such risks shall be assumed by the buyer").

4. Because EUP labels must be used in strict accordance with the EUP program, the warranty on EUP labels may not disclaim control over use. As with No. 2 above, these statements can be considered to be misleading.

B. The reviewer should check the proposed label for warranty/disclaimer/liability language statements (like those above) which appear to negate or detract from Directions for Use or other language. The label reviewer should make sure that the disclaimer statement makes it clear that it is the **registrant's or manufacturer's** warranty disclaimer, by using such statements like "To the fullest extent permitted by law, the manufacturer shall not be liable..." or "It is the manufacturer's intention that...". This way it is clear that the language is coming from the registrant (and not EPA).

C. When a label reviewer is in doubt as to the acceptability of any warranty or disclaimer statement, the statement should be referred to the Office of General Counsel.

VII. CLAIMS MADE IN ADVERTISING

A. Advertising and collateral literature or verbal claims for the product must not substantially differ from any claims made on the label or labeling. See 40 CFR 12(a)(1)(B). In other words, if a claim is not on the label or substantially differs from what appears on the label (or any part of its distribution or sale which for example appears on a brochure), it cannot be made in advertising. Although OPP does not routinely review advertising in connection with the registration, the Agency may require advertising used in the marketing of the product to be submitted upon request and then reviewed it to see that it is in compliance with FIFRA section 12(a)(1)(B). If reviewers come across any advertising inconsistencies, refer them to the following address for further investigation:

Team Leader for Investigation Requests
Agriculture Branch
Agriculture and Ecosystems Division
Office of Compliance (2225A)

Chapter 13 **STORAGE AND DISPOSAL**

I. INTRODUCTION

Labels for pesticide products are required to bear instructions for the storage and disposal of pesticides and pesticide containers. 40 CFR 156.10(i)(2)(ix). Storage and disposal instructions cover the appropriate storage of the pesticide product; disposal of any unused pesticide product or any rinse liquids resulting from cleaning of pesticide application equipment; and the disposal of the pesticide container. See also PR Notice 2001-6.

II. STATEMENT LOCATION

The storage and disposal instructions must appear grouped together, preferably blocked, within the Directions for Use section, and under the subheading "Storage and Disposal" (See 40 CFR 156.10 (i)(2)(ix)). It is preferred that the storage and disposal instructions appear at the end of the Direction for Use section. This placement eliminates the break between the heading "Directions for Use" and the body of the use directions. Where the Directions for Use are contained in a label booklet, at a minimum, the container storage and disposal instructions should appear at the end of the Directions for Use on the container label. In addition, the disposal instructions should be included in any referral statement on the label, e.g., "Refer to booklet for directions for use, and storage and disposal instructions."

III. FORMAT

All products must bear the heading "STORAGE AND DISPOSAL ." The terms "residential," "household," "household-use," "homeowner," and "domestic use" are used interchangeably throughout this chapter and mean the same thing for purposes of this chapter. These instructions must be set apart and clearly distinguishable from other directions for use. 40 CFR 156.10(a)(2). Blocking these statements with a solid line (a box) is suggested as a means of increasing their prominence. For example:

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage . . .
Pesticide Disposal (old) or If partly filled (new) . . .
Container Disposal (old) or If empty (new) . . .

IV. TYPE SIZE REQUIREMENT

The heading "STORAGE AND DISPOSAL" must be set in type of the same sizes as required for the child hazard warning. See 40 CFR 156.10(i)(2)(ix) and the table in 156.60(h)(1)9iv).

V. DETERMINING STORAGE AND DISPOSAL LABELING

A. PESTICIDE STORAGE STATEMENTS. Review the information below to determine the appropriate document to use as the source of pesticide storage statements.

1. **Recent Registration Standard or Reregistration Eligibility Decision (RED) Document**. If a Registration Standard or RED Document exists, and is more recent than PR Notice 84-1 or PR Notice 84-5 (for fumigants only), refer to the Registration Standard or RED Document for recommended storage statements. If the Registration Standard or RED Document does not contain storage statements, use the general guidance contained in this section under A. 3. Storage Guidance (below) from PR Notice 83-3.

2. **No Registration Standard or No RED Document**. If there is no Registration Standard or RED Document, or if the Registration Standard or RED Document does not contain specific storage statements, review the documents below to determine the appropriate document to use as the source of guidance for the pesticide storage statements.

a. Statements for Specific Chemicals: PR Notice 84-1 and an errata sheet dated 4/12/84 contain specific storage statements for the active ingredients listed in Table 1 below:

TABLE 1: PESTICIDE STORAGE STATEMENTS

Active Ingredient	Pesticide Storage Statements
Aluminum phosphide	The following statement should be used in addition to the guidance in PR Notice 83-3: "Not for use or storage in or around inhabited areas."
Liquid Sodium hypochlorite, Liquid Calcium hypochlorite	"Store this product in a cool dry area, away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water. Product or rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer. Do not reuse empty container but place in trash collection. Do not contaminate food or feed by storage, disposal or cleaning of equipment."
Magnesium phosphide	The following statement should be used in addition to the guidance in PR Notice 83-3: "Store only in cool, dry, locked, and ventilated room. Protect from moisture, open flames or heat."
Solid Calcium hypochlorite	"Keep this product dry in a tightly closed container, when not in use. Store in a cool, dry, well ventilated area away from heat or open flame. In case of decomposition, isolate container (if possible) and flood area with large amounts of water to dissolve all materials before discarding this container. Do not reuse empty container but place in trash collection. Do not contaminate food or feed by storage or disposal, or cleaning of equipment."
Terrazole	All manufacturing use products should contain the statement, "This product is corrosive to steel and many other metals. Do not transport or store in unlined metal containers."
Zinc phosphide	The following statement must be used in addition to the guidance in PR Notice 83-3: "Store in a dry place. Do not store in or around the home."

b. Fumigants. Refer to PR Notice 84-5 for specific storage guidance for the following chemicals: methyl bromide; methyl bromide and 2% or less chloropicrin; aluminum and magnesium phosphide; chloropicrin; sodium cyanide; ethylene oxide; and sulfuryl fluoride. For all other fumigants, refer to number 3 below (Storage Guidance from PR Notice 83-3).

c. Storage Guidance from PR Notice 83-3. Review the general guidance on appropriate pesticide storage instructions from PR Notice 83-3 listed below to determine if the label under review is consistent with the guidance in PR Notice 83-3 Section I (A).

3. **All product labels are required to have appropriate storage instructions**. Specific storage instructions are not prescribed. Each registrant must develop storage instructions for each product considering, when applicable, the following factors:

a. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

b. Physical requirements of storage that might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage temperature, potential for breakage of glass, crushing or damage due to stacking, penetration by moisture, and ability to withstand shock or friction.

c. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

d. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

e. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

f. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. PESTICIDE PRODUCT DISPOSAL STATEMENTS. The label of each pesticide product is required to bear pesticide disposal statements.

1. **General Statement**. The Agency historically has required all products, except for residential/household use products, to bear the following statement for risk management purposes:

"Do not contaminate water, food, or feed by storage and disposal."

The Agency prefers that this statement appear immediately under the “Storage and Disposal” heading because it concerns both subjects; however, the statement can be placed elsewhere within the Storage and Disposal instructions.

2. **Other Pesticide Disposal Statements**. Review items a. and b. below to determine the appropriate guidance to follow for pesticide disposal statements.

a. Registration Standard or RED Document Issued after 2/12/86. If the label under review involves a chemical for which a Registration Standard or RED Document was issued after 2/12/86, refer to the Registration Standard or RED Document to determine if any specific pesticide disposal statements exist. If no specific guidance exists, refer to statements under number (2) below to determine the appropriate pesticide disposal statement.

b. If the label under review involves a chemical for which a Registration Standard or RED Document was issued before 2/12/86 or if there is no RED Document, consider the disposal statements in the guidance set out in PR Notice 83-3 and described below.

(1) Except those products intended solely for residential/household-use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes (see PR Notice 83-3 for list) or assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity should generally bear one of the following pesticide disposal statements:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance."

Alternatively, the disposal statement given for Furadan 3G and Furadan 4F in section C below can be used.

(2) The labels of all products, except those intended for household use, containing active or inert ingredients that are Toxic Hazardous Wastes (see Pr notice 83-3 for list) or meet any of the criteria in 40 CFR 261, Subpart C for a characteristic hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Alternatively, the disposal statement given for Furadan 3G and Furadan 4F in section C below can be used if the first sentence is changed to "Wastes associated with the pesticide are toxic hazardous wastes."

(3) Labels for all other products, except those intended for household use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility."

(4) PR Notice 2001-6 provides new disposal instructions for non-antimicrobial residential/household use products. The disposal statements specified in PR Notice 2001-6 for products in pressurized containers and in non-pressurized containers are:

a. For products in Pressurized Containers

Do Not Puncture or Incinerate!
If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or [toll free number which meets the criteria in paragraph II.E] for disposal instructions.

b. For products in Non-Pressurized containers

If empty: Do not reuse this container. Place in trash or offer for recycling if available.
If partly filled: Call your local solid waste agency or [toll free number which meets the criteria in paragraph II.E] for disposal instructions. Never place unused product down any indoor or outdoor drain.

Labels for antimicrobial household products may bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash," per guidance provided in PR Notice 84-1. These products are not covered by PR Notice 2001-6.

3. **Specific Pesticide Disposal Statements**.

Furadan 3G and Furadan 4F

"Wastes associated with the pesticide are acutely hazardous wastes. Excess pesticide, spray mixture or rinsate must be handled and disposed in accordance with local, state and federal regulations. If these materials cannot be used according to label instructions or cannot be returned and must be disposed, contact your State Environmental Control Agency or the Resource Conservation and Recovery Act (RCRA) Hazardous Waste representative at the nearest EPA Regional Office for disposal guidance."

C. CONTAINER DISPOSAL STATEMENTS.

1. All pesticide products, including household products, must bear container disposal statements that are specific for each type of container. For non-antimicrobial, residential/household-use products, PR Notice 2001-6 has replaced the earlier container-specific statements with revised ones (see paragraph 2.a.(1)) below. Registrants still have the option of using more specific recycling statements if they meet the Federal Trade Commission guidelines. Antimicrobial residential/household-use products may use the revised statements but are not required to use them.

PR Notice 94-2 allows registrants, at their discretion, to use alternate container disposal statements permitting the recycling of empty aerosol pesticide containers. The alternate statements must specify that containers be emptied through normal use and note that recycling centers for aerosol containers are not available in many areas. The alternate statements are in addition to the disposal instructions.

2. Review sections a. and b. below to determine the appropriate document to use as the source of the container disposal statements.

a. Residential/household-use Products. If the label under review involves a chemical for which a Registration Standard was issued after 2/12/86 or a RED has been issued, refer to the Registration Standard or RED to determine if specific container disposal statements are provided. If no specific labeling is provided or if no Registration Standard or RED exists, use one of the following container disposal statements:

(1) "Securely wrap original container in several layers of newspaper and discard in trash." (Reference PR Notice 84-1). Note that this statement has been replaced by a new instruction in PR Notice 2001-6 which states, for non-antimicrobial, pressurized containers, "Do Not Puncture or Incinerate! If empty: Place in trash or offer for recycling if available." and for non-antimicrobial, non-pressurized containers, "If empty: Do not reuse this container. Place in trash or offer for recycling if available." EPA will monitor for the new statements beginning October 1, 2003. Note for partly filled containers specific language see PR Notice 2001-6.

(2) For aerosol containers, "This container may be recycled in aerosol recycling centers. At present, there are only a few such centers in the country. Before offering for recycling, empty the can by using the product according to the label (DO NOT PUNCTURE!). If recycling option is not available, wrap the container in several layers of newspaper and discard in the trash." (Reference: PR Notice 94-2) The phrase "wrap the container in several layers of newspaper and" may be omitted from the instruction, per PRN 2001-6, so that it would read....option is "not available...discard in the trash."

Note: The older allowable statement in 2.a.(1) above is identical to the older statement required for the disposal of residential/household-use pesticides. Consequently, the same statement could serve as disposal instructions for the pesticide and the container.

b. All Other Products. If the label under review involves a chemical for which a Registration Standard or RED Document was issued after PR Notice 83-3 (issued 3/29/83), refer to the Registration Standard or RED Document to determine if specific container disposal statements are provided. If no specific labeling is provided or if no Registration Standard or RED Document exists, refer to Table 2 which provides the container disposal statements from PR Notice 83-3. These statements are still applicable to all non-residential/household use products and antimicrobial, residential/household use products.

c. Specific Container Disposal Language.

Furadan 3G

"Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. Then dispose of bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. Otherwise, the bag is an acute hazardous waste and must be disposed in accordance with local, state and federal regulations."

Furadan 4F

"Non-returnable Plastic or Metal containers: Triple rinse (or equivalent) and empty rinsate into application equipment. Then offer for recycling or reconditioning, or puncture and dispose in a sanitary landfill, or by other procedures approved by state and local authorities. If rinsate cannot be used, follow pesticide disposal instructions. If not triple rinsed, Furadan containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations. DO NOT cut or weld metal containers."

TABLE 2: DISPOSAL STATEMENTS

Container Type	Disposal Statements
Metal Containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of container in a sanitary landfill, or by other procedures approved by state and local authorities.
Paper and Plastic Bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass Containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber Drums with Liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.
Plastic Containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Compressed Gas Cylinders	Return empty cylinder for reuse (or similar wording).
Foil outer pouches of water soluble packets (WSP)	Dispose of the empty outer foil pouch in the trash, as long as WSP is unbroken.

Chapter 14 **IDENTIFICATION NUMBERS**

I. INTRODUCTION

The EPA Registration Number and the Establishment Number are required on all pesticide products. The purpose of an Identification Number is to provide a unique product number for regular registrations, distributor registrations, Special Local Needs registrations, and Experimental Use Permits.

II. EPA REGISTRATION NUMBER

A. PURPOSE AND FORM OF THE REGISTRATION NUMBER. The EPA Registration Number indicates which company holds the registration for the pesticide product, and in which sequence the product was submitted to EPA by the company. For example, the first product submission by a particular company will receive EPA file symbol -R which upon registration will become product number one; the second will be two; and so on. The reviewer should see the registration number preceded by the phrase, "EPA Registration No.", or "EPA Reg. No." This phrase will be followed by a company number then a dash (-), and then the product number.

B. ASSIGNMENT OF REGISTRATION NUMBER. Before a pesticide product is registered under the FIFRA Section 3, it is assigned an EPA File Symbol which is comprised of the company number followed by a series of letters representing the potential product number. Product numbers are assigned sequentially to each company. The letters are used to indicate that the product is not registered. The letters come from the word "REGULATION." Each letter represents a number starting with "1 (one)," and ending in "0 (zero)." Accordingly, R=1, E=2, G=3, U=4, L=5, A=6, T=7, I=8, O=9, and N= 0. Therefore, if 6767-EGN were registered, it would become EPA Registration Number 6767-230. "6767" is the number identifying the company holding the registration and "230" is the number identifying that specific product.

C. LOCATION OF THE REGISTRATION NUMBER. The Registration number has no required location on the label, but is usually found on the front or back panel of the product label, and near the registrant's name and address. The registration number must be set in type and style similar to and running parallel to other print on the section of the label where the registration number is located. (40 CFR 156.10 (e)).

III. SUPPLEMENTAL DISTRIBUTOR NUMBERS

A. FIFRA and the regulations permit distribution or sale of a registered product under a distributor's name and address (40 CFR 152.132). This is called "supplemental distribution." Although distributor labels are not submitted to EPA for review or stamped accepted, questions that concern them may arise from internal or external customers. The distributor label must be the same as that for the federally registered product (basic registration) except for: product name, name and address of distributor, distributor number, establishment number (final establishment at which the product was produced), and any claims (uses, for example) that are deleted from the label. No new

claims may be added. Distributors may not amend their product labels separately. Only the basic registrant can amend a product's registered label.

B. Subject to the exceptions above, this regulation was intended to ensure that labeling statements made for a distributor product are *identical* to those made for the EPA-reviewed and approved basic product labeling. The Agency will however, generally permit minor formatting differences, such as different label colors and backgrounds, type styles or label sizes, provided the text, prominence and location of labeling statements on the distributor product are identical to that of the basic product and that the distributor label meets all applicable regulatory requirements.

C. The company's name cannot be abbreviated on a distributor label unless it is complete enough to enable a reader to identify the company so that he/she may contact the company. Company names must be clearly understood by the reader, so, for instance, multiple company names that are confusing would not be allowed on distributor labels. The company name that appears on the distributor label must be the same as the company name on file with the Agency for the distributor's EPA company number and must agree with the company name on the supplemental registration form. If multiple addresses appear on the label, the initial address should correspond with the address that is in the EPA Company Name and Address File and on the supplemental registration form. *The label or container must show the "EPA Establishment Registration Number" of the final establishment at which the product was produced.*

D. Both a registrant's name and a distributor's name can appear on the label, but it has to be VERY clear who is doing what. For example, the preferred wording, "Distributed by..." (distributor) (see Chapter 15, Company Name and Address)

E. Distributor products must bear the EPA Registration Number of the basic product, followed by a dash [-], and then followed by the distributor's company number. For example, Company A has a registered product, Kill It Dead Herbicide, EPA Registration No. 262-598. Company A enters into a supplemental distribution agreement with Company B as a distributor. The Agency receives the necessary documentation substantiating this supplemental distributor arrangement and then assigns to Company B the Number 10007. The herbicide marketed by Company B (under their product name, Make It Brown Herbicide) must bear the EPA Registration No. 262-598-10007. An EPA Registration Number consisting of three sets of numbers partitioned by dashes can readily be identified as a distributor product. As discussed above, only Company A could amend this registered label.

IV. EPA ESTABLISHMENT NUMBER

A. The Establishment Number is assigned by EPA Regional Offices (domestic establishments) and the Office of Enforcement and Compliance Assurance (OECA) (foreign establishments). See 40 CFR 167. A facility that produces pesticides must have a company number before an EPA Establishment Number is assigned. The Establishment Number is not reviewed by the Product Management teams. The PM teams only responsibility is to ensure that the number is formatted correctly.

B. PURPOSE AND LOCATION OF ESTABLISHMENT NUMBER. The Establishment Number indicates the final establishment at which the product was produced. See 40 CFR 167.3 This number is preceded by the phrase, "EPA Est.," and may appear anywhere on the pesticide product label or the immediate container but it must appear on the outer container or wrapper of the product if the establishment registration number cannot be clearly read through the outer container or wrapper. 40 CFR 156.10(f). It often is grouped together with the EPA Registration Number but is not required to be. [Note: The Establishment Number may be changed by non-notification. See PR Notice 98-10.] Because the reviewer may never see the actual outside container of the product, the Establishment Number may not be shown on the draft product label submitted for review by the company.

C. STATE DESIGNATION. As a matter of Agency practice, letters such as MO, AZ, or PA appear after the producer's company number. These letters represent the state in which the product was produced.

1. Example: an establishment number may be written as EPA Est. (Company No.)-MO-1, which would indicate that the product was produced in the first establishment registered by that company in Missouri.

2. Example: If corporation XYZ's company number is 98989, and the last phase of pesticide production takes place at producing Establishment Number 002 in Hawaii, then the Establishment Number for this product would read EPA Est. 98989-HI-002.

D. MULTIPLE ESTABLISHMENT NUMBERS.

1. The Agency permits the use of multiple establishment numbers on products on a case-by-case basis provided that the registrants meet existing labeling requirements and follow the format for multiple establishment numbers. Note: A company must be in place first, then the establishment number may be set up to reflect both the state in which the establishment is registered and also, which number it is in the state itself.

2. If a producer lists multiple establishment numbers, the establishment number for the actual production site must be very obviously marked or highlighted, for example, with an arrow, a notch, a bullet, etc. For instance, a label may list three establishments in two states, all of which produce the product. One label can be used at all three establishments by marking the actual production site. Use of the word "last" implies that sequential changes are made to the product at various sites. If the product is changed as it moves from site to site, the label required would change at each site so only one establishment number would be needed for the product label at each site (assuming that it actually is a registered product at all sequential sites).

V. SPECIAL LOCAL NEED (SLN) REGISTRATION NUMBER

A. The Special Local Need registration number (SLN number) is also known as a FIFRA Section 24(c) Registration Number. These registrations are issued by the states to meet special local needs. (40 CFR Part162) The number is written as "EPA SLN No." followed by the two letter state designation, then the last two digits of the year of issuance, and finally a four digit number which is the consecutive number of registrations that the registering state has issued in that particular year.

1. For example: If the company ABC applied for a section 24(c) registration in the State of North Carolina and it was the 34th SLN registration accepted by North Carolina in the year 1995, then the 24(c) registration number would be EPA SLN No. NC950034.

B. The EPA 24(c) registration number is assigned by the state and entered on the Application for Notification of State Registration of a Pesticide To Meet a Special Local Need (EPA form 8570-25). In addition, if the 24(c) registration is an amendment to a federal section 3 registration, the EPA registration number of the federal product is also entered on the application form.

VI. EXPERIMENTAL USE PERMIT NUMBER

A. A person may apply for an Experimental Use Permit (EUP) under Section 5 of FIFRA to develop data on either a new product or a new use site for a future FIFRA Section 3 registration. EUP applications (EPA form 8570-17) are assigned file symbols, which are written as Company Number-EUP-File Symbol. The file symbol is translated to an EUP registration number once the EUP has been issued by the Agency and/or an associated temporary tolerance has been established. Note the application for a permit may be denied. Refer to page 14-1, item IIB for information on the translation of file symbols to registration numbers. (See 40 CFR 172.6 (a)(2))

B. For example: Company MNO, whose company number is 98979, applies for an EUP to collect data on the crop kale and no tolerance is yet established for kale. It is given a file symbol RLE until the EUP has been issued and the temporary tolerance has been established, if applicable. If this EUP application is issued, the file symbol 98979-EUP-RLE will become EUP Number 98979-EUP-152, indicating this is the 152nd permit for which this company has applied.

Chapter15 **COMPANY NAME AND ADDRESS**

I. INTRODUCTION

The company name and address of the registrant, the producer, or the person for whom the product was produced must appear on the pesticide product label See 156.10(c) . An unqualified name and address given on the label shall be considered as the name and address of the producer. For pesticide products distributed under a supplemental registration agreement (a.k.a. "distributor agreement"), the name and address on the supplementally registered or "distributor brand" pesticide product must be qualified by phrases such as "Manufactured for..." Distributed by..." or "Available exclusively from..." to indicate that the name shown is not the basic registrant of the pesticide product. (See Chapter 14, Distributor Numbers) The name and address must be displayed prominently and within the range of type size that is required for all label text. (See chapter 3). The company name and address may be placed anywhere on the label, but is preferred on the front panel.

II. TELEPHONE NUMBERS

The Agency encourages each registrant to include a company telephone number or toll-free hotline number along with its name and address. This number can be used by the pesticide product user to obtain additional product information. Registrants may also include the National Pesticide Information Center (NPIC) hotline number for emergency information on the pesticide product label. The NPIC number, alone or along with a company phone number, may be placed on the pesticide product label using the following statement:

> "For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378."

See PR Notice 97-4 for more information.

Note the National Pesticide Telecommunications Network (NPTN) is now called National Pesticide Information Center (NPIC).

III. FOREIGN REGISTRANTS

Applicants for pesticide registrations must provide a U.S. address for correspondence. 40 CFR 152.50. Generally a registrant not located in the United States will designate an agent who resides in the United States. See 40 CFR 152.50. All correspondence concerning the pesticide product or any subsequent registration actions will be mailed to the resident agent for the foreign registrant at the resident agent's U.S. address. Therefore, the resident agent's address is considered to be the U.S. address of record for the foreign registrant.

IV. NAME OF RECORD

In order to accurately track pesticide registrations the Agency must be able to link company names appearing on product labels with company names appearing on registration documents. Therefore, if a company changes its label to reflect that it is "a division of ", "a subsidiary of " or "doing business as" (DBA) another company, the Agency asks that the company also change its registration documents on record at the same time.

V. COMPANY NAME AND ADDRESS CHANGES

Registrants are required to inform the Agency when there are changes to its company's name or address. See 40 CFR 152.122. If a company changes its name or address, it must inform the Agency of the change by sending a letter to the Document Processing Desk (Distribution Code **COADR**), Office of Pesticide Programs, 7504C, U.S. Environmental Protection Agency, Ariel Rios Building 1200 Pennsylvania Ave. NW, Washington, D.C. 20460-0001. This allows the Agency to accurately track ownership of pesticide registrations, which is critical to agency oversight of pesticide products. In practice, the Agency allows a registrant to start using the new name as soon as EPA approves the change. A registrant may use the existing label with the old name label until the next label printing or for 18 months, whichever comes first. If the registrant is also a producer, the registrant must also inform the Office of Enforcement and Compliance Assurance (OECA) (for foreign Establishments) and the EPA Regional Office where the company headquarters is located (for domestic Establishments) of the change of address in order to meet its obligations under Section 7 of FIFRA and 40 CFR Part 167.

Chapter 16 **GRAPHICS & SYMBOLS ON LABELS**

I. INTRODUCTION

A. Graphics or symbols in addition to written text are permitted on pesticide product labels if they are accompanied by explanatory text, are clear in their meaning to the reader, do not obscure or crowd required label language, do not misbrand the product, and are not false and misleading. Symbols may not be used in place of required text. Refer to the sections below for guidance in determining whether graphics and symbols are acceptable or unacceptable based on applicable regulatory standards. Consultation with the PM/Team Leader and/or Branch Chief may be necessary. The regulations at 40 CFR 156.10(a)(5) provide examples of statements and representations that are false and misleading; see also FIFRA 2(q)(1)(A) which provides that a pesticide is misbranded if its labeling bears "false and misleading" designs or graphic representations.

II. ACCEPTABLE GRAPHICS & SYMBOLS

A. Acceptable graphics and symbols on product labels should serve to enhance the understanding of the accompanying text. Acceptable examples of graphics and symbols, which may be added by notification (see PR Notice 98-10 for the procedure), include the following. Note, however, that the label reviewer must carefully evaluate the graphics and symbols to determine that they meet statutory and regulatory requirements.

1. Diagrams of how to open product containers.

2. Graphics which display spray patterns of nozzles and/or application patterns.

3. Pictograms located near the precautionary labeling statements that illustrate the different exposure routes (oral, inhalation, and/or dermal) to pesticides.

4. Pictures consistent with the label text showing examples of places where the pesticide may be used, such as in a household or on a specific commercial site.

5. Child hazard drowning pictogram and labeling (a picture showing a bucket with a child turned upside down in the bucket negated with the universal nonverbal symbol for negation: a circle with a diagonal slash through it). The pictogram can not be accompanied by the word "WARNING", as it may be confused with the human hazard signal word for the pesticide product. To avoid such confusion the Agency recommends the registrants use the word "precaution"or "notice."

6. The "Mr. Yuk" symbol on the label and/or outer container of the pesticide product. The "Mr. Yuk"consist of a green frowning face with its tongue hanging out. This symbol may be used with the Skull & Crossbones when the product is a Toxicity Category I product used in or around the home or pool where children may be present.

7. Pictures illustrating appropriate protective gear.

8. Pictures illustrating proper pesticide use.

9. Kosher symbols.

10. Hazardous Materials Identification System/National Paint & Coatings Association/National Fire Protection Association (HMIS/NPCA and NFPA) ratings systems for hazard codes.

11. Use of a logo to indicate absence of chlorofluorocarbons (CFCs) in a pesticide product. The logo must consist of the universal nonverbal symbol for negation - a red circle with diagonal red slash through the circle - with

a. wording as discussed in PR Notice 92-2 immediately next to the logo; and,

b. text set in type size of at least 6 points (the minimum type size permitted by regulation).

III. UNACCEPTABLE GRAPHICS & SYMBOLS

A. If the draft label under review contains graphics or symbols that violate FIFRA e.g., 12(a)(1)(b) or the applicable regulations e.g., false and misleading in 156.10(a)(5), then the label reviewer must advise the registrant to remove these from the label. Examples have included the following:

1. A food or flower pictured on a label which bears no directions for use on that food or flower. For example, a picture of cherries may not appear on a label if the product is not registered for use on cherries, or a picture of roses may not appear on a label if the product is not registered for use on roses.

2. Pictures of people using a product without the required personal protective equipment. Pictures of users must be consistent with personal protective equipment (PPE) requirements on the label. For example, if the label requires that the applicator wear full chemical-resistant coveralls with goggles, the label illustration cannot show a person wearing shorts and no protective eyewear.

3. Pictures of a pest not claimed to be controlled by the product.

4. Pictures that depict the fragrance of the product.

5. Pictures depicting food or food contact utensils even if food handling area treatments are allowed on the label. Food items and food contact utensils are usually covered or removed before the pesticide is applied.

6. Pictures of persons applying pesticides in areas accessible to children, pets, and other nontarget organisms when such products may only be applied in areas inaccessible to children.

7. Pictures of children unless the product is registered for use on children or the product is registered for use in swimming pools.

8. Pictures of candy. Similarly, containers that look like food or candy are prohibited.

9. Symbols implying safety or nontoxicity, such as a Red Cross or a medical seal of approval (caduceus) .

10. Pictures of residential use sites when the label limits use of the product to commercial or industrial sites.

11. The Mobius Loop (a recycling symbol in the shape of three chasing arrows forming a triangle) or any other symbol on the printed label implying that the **product** could be recycled when in fact it cannot be. If the packaging can be recycled, then it is appropriate for a recycling symbol to be shown in an inconspicuous location on the **container or package** with the word "package" printed near the Loop.

12. The EPA logo or any other Agency logo which implies endorsement by a government agency, such as the Circle and Statement "In Compliance With WPS."

13. Symbols which contain the words "Slow Release Nitrogen" and "Organic" are not permitted if the prominence of the symbol, large type size of the word "organic" and its position relative to the words "Slow Release Nitrogen" make it unclear whether the word "organic" refers to the fertilizer component or to the entire product.

IV. OTHER GRAPHICS AND SYMBOLS WHICH ARE ACCEPTABLE

A. The following graphics and symbols are considered acceptable and may be ignored during, and are not part of, the label review.

1. The "Good Housekeeping Seal of Approval" is a limited warranty to consumers and promises to refund the purchase price or replace the product if defective. While the Agency allows this symbol to be placed on products, the agency does not endorse the warranty message provided by this symbol.

2. Department of Transportation symbols indicating the hazard and flammability of a particular pesticide product.

3. Bar codes which allow for easier scanning of prices in retail stores.

Chapter 17 **NET CONTENTS/NET WEIGHT STATEMENT**

I. INTRODUCTION

The Net Contents/Net Weight statement indicates how much pesticide product is in the container and must appear on the pesticide label pursuant to FIFRA 2(q)(C)(iii). Usually draft labels include the phrase "Net Weight:" or "Net Contents:" as a means of identifying where the statement will actually appear on the final printed label. The applicable regulation at 40 CFR 156.10(d) does not require the term/heading "Net Weight" or "Net Contents" to be stated on the label. Even so, the Agency strongly recommends that the terms "Net Weight" or "Net Contents" be placed on the label because it describes the amount of pesticide product in the container as opposed to the total weight of the pesticide product plus the weight of the container.

II. LOCATION OF NET CONTENTS/NET WEIGHT STATEMENT

There is no required location for the Net Contents/Net Weight statement. The preferred location is the bottom of the front panel below the company name and address. If the draft label under review shows the Net Contents/Net Weight statement in some other location, the reviewer should suggest that the statement be placed at the bottom of the front panel. The Net Contents/Net Weight should be exclusive of any wrappers or other materials. 40 CFR 156.1(d)(1).

III. TYPES OF PRODUCTS/MEASUREMENT

A. Check the draft label to determine if the Net Contents/Net Weight statement is expressed correctly. See 40 CFR 156.10(d)

1. **Dry Formulations** (includes solids or semisolids such as dusts, granulars, pelleted or tableted baits, wettable powders, microencapsulated product, impregnated materials). The net weight must be expressed as pounds or ounces.

2. **Liquid Formulations**. The net contents must be expressed in terms of liquid measure at 68 F(20 C): gallons, quarts, pints or fluid ounces.

3. **Pressurized Products (includes gases and aerosols).** The net contents must be expressed as pounds and ounces.

IV. EXPRESSION OF THE STATEMENT

Review the draft label to make sure that it meets the following requirements:

A. UNITS OF MEASURE. Conventional U.S. units of measurement are used on pesticide labels. Pesticide labels may also declare net contents in metric units (liters, kilograms, etc.), so long as U.S. units of measurement are declared. For example, "Net Contents: 1 gallon (3.785 liters)."

It is not acceptable to declare net contents ONLY in metric units. Directions for Use are treated the same way. For example, in addition to expressing the application rate(s) in the required U.S. units of pound per acre, the registrant may also elect to express the application in equivalent metric units: kilograms per hectare.

B. EXPRESSION OF NET CONTENTS. The Net Contents must be stated in terms of the largest suitable units. For example, for a package containing 26 ounces of pesticide product, the label must state: “Net Contents: 1 pound (lb.) 10 ounces” rather than “Net Contents: 26 ounces.”

C. CONSISTENCY WITH DIRECTIONS FOR USE. The Directions for Use on the label must not require a quantity of pesticide product that exceeds the Net Contents/Net Weight of the package. An example would be a granular product with the following label language: "Net Contents: 1 pound," that requires an application rate 5 lbs/acre. This problem often occurs with baits used to control rodents.

Chapter 18 **UNIQUE PRODUCT LABELING**

I. INTRODUCTION

Certain specialty products pose a challenge to meeting the regulatory labeling requirements. Package size, shape, and composition often dictate unorthodox approaches to attaching the necessary information. While many labeling provisions of 40 CFR 156.10 are mandatory, other provisions provide the flexibility necessary to address challenging specialty products. The following examples have been accepted by the Agency and may be used as models for new and novel products that may be developed in the future. Label reviewers must address each product on a case-by-case basis, and determine whether the labeling meets applicable legal requirements.

II. MULTI-PACKS/CO-PACKS

A. A REGISTERED PESTICIDE PACKAGED WITH A NON-PESTICIDE. A registered pesticide product, in one container, may be packaged with a non-pesticide component, such as an adjuvant, in a separate container (which is to be added to the pesticide during mixing). These two containers, combined in one package, may be sold as a single unit only if the adjuvant is referred to in the Directions for Use on the label.

1. The two containers are distributed and sold as a single retail unit, and together comprise the pesticide product. (See 40 CFR 152.3 and FIFRA 2(u) defining pesticide to include a "mixture of substances"). If the two components are bound together with a shrink-wrap sleeve or in a box, the full panel of the pesticidal component must be visible through the wrapping, or the label must be duplicated and attached to, or printed on, the outermost container.

2. The regulation at 40 CFR 152.3(t) states that the "pesticide product" includes the package intended to be distributed or sold. EPA has jurisdiction over the packaging and <u>labeling</u> of any "non-pesticide" which is part of the package. This means that the Agency reviews and accepts or disapproves of the non-pesticide that is packaged with the pesticide. The reviewer examines the non-pesticide labeling to determine whether it contains any language that conflicts with the pesticide label, but the reviewer does not actually stamp the non-pesticide label. An example of such a non-pesticide would be an activator (such as potassium permanganate) which accompanies a pesticide (sodium bromide). EPA reviews the labels for both products, but stamps only the accepted pesticide label, noting any problems or changes needed for the non-pesticide label.

B. TWO OR MORE PESTICIDES PACKAGED TOGETHER. Two or more pesticide products may be packaged in separate containers but sold together as a single unit and intended to be tank mixed just before application. [FIFRA 2(u)]

1. Each container must bear, or be accompanied by, full labeling, and the full labels of both containers must be visible. If the outermost packaging obscures any part of the labeling of the pesticides, the full labels must be duplicated and attached to the outermost container. [40 CFR 156.10(a)(4)(i)]

2. Policies regarding the labeling for multi-packs and co-packs are being clarified by the Agency. Registrants should contact the Registration Division for additional information before submitting registrations or amendments that feature multi-packs or co-packs.

III. SMALL CONTAINERS

A. Some containers are too small to contain all required label text. In such cases, it is permissible to have text located on accompanying pamphlets which are considered labeling. The Agency historically required certain information to appear on the label of small containers: ingredient statement, signal word, skull and crossbones (when required), child hazard warning, EPA Registration Number and EPA Establishment Number, the phrase "RESTRICTED USE PESTICIDE" (if so classified), and a reference statement to any accompanying pamphlets. Outer boxes, bubble packs, accordion-pleated attached labels, and plastic self-sealing envelopes containing additional labeling have been accepted.

B. Whatever the approach, it is important to stress that ALL labeling must accompany the product at point of sale, and that the immediate container must bear a statement referring the user to the location of any additional labeling which is securely affixed to the container. All of this labeling must be reviewed and accepted. Registrants are encouraged to consult with the Agency about special labeling needs.

IV. SOLUBLE PACKETS

A. An increasingly popular means of packaging dry pesticides is the water-soluble packet. For some chemicals, EPA has required water-soluble packaging to reduce exposure of mixer-loaders to dust, vapor, or liquid pesticides. This method of packaging, however, presents problems in labeling. Since the immediate container is the film, a strict application of the regulations would require front panel text to be printed on the film itself. Although recent technological advances have made such printing possible, most standard printing techniques and inks are not compatible with the polyvinyl alcohol films. In order to accommodate this desirable method of packaging, the Agency has accepted other labeling approaches. See PR Notice 94-8 for complete information.

B. The most widely used packaging is a tear-open foil envelope containing each soluble packet; the foil envelope bears the required labeling. This foil envelope method has the added benefit of protecting the soluble packet from moisture which could cause shelf-life problems. Another acceptable method is a muffin-pan type of package where each packet is enclosed in a depression with a tear-off top that seals each chamber. The tear-off top bears the required labeling.

C. A vital consideration in dealing with soluble packets is how to reduce the likelihood of the user removing unlabeled packets from labeled containers long before use and then forgetting what they are. Because laundry detergents and dry bleaches are also manufactured in soluble packets, there is the possibility that pesticides could be mistaken as these products. The Agency believes that simply packaging a quantity of unlabeled soluble packets in an outer container where they could be easily separated from the accompanying labeling does not meet the FIFRA registration standard. EACH packet must either bear identifying labeling on the film itself (where feasible) or on

packaging immediately enclosing that packet. PR Notice 94-8 describes in more detail the concerns the Agency has with pesticide products containing water-soluble packaging (See Chapter 10 for reduced Personal Protective Equipment for water-soluble packaging products subject to the Worker Protection Standard.)

V. BULK CONTAINERS

Agricultural pesticides are often sold by dealers out of bulk tanks and pumped directly into spray rigs or truck-mounted tanks brought to the dealer by the farmer or applicator. This method of sale has the advantage of reducing the number of empty pesticide containers and the attendant disposal problems. In such cases, the dealer is obligated to deliver the full label to the purchaser at the time of sale. Such labels are supplied to the dealer by the registrant. Often registrants are using smaller containers in the field filled with products from these bulk containers which are called "Refillable Containers". The label reviewer must ensure that the label language does not preclude the reuse of the container.

VI. FOREIGN LANGUAGE LABELING

A. Foreign language text, in addition to the full English text, is permitted in part or its entirety on the product so long as it is a true and accurate translation of the English text. (See PR Notice 98-10) A registrant may provide bilingual labeling on any product without notification. However, if it is submitted, the Office of Pesticide Programs (OPP) currently does not review the translation for accuracy or stamp/approve it. If the foreign text is inaccurate or goes beyond the reviewed and accepted English labeling, the Office of Enforcement and Compliance Assurance may take enforcement action. Products marketed in Puerto Rico can be labeled in English only or in English and Spanish.

B. Some registrants have requested that they be allowed to translate just the signal word and the statement used on the labels of products falling under the scope of the Worker Protection Standard (WPS) in cases where they know that their product users are not fluent in English. This is allowed by OPP. In cases where they are translating into Spanish, the Spanish signal word for toxicity category I products is "PELIGRO" and for toxicity category II products is "AVISO." The statement that appears on toxicity category I and II WPS products is as follows:

> **"Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)"**

VII. PESTICIDES USED TO TREAT SEEDS

A. Pesticides bearing directions for seed treatment (as opposed to drill-box, planter-box, and slurry treatments done by the farmer immediately before planting) are required to have either a dye in the formulation unless there is a tolerance for residue of the pesticide. [40 CFR153.155(a).] Products intended and labeled for use only by commercial seed treaters need not have dyes if the

labeling clearly advises the user to add an EPA approved dye with the pesticide during the seed treatment process. [40 CFR 153.155(b)(1).]

B. Below are EPA policy statements regarding seed treatment label statements about the use of the treated seed for food, feed, or oil. See Criteria and Policy Notice 2170.1. For certain products, the Agency has found these statements to be required in light of incidents involving use of treated seed for food/feed purposes.

C. FOR COMMERCIAL SEED TREATMENT PRODUCTS

Treated seed must not be used for or mixed with food or animal feed, or processed for oil. Seed commercially treated with a pesticide must be labeled as follows: "Treated Seed. Do not use for food, feed or oil."

D. FOR HOPPER-BOX USE PRODUCTS, that is, if the product is intended for direct use on seed at planting time:

1. "Do not use treated seed for food or feed purposes or process for oil. Treat only those seeds needed for immediate use, minimizing the interval between treatment and planting. Do not store excess treated seeds beyond planting time."

2. Dye used to color the treated seed must be an EPA approved dye. Refer to 40 CFR 153.155(c).

3. For seed treatment products that may be under the scope of WPS depending on the type of treatment please add the following:

> "Seed treatment on agricultural establishment in hopper-box, planted box, or other seed-treatment application at or immediately before planting is within the scope of WPS, while commercial treatment of seeds is not within the scope."

VIII. CHILD-ATTRACTING PACKAGING ("ATTRACTIVE NUISANCE")

A. From time to time, registrants package pesticides in containers attractive to children. Bait-type pesticides for rodents and roaches have been marketed in little doll houses, fire trucks, and other toy-like dispensers or containers that look like food containers, e.g., a milk-carton shape. The Agency has not found these types of packages to be acceptable. It may be difficult for the reviewer to determine the package style when the final printed label is only a printer's proof and is not usually given a final review. However, certain types of products amenable to such unacceptable packaging should be checked and if any doubt or suspicion arises, the applicant should be required to submit the intended packaging before the product is registered. The Agency can require child-resistant packaging when the toxicity criteria and use criteria are met. See 40 CFR 157.22.

IX. SECONDARY CONTAINERS

A. There are limited cases (e.g., custom blenders at 40 CFR 167.3) where users of concentrated products dilute and then use/store the product in a separate unmarked container (secondary container). Although the Agency does not require labels on secondary containers, it will allow registrants to provide labels to users for secondary containers that are used to apply or temporarily store end-use pesticides as long as the labels that accompany the secondary container are "not inconsistent" with the EPA approved label and the label includes the following information:

1. Product name;
2. EPA registration number;
3. Name and percentage of active ingredient, followed by the phrase *"The product in this container is diluted as directed on the pesticide product label."*
4. Signal word and precautionary statements from the registered label unless the registrant has acute toxicity data supporting a lesser precautionary statements for the diluted product; and
5. The statement: *"Follow the directions for use on the pesticide label when applying this product."*

(Note to reviewer : There are also secondary containers which are not diluted, but are filled from a large container to be used/stored in the field. These may need less or additional label information. Contact your product manager or the for guidance.)

B. "Not inconsistent" means that the registrant has met the above conditions and that the secondary labeling has no other statements which directly conflict with the approved pesticide label.

C. Registrants are not required to submit secondary labels for review by the Agency; however, if the secondary label is inconsistent with the EPA approved label, the Agency will consider the product misbranded. This guidance does not apply to hand-held containers used by structural pest control operators.

X. CHILD-RESISTANT PACKAGING

A. Child-Resistant Packaging (CRP) is defined as packaging that is designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a harmful amount of the substance contained therein in a reasonable time and that it not be difficult for normal adults to use properly. See 40 CFR 157.21(b)

B. If the pesticide is subject to CRP regulations the registrant must certify (40 CFR 157.34) to the Agency that the pesticide as packaged meets the standards set forth in the regulations (40 CFR 157.32). These standards are Child-Resistant Effectiveness (85% before demonstration, 80% after demonstration, 42-51 months of age), Senior Adult-Use Effectiveness (90% 50-70 yrs old), product packaging compatibility, and product-packaging durability (for its lifetime the product as packaged must continue to meet the effectiveness and compatibility standards). An example of the proper

CRP certification language is found in PR Notice 96-2. Additionally, a registrant must maintain adequate records to substantiate the CRP certification for the life of the pesticide registration. The Agency has exempted some products from CRP (i.e., prefilled, nonrefillable ant and roach insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact). This exemption set out in the Federal Register is discussed in PR Notice 97-9.

C. Any changes in CRP will require an amendment of the pesticide registration (40 CFR 152.44) and a new CRP certification, including its **designation** using the American Society for Testing Materials (ASTM) standard D3475-95 "Standard Classification of Child-Resistant Packages," should accompany the amendment. Agency approval is required **before any packaging change can occur**. CRP changes are not notifications.

D. A pesticide product may be exempt from the CRP requirements if it is classified for restricted use, if a package is a large size as defined in (40 CFR 157.24 (a)(2)), if the pesticide is not toxic, or if an exemption is based on technical factors that preclude using the product. In the last two cases, the exemption must be approved by the Agency before the exemption can occur.

XI. ATTACHED LABEL BOOKLETS

OPP's preference is that the precautionary information be placed on the outside of the booklet and that, if necessary, the Directions for Use be placed on the inside. However, reviewers need to keep in mind what information would be left on the container if the booklet was detached, lost, or damaged.

Chapter 19

THE CONSUMER LABELING INITIATIVE AND PESTICIDE LABELS

I. BACKGROUND

Pesticide product labels contain valuable information including what the product is intended to control, how to use the product safely, how to dispose of it, and what to do in case of emergencies. However, for a variety of reasons, many people do not receive the full benefit of the information on the label. Potential reasons could be because some labels are too difficult to read, or because people assume they know how to use the product, or because they aren't aware of the types of information on the label. The Consumer Labeling Initiative addressed these issues.

A. WHAT IS THE CLI? In 1996, the Office of Prevention, Pesticides and Toxic Substances (OPPTS), in cooperation with pesticide registrants and other interested parties, began the Consumer Labeling Initiative (CLI). The CLI is a voluntary, cooperative partnership among federal, state, and local government agencies, industry, and other interested parties working to improve product labels on residential outdoor pesticides, indoor insecticides, and household hard surface cleaners in order to improve consumer understanding of the health and safety and environmental, information contained on household consumer product labels. The objectives of the CLI were to: 1) learn directly from consumers how to provide the label information they want and need; 2) make essential safety and appropriate use, environmental, and health information easier to find, read, understand, and use; 3) help consumers make informed product choices–based on their own needs and values; and, 4) help consumers use, store, and dispose of products safely.

B. CLI, PHASES I AND II. Phase I occurred in 1996 and consisted of three components: 1) qualitative consumer research, consisting of over 135 one-on-one interviews with people in five cities around the country; 2) a literature review of relevant studies and publications; and, 3) a review of the information and comments solicited by the March 1996 *Federal Register* notice that initiated the effort. Phase II began in early 1997 and encompassed the remaining research done under the CLI. It included quantitative and qualitative research with consumers, as well as several CLI workgroups, made up of several CLI participants each, which addressed complex topics not easily addressed by the quantitative research alone. The workgroups addressed how to present health and safety and ingredient information meaningfully; how to revise the disposal instructions so they are useful to everyone; and how to standardize messages on product labels (e.g., format, elements of the message).

C. QUANTITATIVE RESEARCH. The quantitative survey results were projectable to the entire population and the respondents were statistically representative of the United States; this means the survey data are considered to reliably represent the whole population. The survey, conducted in the Spring of 1998, had two parts: a phone survey to test people's ability to locate and understand specific information on labels; and, a written survey which collected information on how and when people read labels, what they read, what they understand, what they like and dislike about

labels, and what changes they would like to see made. The phone and written surveys were conducted for each of the three residential product categories: outdoor, indoor, and hard surface cleaner products.

D. QUALITATIVE RESEARCH. Unlike quantitative research, qualitative research results cannot be projected to a larger group. This type of research, done with interviews, focus groups, etc., is used to provide insights into what the participants think or feel. The Phase II qualitative research had two parts. There were interviews held in 1997 to determine consumer understanding of the first aid statements on labels. The information from those interviews led to revised statements which are clearer to consumers. The research also included 27 mini focus groups, with three to five people each, which were held in three cities. The purpose of the focus groups was to try to verify, learn more about, and test the information acquired from the written and phone surveys. CLI participants designed numerous sample labels incorporating a variety of language and layout changes based on the survey data. Focus group participants were asked to compare the various label revisions against each other and with a standard sample label, representative of current label designs, and explain their preferences to the moderator.

II. RESEARCH FINDINGS

A. Overall comprehension is high (except for ingredient names; environmental hazard information for outdoor uses; and some first aid information).

B. Consumers asked for clear, concise, easy-to-read information that connects consequences with actions. Consumers prefer directions to provide specific time references where appropriate. For example,"do not reapply for 1 week"; "do not re-enter treated area for 4 hours."

C. Label comprehension can be improved by using standardized formats; this increases ease of use and encourages more frequent label reading.

D. Consumers preferred important information be set off, boxed, highlighted, or somehow made to look different from the rest of the text.

E. Outdoor pesticide users read labels more often and more completely than do indoor insecticide users who in turn read labels more completely than household cleaner users. This often seems to be related to the reader's familiarity with the product, and or how complex the product is to use.

F. For the three product categories, the *label information read in the store and before use* include: brand name, directions for use, a description of what the product does, a description of where not to use the product, and precautions concerning the effects on personal health/kids.

G. For the three product categories, respondents indicated that the following information is *important, and they would like to locate it easily*: 1) Directions for use; 2) Description of what the product does; 3) Description where not to use the product; 4) Precaution concerning the effect on personal health/kids; and 5) Emergency information.

H. The information respondents found *most difficult to locate* is as follows:

For all three product categories	-	where the product should not be used.
For outdoor	-	first aid information and precautions for pets and the environmental effects for wildlife.
For indoor	-	precautions on personal health.

I. In all three product categories, consumers always indicated that the *least important* of the current label information are the environmental claims (e.g., contains no CFCs, contains no phosphates), and the name of the manufacturer. In all three product categories, consumers ranked disposal, storage, ingredients, and a phone number as a grouping of the next least important label information to them.

J. In all three product categories, given a description of different formats, consumers preferred a box format on the label, like the nutrition facts box that presents information consistently among products in the category.

K. The most frequent reasons given for not reading storage and disposal information in the store was that it is "information they already know," followed by "just don't read it."

L. Besides the packaging, respondents identified the *top sources* to which they refer for product information to be:

Indoor insecticides -	store displays, TV ads, friends/family/co-workers, product brochures, and magazine ads.
Outdoor pesticides -	store displays, product brochures, friends/family/co-workers, store salespersons, and TV ads.
Household cleaners -	TV ads, friends/family/co-workers, store displays, magazine ads, product brochures.

M. Consumers don't understand the real purpose of the signal word (Danger, Warning, Caution) that appears on every product and conveys the level of hazard of the product. All three words do convey some level of concern to readers, but most readers thought the manufacturer chose whatever word they wanted, they didn't realize the words are assigned based on science.

N. Less than half of consumers look for ingredient information; only 3% of consumers voiced a need for a complete listing of ingredients. When presented with a variety of ingredient statement formats, options listing functional categories of the ingredients and their purpose were preferred.

III. MAJOR RECOMMENDATIONS FROM CLI

The CLI participants used the findings from the data to develop a set of recommendations for label changes and label education. The major recommendations addressed three categories: label changes; educational activities; and the workgroup issues. All the recommendations were approved by EPA. Some recommendations have already been incorporated into the Label Review Manual, as well as other Pesticide Registration Notices. Note: Other recommendations remain to be implemented.

A. LABEL CHANGES. The major label recommendations follow.

1. Recommended the use of more bulleted text rather than long narrative formats; the use of simpler, less technical language; the inclusion of more white space; the use of more tables and graphics as appropriate; and, where a recognizable sequence of events occurs, that the steps be numbered.

2. Recommended that manufacturers be allowed more flexibility regarding the content and location of the ingredient statement;

3. Recommended the addition of short phrases describing just the major hazards under the signal word on the front label.

4. Recommended that the Federal misuse statement be revised to something simpler and easier to understand. The statement currently reads "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling."

5. Recommended that registrants be allowed to delete the signal word from Toxicity Category 4 products. EPA proposed this change in a 1999 Federal Register Notice concerning anti-microbial products. The change was finalized on December 14, 2001 in 66FR 64759-64768.

B. EDUCATIONAL CHANGES. The recommendation was made to encourage and continue the consumer education campaign. The education has been undertaken under the Read the Label First! campaign and the campaign is continuing.

C. WORKGROUP ISSUES. Additional work by OPP on the ingredients statement and storage and disposal issues was recommended. The completed work on disposal is reflected in PR Notice 2001-6, September 7, 2001. The work on the ingredients statement continues.

IV. FORMAT SUGGESTIONS BASED ON CLI RESEARCH

A. Labels should be presented so they are easy to read and understand by the user. The CLI research, as well as other label research done around the world, shows that in many cases, charts, graphs, symbols, or pictures can be used to help convey information. However, care needs to be taken that the graphics actually do convey the message intended.

B. Subheadings, like paragraph headings in a book, help to organize the information and also make it easier to find. The data also showed that 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.

C. Due to the variety in size and shapes of labels, not all the CLI 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.

D. The following is an example of a typical narrative format which has been used on labels in the past.

> **PRECAUTIONARY STATEMENTS**
> **HAZARDS TO HUMANS AND DOMESTIC ANIMALS**
> **DANGER**: Fatal if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear protective clothing and rubber gloves. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before use. Provide adequate ventilation of area being treated. Do not apply to humans, pets, plants or contaminate feed, foodstuffs, dishes or utensils. Cover and avoid spraying fish aquariums. Cover or remove exposed food, dishes, utensils and food handling equipment.

E. The following are some suggested formats, based on the CLI data and recommendations.

1. **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."

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION
- Harmful if swallowed or absorbed through the skin.
- Avoid breathing spray mist.
- Avoid contact with skin or clothing.
- Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco.
- Provide adequate ventilation of area being treated.
- Do not apply to humans, pets, plants, or contaminate feed, food stuffs, dishes or utensils.
- Cover and avoid spraying fish aquariums.
- Cover or remove exposed food, dishes, utensils and food handling equipment.

DIRECTIONS FOR USE

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

General Precautions/restrictions
- Use may damage marble surfaces.

Application Instructions
- Turn nozzle to "Spray" or "Stream."

For General 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 General Cleaning Directions.
2. Spray until thoroughly wet.
3. Let stand 10 minutes before wiping or rinsing.

2. **Modified Paragraph Format**. The modified paragraph format presents text in a series of full sentences, like the old standard narrative format, but includes subheadings, numbering, etc. to make it easier to locate information. If a paragraph format must be used, try to help your reader out by including either subheadings, or highlighting key words/phrases, etc. Also, the language should be simple and use correct grammar and punctuation.

Application Instructions:

BROCCOLI (PHI) : **Pests**; **Application Method(** Spray, Broadcast, etc.); **Dose** (amount per unit area); **Type of Equipment** (Sprayer, Aircraft, Spreader, etc.); **Timing** (e.g., Spring, Foliar, Pre-plant, Pre-plant Incorporated, etc.); **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, etc.). **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. Avoid over wetting asphalt tile, rubber and plastic materials. 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.

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3. **Tabular Format**. When using a tabular format make sure that all the appropriate information is included; that it is easy to follow; that types of information are clearly divided or discernible; etc.

FIRST AID	
If inhaled	•Move person to fresh air. •If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. •Call a poison control center or doctor for further treatment advice.
If on skin or clothing	•Take off contaminated clothing. •Rinse skin immediately with plenty of water for 15-20 minutes. •Call a poison control center or doctor for treatment advice.
If in eyes	•Hold eye open and rinse slowly and gently with water for 15-20 minutes. •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. •Call a poison control center or doctor for treatment advice.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip a glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

CROP	PHI	TARGET PESTS	RATE	SPECIAL DIRECTIONS
Broccoli For use only in California, Oregon, and Washington	Do not apply within 5 days of harvest	Aphids Flea beetles Leafhoppers Whiteflies	__ fl. oz in __ gal of water (diluent) by ground or ___ gal of water (diluent) by aircraft	**Method of Application** Spray, Broadcast, Chemigation, Ultra Low Volume, etc. **Equipment** Sprayer, Sprinkler Irrigation, Mist Sprayer, Spreader etc. **Timing** Foliar, Pre-plant, Post-plant, Post-harvest, Dormant, etc. **Application Interval** Can be __-__ days as needed or can be __-__ days or as needed. **Notes**: (applying to a specific pest)
		Armyworms Lygus bugs	Higher dosage than above with same amount of diluent	Same as above but with different timing, e.g., pre-plant incorporated including a different type of equipment, e.g., tiller
		Limitations: 1. Do not apply more than___ fl. oz. of Product per acre per application 2. No more than __ gallons per acre per season or year 3. Make no more than ___ applications per season or year. **Grazing Restrictions:** Can apply to Grazing, Harvesting of Hay or Green Forage. NOTES: Can give information on phytotoxicity, pest resistance, other general comments that apply to the site, etc.		