Label Review Manual

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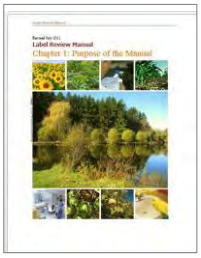

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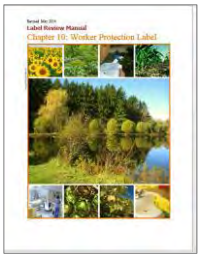

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Revised July 2011

Label Review Manual

Chapter 1: Purpose of the Manual

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I. Purpose

This Label Review Manual (LRM) serves as a training tool for the 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, and enforceable pesticide labels.

Pesticide product labels provide critical information about how to safely handle and legally apply pesticide products. Unlike most other types of product labels, pesticide labels are enforceable, and all of them carry the statement: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." In other words, the label is the law.

For EPA, a critical function of the label is to translate the results of the science evaluations into a set of conditions, directions and precautions that define who may use a pesticide, as well as where, how, how much and how often it may be used.

The label reviewer's work, therefore, affects individuals and companies that register their pesticide products; EPA, which uses the label to manage the potential risks pesticides may pose; state and federal agencies that enforce pesticide label requirements; educational programs that certify pesticide users; and, of course, pesticide users, who use the labels to make decisions that could affect human health and the environment.

It is important to note that the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and its 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 one and Pesticide Registration Notices ("PRN's") provide guidance on how the Agency interprets the applicable law.

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") when choosing appropriate label language for each product. The Agency considers this manual to be an instructional aid that does not establish new requirements, policies or guidance, but instead summarizes and cites current requirements, policies and guidance that are found in published regulations, publicly available documents or historically established practices. Finally, this manual is useful in understanding 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.

II. Approach

Information in the manual is roughly arranged in the order of use by reviewers. 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.

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 should not rely solely on a label-to-label comparison, but review a label based on applicable law and guidance.

III. Availability

The LRM is located on the Internet at: http://www2.epa.gov/pesticide-registration/label-review-manual A PDF is available on the Webpage for ease of printing.

IV. Maintenance/Update

For accurate maintenance of this manual, it is imperative that OPP staff bring to the attention of the Labeling Committee any document which affects generic labeling policy. If users at any time come across a document or create a document that establishes labeling policy or find any discrepancies, contact a representative on the Labeling Committee or visit *www.epa.gov/opp00001/regulating/labels/label_review.htm*

The Label Review Manual Team will update the existing Chapters of the LRM on an ongoing, as needs basis. Each Chapter will maintain its own "Current as of…" date. Therefore, the documents on the Webpage will always be the most up-to-date Chapters. OPP will announce when certain Chapters have been updated.

Revised April 2014

Label Review Manual

Chapter 2: What Is a Pesticide?

I. Introduction

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.

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.

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

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 that fall into this category.

A. 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. See *40 CFR 152.6(a)*. Excluded products are regulated by the Food and Drug Administration (FDA). Products excluded are those meeting all of the following criteria:

1. **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 from regulation under FIFRA. Ethylene oxide products are not liquid products and are therefore not excluded by this provision.

2. **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.

3. **Use site**

   - 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.
   - Liquid chemical sterilants that bear claims solely for use on non-critical medical devices are jointly regulated by EPA and FDA, and must be registered by EPA.
   - 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.
   - Liquid chemical sterilants intended to treat aseptic food packaging systems are also not excluded from FIFRA; these products are subject to registration by EPA as pesticides as well as approval by FDA as food additives.

B. 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 found in *40 CFR 152.6(b)*:

1. 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.

2. 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.

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

4. 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(b)(4) and (5)* 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.

C. Products Labeled Only for Use in or on Living Man or Animals

Products excluded are those meeting one of the following criteria:

1. Products intended for use for the control of fungi, bacteria, viruses, or other microorganisms in or on living humans or animals, and labeled accordingly. See *40 CFR 152.6(c) and (d)*. 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) 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*. See also *40 CFR 152.6(e)*. An animal feed containing an animal drug is subject to regulation by the FDA under the FFDCA.

2. Products intended for use for control of internal invertebrate parasites or nematodes in living humans or animals, and labeled accordingly. See *40 CFR 152.5(b)*.

D. Products Intended Only to Aid in the Growth of Desirable Plants

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)*), and in Section III. D. of this chapter. Plant nutrients are described below.

Examples of products that aid in the growth of desirable plants, types of which are found in *40 CFR 152.6(g)*, include:

1. **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.

2. **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.

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

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

5. **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. See *40 CFR 152.6(g)(2)*.

6. **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 *40 CFR 152.6(g)(3)*. 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 non-pesticidal uses as a foliar plant nutrient at low concentrations.

7. **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. See *40 CFR 152.6(g)(1)*.

E. Antimicrobial Products Used Solely in Processed Foods or Feeds, in Beverages, or in Pharmaceuticals

The Antimicrobial Regulation Technical Correction of 1998 (ARTCA) amended the Food Quality Protection Act (FQPA) to clarify the jurisdictions of EPA and FDA regarding food use antimicrobial pesticides. Following is a brief summary of ARTCA's jurisdictional clarifications. For further details, see FDA's July 1999 "Antimicrobial Food Additives Guidance Document" at *http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm077256.htm*.

The following activities constitute food processing and any food subjected to these activities becomes a "processed food" within the meaning of 40 CFR 152.5 (definition of a pest): canning, freezing, cooking, pasteurization, or homogenization, irradiation, milling, grinding, chopping, skinning, cutting or peeling. Processing also includes carcasses post-slaughter which includes skinning, eviscerating and quartering. These post-slaughter activities result in "processed food" within the meaning of 40 CFR 152.5. In addition, seafood that is harvested is processed food. Activities done post-harvest to seafood include handling, storing, preparing, heating, eviscerating, shucking or holding. Substances used in these processes against microbes in or on the processed food are not pesticides under FIFRA and are regulated solely by the FDA under the FFDCA.

The following post-harvest activities do not constitute food processing within the meaning of 40 CFR 152.5: washing, coloring, waxing, hydro-cooling, refrigeration, shelling of nuts, ginning of cotton, and the removal of leaves, stems and husks. These processes do not meet the definition of "processed food" and are not subject to the exclusions of 40 CFR 152.5. Therefore, pesticides used during the processes are FIFRA pesticides and are regulated by EPA under FIFRA.F. Products with No Pesticidal Claims 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.

   EPA has also posted guidance on its web page entitled, "Determining If a Cleaning Product is a Pesticide under FIFRA". This document provides details on what kinds of cleaning-related claims may be considered pesticidal versus non-pesticidal.

2. **Attractants.** Products that are intended only to attract pests for survey or detection purpose, that are labeled accordingly, and which contain no toxicants.

3. **Physical barrier.** 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?

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:

A. 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. *40 CFR 152.15(a)*.

B. 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. *40 CFR 152.15(b)*. 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.

C. 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. *40 CFR 152.15(c)*.

D. Plant Growth Regulators

A plant growth regulator, through physiological action, is intended to accelerate or retard growth, or alter plant behavior or the produce of the plant. Examples of claims that can be considered to be plant growth regulator claims include: increased blossom set, stimulation of root or plant growth, prevention of sucker growth, delayed onset of sprouting of harvested root crops, abscission stimulation of fruit crops, stimulates plant growth and fruiting, promotes fruit and seed development, increases stem and stalk strength, and increases fruit size. Whether a product is considered to be a plant growth regulator depends on whether the plant response or mode of action being claimed would go beyond what would be expected from simple nutrition. The composition of the product may aid in making the determination.

1. **Plant hormones and other compounds,** such as auxins, cytokinins, and gibberellins have no other uses except as plant growth regulators. Therefore, the presence of any of these types of compounds generally causes a product to be considered a plant growth regulator.

2. **A vitamin-hormone horticulture product** is not a plant growth regulator if the product is not intended for use on food crops and is labeled accordingly, and meets the other

criteria 40 CFR 152.6(f). Vitamin-hormone horticulture products containing auxins, cytokinins, and gibberellins are exempt from registration if these criteria are met.

IV. Pesticides exempted from the requirements of FIFRA

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 to have 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):

A. Pesticides Regulated By Another Federal Agency

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

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

   (b) Procaryotic microorganisms, including bacteria; and

   (c) Viruses.

B. Pesticide Not of a Character Requiring FIFRA Regulation

1. **Treated Articles or Substances.** The Agency has determined that an article or substance containing a pesticide to protect the article or substance itself does not require registration and is exempt from all provisions of FIFRA, provided the pesticide is registered for such use and bears appropriate directions for such use. Claims for the preserved article or substance are limited to the protection of the article or substance itself. See *40 CFR 152.25(a)* and *PR Notice 2000-1*. Examples include:

   (a) Paints that have been treated with antimicrobial pesticides and bear claims that the dried paint film will be resistant to mold or mildew. Paints with expressed or implied claims made for protection of the surface beneath the paint film or for preventing or destroying mold or mildew on the surface of the paint or beneath the paint are not within the treated articles exemption and, therefore, will require registration under FIFRA. 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, are regulated under FIFRA.

(b) 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 (all of which uses are intended to protect the treated articles themselves) are other examples of products that have been historically exempted from the requirements of FIFRA.

(c) Shirts and other articles of clothing treated with an insecticide to repel mosquitoes and other insect pests are examples of products treated with insecticides that require registration of the article of clothing. Because the treatment would be for the benefit of the wearer rather than to protect the clothing, the treated article exemption would not apply and the article of clothing would be subject to registration.

2. 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.

3. Preservatives for Biological Specimens

(a) Embalming Fluids. Mortuary supplies intended to prevent or mitigate mold and bacteria on or in human cadavers are exempt. *40 CFR 152.25 (c)(3)*. 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.

(b) Animal and animal organ preservatives. Products used to preserve animal or animal organ specimens in mortuaries, laboratories, hospitals, museums, and institutions of learning are exempt. *40 CFR 152.25(c)(2)*.

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

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

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

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

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

   (c) 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. *40 CFR 152.25(e)*.

5. **Minimum Risk Pesticides.** 40 CFR Section 152.25(f) (previously 40 CFR 152.25(g)) exempts certain "minimum risk pesticides" from the requirements of FIFRA if they satisfy all the conditions described in that provision (i.e., 152.25(f)(1)-(3)). Some of the conditions of exemption specifically relate to a product's labeling (see *152.25(f)(3)*). For further information, *PRN 2000-6:* "Minimum Risk Pesticides Exempted under FIFRA Section 25(b) Clarification of Issues". See also EPA's webpage for Minimum Risk Pesticides http://www.epa.gov/pesticides/biopesticides/regtools/25b_list.htm and the list of permissible inerts http://www.epa.gov/pesticides/biopesticides/regtools/25b/25b-inerts.htm

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" *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 number identifying the location where the device was produced. See *40 CFR 152.500* and Chapter 13 of EPA's Pesticide Registration Manual (*http://www2.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices*) for more information on devices and additional FIFRA requirements.

Equipment that generates a pesticide (e.g., a CO_2 or ozone generator) may or may not be considered a device. The reviewer should consult with the PM if there is any question about the product's status

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Label Review Manual

Chapter 3: General Labeling Requirements

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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. General labeling requirements can be found in *40 CFR 156.10*.

II. General information

A. Definition of "Label" and "Labeling"

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

1. **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."

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

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

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

B. 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. However, the following label information must be on the label which is on or "securely attached" to the container, subject to the exceptions in 40 CFR 156.10.

- 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 and Domestic Animals
- EPA Registration Number and EPA Establishment Number
- Storage and Disposal Statements

- Referral Statement to Directions for Use in booklet, if any
- Net weight or measure of contents

Other parts of the label may be placed in a booklet or other "pull off" type labeling. At a minimum, the booklet or "pull off" labeling should include the following:

- Name and address of the producer, registrant, or person for whom produced
- Restricted Use Statement (if required)
- Product Name, Brand or Trademark
- Signal Word, including Skull & Crossbones, if either are required
- "Keep Out Of Reach Of Children" (KOOROC)
- Precautionary Statements, including Hazards to Humans and Domestic Animals
- EPA Registration Number and EPA Establishment Number
- Directions for Use

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. In addition, all required label text must appear on a clear contrasting background and not be obscured or crowded. *40 CFR 156.10(a)(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. In addition, collateral labeling may not bear claims or representations that substantially differ from those accepted in connection with registration of the product. (*FIFRA 12(a)(1)(B)*) Collateral labeling must be submitted along with the application for registration and must be accepted by EPA before it can be distributed. However, official publications of federal and state agencies referenced on or accompanying a label or labeling are excepted by FIFRA Section 2(p)(2)(B) from the definition of label and labeling, and therefore should not be submitted for review.

D. Safety Data Sheets (formerly called Material Safety Data Sheets or MSDS's)

The Occupational Safety and Health Administration (OSHA), and not the Agency has direct authority over SDSs. However, when an SDS is distributed with a pesticide it becomes a part of the pesticide labeling because it is accompanying the product (*FIFRA 2(p)(2)(A)*). Because an SDS becomes part of the labeling, an SDS could render the pesticide misbranded if it includes warnings, precautions or any other information that conflict with the FIFRA-approved label. However, in 2012 OSHA adopted a revised Hazard Communication Rule for SDSs which utilizes the criteria for signal words adopted by multiple countries under the Globally Harmonized System (GHS) for hazard communication language and symbols. EPA has not adopted the GHS criteria, and thus an OSHA SDS may have a signal word that differs from the one EPA approved for a pesticide product label. PR Notice 2012-1 explains how a company can explain and

justify such a difference if it occurs. Note that although an SDS which accompanies a pesticide product is considered to be labeling, EPA required statements cannot be placed directly on the SDS instead of the label. For the purpose of labeling the Agency *does not review or approve* (stamp) SDSs. Also, under the terms of OSHA's rule, that agency has no jurisdiction to require that anything be placed on a pesticide product label.

E. Websites

If there is a reference to the company's website on the label, then the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on a product's label, claims made on the website may not substantially differ from those claims approved through the registration process.

F. Placement of Label

The label must appear on or be securely attached to the immediate container of the pesticide product. "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)(i)*) Also, if the immediate container is enclosed with a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is part of the package as customarily distributed or sold. Requirements for placement of labels and labeling on tank cars and other bulk containers during transport and storage are described in *40 CFR 156.10(a)(4)(ii)*.

G. Web-distributed Labeling

Registrants can opt to make legally valid pesticide labeling accessible online. Web-distributed labeling allows pesticide applicators to download streamlined labeling, including instructions specific to the state and use site where an application will be made. The actual labeling on the container will not be shortened in any way with the addition of distributed labeling. PR Notice 2014-1 includes information on what registrants need to submit and suggested label language statements for adding web-distributed labeling to a pesticide product.

III. Mandatory and advisory statements

Label and labeling statements need to be clearly stated in either a mandatory or advisory manner in order to avoid confusing label/labeling language that may lead to applicator misuse and/or adverse effects to human health and the environment, and to avoid making key label and labeling statements unenforceable. See *PR Notice 2000-5* for additional guidance on mandatory and advisory statements.

A. Mandatory Statements

Mandatory statements relate to the actions that are necessary to ensure the proper use of the pesticide and to prevent the occurrence of unreasonable adverse effects on the environment, which is defined 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 *necessary* 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.

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. Note that the preferred advisory statement usually explains the purpose or benefit of doing something, instead of just asserting that it should be done.

- Following are hypothetical advisory statements followed by examples of how they can be rewritten using descriptive terms, which is EPA's preference. The examples are paired. The first showing the problematic statement and the second showing the preferred statement in accordance with *PR Notice 2000-5*.

1. Precautionary Statements

Problematic Latex gloves are recommended.

Preferred *Latex gloves provide the best protection.*

2. Physical and Chemical Hazards

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

Preferred *Opening aluminum phosphide containers outdoors or indoors near an exhaust fan or other ventilation [helps to ensure/ensures] that the gas will be rapidly dispersed if the product flashes.*

3. Directions for Use

Mixing

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

Preferred *Applying the product immediately after preparation [helps to ensure/ensures] that it is in suspension. If application is delayed, agitation to re-mix the products and checking for resuspension ensures proper blending.*

Application

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

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

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

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

Problematic 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.

Preferred *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 [help to ensure/ensure] soil incorporation.*

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

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

Cleaning

Problematic 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.

Preferred *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 [help to ensure/ensure] a clean sprayer and trouble-free operation.*

IV. Types of labels and labeling

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

A. Master Label

The “Master Label” (reference label) is the label that contains all of the approved uses for a given product and all associated required labeling. All other labeling for a given product must not contain any text beyond that which is approved in the Master label. This label goes on file with the Agency once it is stamped “accepted”.

B. Sub-Label or Split-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 Master label, but is a complete label in 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. (*40 CFR. 152.130(b)*). Since Sub or Split labels only contain labeling text contained in the Master label, the Sub or Split labels are not stamped "accepted" separately. Final printed labeling must be submitted according to *40 CFR 156.10(a)(6)*. If these labels are intended to be distributed under a different product name, the Agency must approve the alternate brand name according to *40 CFR 156.10(b)(2)(ii)*.

Applicants if submitting a Sub-label or Split-label should clearly:

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

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

A new "Master Label" containing all the uses currently approved under the product's registration is required when a sub-label is submitted with additions not on the "accepted" Master label. Only the "Master Label" will be stamped "accepted". Note: the previously approved labeling may be distributed or sold for a period of 18 months after approval of the revision, according to *40 CFR 152.130(c)*.

C. Distributor Labeling

Distributor labels are labels for a product which is registered to one company, but distributed by another company (sometimes referred to as a "sub registrant"). A distributor label must be the same as that of the registered product except for product name, name and address, registration number (EPA Reg. No. xxxx-xx-xxxx, where the third set of numbers refers to the distributor's company number), and establishment number. Claims may be deleted but new claims cannot be added. (*40 CFR 152.132(d)(3)*). In addition, because warranty statements are not required by EPA to be on pesticide labels, the Agency will allow distributors to use their own warranty statements so long as such a change to the labeling is allowed by contract between the registrant and the distributor and the substitute warranty statement is not false or misleading. (Labeling Consistency Q&A LC08-136). Any revised warranty statement on a distributor's label cannot expand upon, either explicitly or

implicitly, the uses allowed on the basic registrant's label and cannot conflict with the claims stated on the label (*Id.*). A distributor warranty statement that differs from that of the registrant is a type of registration amendment that may be accomplished by notification from the registrant. The Agency must be notified before distribution by submission of a Notice of Supplemental Distribution (*Chapter 4*, Section II.A.). Distributor labels are not submitted to the Agency. The EPA basic registrant is responsible for both the content of the distributor product and the content of the distributor label. (Note that the term "supplemental distributor labeling" although used by some people, is not proper terminology because it does not appear in EPA regulations, and creates confusion with a true supplemental label as described in section IV.D. below. A true supplemental label is used to add new uses or directions, while distributor labels are prohibited from adding any uses or directions that differ from the basic registration).

D. Supplemental Labeling

"Supplemental labeling" is a term used by the Agency to describe labeling which includes newly approved uses, use directions, or other instructions which have been added since the last accepted Master label. These are partial labels distributed with the product by the registrant or distributors. Since these are partial labels, they must bear a statement referring the user to the product label for complete directions, precautions and a statement that 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.

The Section 3 supplemental labeling must be submitted and stamped "accepted" by the Agency. The Agency requires that these labels bear the following information:

- Misuse statement: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling".
- 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)

Normally, supplemental labeling will be incorporated into the Master label at the next printing of the product label (final printed label) or within 18 months, whichever comes first. However, there are circumstances when this might not be done, for example if the directions for use on the supplemental labeling are subject to continual, frequent change, e.g., California aerial application county restrictions can change every six months or so. Note that just like other labels, supplemental labels must be accepted prior to distribution.

Supplemental labeling is also used for state registration of special local needs (SLN) under *section 24(c) of FIFRA*. For labeling requirements for supplemental labeling for State registrations, refer to *40 CFR 162.153(e)(3)*.

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. For more information on non-FIFRA label statements, see LRM Chapter 12.

VI. Label submission requirements

Reviewers should only accept draft labeling for review that meets the regulatory requirements including those set out in (*40 CFR 152.50*.) The Agency has asked registrants to follow some of the other steps outlined below, that are not required by law.

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 asks 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.

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.

Registrants are asked to submit draft labeling on 8 1/2"x 11" paper.

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

The Agency encourages but does not require labels to be submitted in electronic form. For guidance on this topic, see [link to: http://www.epa.gov/pesticides/regulating/registering/submissions/]. The Agency is moving forward with several electronic submission initiatives. Labeling may be submitted electronically in two ways:

1) An e-label (in text searchable .pdf format) may be submitted on a CD-ROM or DVD along with a paper application. In this case, only one paper copy of the label needs to be submitted with the paper application.

2) The entire product application, including labeling, may be submitted in electronic format using an XML structured application on a CD-ROM or DVD. Again, the labeling is a text searchable .pdf file. No paper needs to be submitted with XML applications.

The use of electronic labels will help to increase EPA review efficiency and improve the quality of labeling. The submission of electronic labels by registrants is voluntary but strongly encouraged. For more information on electronic submissions see: http://www2.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications

VII. Label format

Listed below are the various sections of the label in the *approximate* order they should appear on a label. 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).

A. 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** (*Chapter 7)*
   Each product must bear a first aid statement if the product has systemic effects in Category I, II or III, or skin or eye irritation effects in Category I or II. 40 CFR 156.68(a) 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.
   The front panel must include a reference such as "See First Aid statement 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.

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 156.10(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.

B. 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 CFR 156.10(e)*). The format for the EPA Registration Number is specified in 40 CFR 156.10(e). The EPA Registration Number assigned to the product is to be preceded by the phrase "EPA Registration No." or the phrase "EPA Reg. No." 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. (*40 CFR 156.10(f)*). The format for the EPA Establishment number is specified in 40 CFR 156.10(f). The producing establishment registration number is to be preceded by the phrase "EPA Est."

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.

3. **Mode of Action Numerical Classification Symbol (*Chapter 11*)**

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

C. 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 (*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. See *40 CFR 156.10(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 or explosive characteristics, and the various precautions to be taken must be identified, as applicable. Warning statements pertaining to other physical/chemical hazards (e.g., oxidizing potential, conductivity, chemical reactions leading to production of toxic substances) may be required on a case-by-case basis. (*40 CFR 156.78*).

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 or dosages, contact times, 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. When it is included it must conform to requirements in chapter 12.

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

Final printed labeling must be submitted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency. In some cases, reproductions of unusual labels (e.g., silkscreen) are acceptable. (*40 CFR 156.10(a)(6)*). The Agency requests 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.

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18 point POISON DANGER WARNING CAUTION

12 point KEEP OUT OF REACH OF CHILDREN

12 point Keep Out of Reach of Children

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14 point POISON DANGER WARNING CAUTION

10 point KEEP OUT OF REACH OF CHILDREN

10 point Keep Out of Reach of Children

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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

Revised December 2011

Label Review Manual

Chapter 4: Types of Label Reviews

http://commons.wikimedia.org, photo by "Linda in Chicago"

I. Introduction

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 follow-up to a previous submission.

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.

Labeling use patterns (sites and pests) are captured for the purpose of registration, re-registration and registration review and are internally available in the Office of Pesticides Program Information Network (OPPIN) database. This will soon become PRISM, the "Pesticide Registration Improvement System". It is very important that the Agency be able to easily and accurately identify the registered uses for pesticide products. OPPIN/PRISM captures registration numbers, active ingredients, use sites, etc. from approved Section 3 and Section 24(c) labels. OPPIN/PRISM provides the basis for determining what products are currently registered and their use patterns. The registrant must submit and maintain a "Master Label" bearing all registered uses for each registered product (whether or not they use sub-labels or split- labels as described in Chapter 3 IV.B). The regulations allow the reviewer to request the complete text of the proposed amended label at any time. *40 CFR 152.50(e)*.

Electronic Label Review

OPP has begun to use electronic label review to assist in the review and approval of pesticide labels.

Q: What is E-Label Review?

A: Use of a text searchable .pdf label during EPA review of any label submission. The label reviewer will use a computer to:

a) *compare* the proposed e-label to the last version to quickly identify changes,

b) *comment* directly on label to indicate any revisions required on the label.

Q: How are e-labels submitted?

A: Registrants should submit a text searchable .pdf of the label on a CD-ROM along with the usual paper application. The paperwork should also include a signed affidavit (see website for form) that states that the paper label matches the e-label. Alternately, the entire application can be submitted in electronic XML format on a CD-ROM. E-labels can be submitted for an initial product application, a label amendment, or a label notification. Resubmission of corrected labels per EPA comments can be sent via email directly to the label reviewer.

Q: What are the technical requirements for e-labels?

A: See website: http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm

Critical requirements for e-labels:

a) must be a text searchable .pdf (not image)

b) use of filename syntax*: reg#.yyyymmdd.anything else.pdf*.

c) embed the fonts used in label in the .pdf

Q: What are the benefits to using E-Label Review?

A: The use of electronic labels will help to increase EPA review efficiency and improve the quality of labeling. The comparison function can quickly identify changes (intentional and unintentional) in the proposed version of a label and can be used to ensure conformance to any standardized text requirements. The commenting function allows the reviewer to pinpoint where changes are needed to the label and provide text which the registrant can copy/paste into a revised label. Using email, rather than paper mail, to exchange comments and revised labels makes the process more efficient and saves paper. Ultimately, e-label review allows the label reviewer and registrant to work interactively to achieve a label stamped "accepted" without any qualifying comments.

II. Labeling and labeling changes that do not require submission or review

A. Distributor Labeling

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"). The registrant confirms the agreement, both the registrant and the distributor company sign the Notice of Supplemental Distribution of a Registered Pesticide Product form (EPA Form 8570-5) for each distributor product, and the registrant submits the original signed form to the Agency. The distributor does not submit the form. (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 in writing if it terminates its agreement with a distributor (See the *Pesticide Registration Manual* (Blue Book)). Distributor labels should *not* be submitted to EPA for review even though distributor products are subject to FIFRA and its implementing regulations. If submitted they will *not* be stamped "Accepted", or even retained in Agency files (See *Chapter 14* for more information on distributor labeling).

B. Minimum Risk Pesticide 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. The Agency has exempted certain minimum risk pesticides by regulations, which are listed at *40 CFR 152.25(f)(1)*. *40 CFR 152.25(f)(3)* and *PR Notice 2000-6* describe additional conditions required to be met in order for the product to be exempt. No false or misleading labeling statements, including those listed in *40 CFR 156.10(a)(5)(i) through (viii)* may appear on an exempt pesticide product. *40 CFR 152.25(f)(3)(iii)*. Only minimum risk inerts from the current updated list may be used to formulate exempt pesticides. *40 CFR 152.25(f)(2)*. The list can be found at *http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf.*

C. Non-Notification

There are changes to labels that can be made without notification to the Agency. See *40 CFR 152.46(b)*. 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. Also be aware that the Antimicrobials Division's notification process is different in some respects from other Divisions. See *PR Notice 98-10* for details relating to notification pursuant to *FIFRA § 3(c)(9)*.

D. Devices

A device is defined by Section 2(h) of FIFRA as any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than a bacterium, virus, or other microorganism on or in living man or living animals) but not including equipment used for the application of pesticides (such as tamper-resistant bait boxes for rodenticides) when sold separately therefrom.

A device is not required to be registered under *FIFRA sec. 3*. The Agency has issued a policy statement concerning its authority and activities with respect to devices, which was published in the Federal Register of November 19, 1976 (*41 FR 51065*).

A device *is* subject, however, to the requirements set forth in:

(1) *FIFRA sec. 2(q)(1)* and Part 156 of this chapter, with respect to labeling;

(2) *FIFRA sec. 7* and Part 167 of this chapter, with respect to establishment registration and reporting;

(3) *FIFRA sec. 8* and Part 169 of this chapter, with respect to books and records;

(4) *FIFRA sec. 9*, with respect to inspection of establishments;

(5) *FIFRA sec. 12, 13, and 14*, with respect to violations, enforcement activities, and penalties;

(6) *FIFRA sec. 17*, with respect to import and export of devices;

(7) *FIFRA sec. 25(c)(3)*, with respect to child-resistant packaging; and

(8) *FIFRA sec. 25(c)(4)*, with respect to the Agency's authority to declare devices subject to certain provisions of the Act.

III. Labeling and Labeling Changes that require review

The following types of submissions require label review:

- New Active Ingredients and New Uses
- Technical Grade and Manufacturing Use Products
- New Products Containing Existing Active Ingredients
- Labeling Changes by Notification
- Amendments
- Identical or Substantially Similar Products
- Products for which Efficacy Data Must be Submitted
- Special Local Needs, state FIFRA section 24(c) labels
- Experimental Use Permits
- Re-registration

A. New Active Ingredients and New Uses

This type of submission involves a new active ingredient (a.i.) that 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.

B. Technical Grade and Manufacturing Use Products

This type of submission involves a product that is used to manufacture or formulate other pesticides (MP). 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 technical grade active ingredient (TGAI) is the pesticide chemical in pure form (with impurities) as it is manufactured by a chemical company prior to being formulated into other pesticide products.

2. An MP contains the technical grade active ingredient and may contain intentionally added inerts. A TGAI product is considered an MP, but not all MPs are technical grade products. (See *40 CFR 158.300*; *40 CFR 161.155 (h) and (k)*). The following statement in item 3 below applies to TGAI and MP products.

3. MP registrants are required to identify in their labeling which uses they are supporting for reformulation into end use products. 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 the *Pesticide Use Site Index*. *See* also, Appedix A, part 161 of the CFR (Use Pattern Index for Antimicrobial Pesticides). *40 CFR 156.10(i)(2)(iii)*. 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.

The labeling of the MP source product used to produce the applicant's product must either:

- List the uses sought by the applicant *or*
- Allow the applicant to formulate the MP product for the uses sought if the applicant satisfies the applicable EPA data requirements for such uses (see *PR Notice 94-1*).

  If an applicant wishes to use an MP product for a use that requires the applicant to first satisfy EPA data requirements in order to reformulate the MP product, the applicant must comply with EPA data submission/compensation obligations to support that use.

4. The labeling of the technical grade or manufacturing use product should include a listing of the use patterns and sites for the end use products to be formulated from the MP, and will also include a statement such as:

   "For Manufacturing or Formulating Use Only"

   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.

   "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)".

   or

"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". See *PRN 94-1*.

C. New Products Containing Existing Active Ingredients

This type of submission involves an application for registration of a product containing an active ingredient (a.i.) that is currently registered for use as a pesticide. Label reviewers should consult label recommendations specified in the latest relevant Agency decision documents. Such documents may include the Reregistration Eligibility Decisions (REDs), Interim Reregistration Eligibility Decisions (IREDs), Biopesticide Registration Action Documents (BRADs), Registration Review Decisions, Registration Review Interim Decisions.

D. Labeling Changes by Notification

PR Notice 98-10 sets forth what actions can be done through notification and non-notification. Some of these changes can be made simply by "Notification"; which generally involves an Application for Pesticide Registration/Amendment 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. *PR Notice 98-10*. Notifications are processed separately from amendments. The Agency will respond in writing as it is able to do so. If the "notification" documents raise a concern with the label reviewer, he or she may require the registrant to submit an application for amendment when necessary. *40 CFR 152.46(a)(2)*. 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 the Agency has determined 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
- Addition of certain relevant information to the labeling of an antimicrobial pesticide product regarding product efficacy, product composition, container composition or design, or other characteristics that do not relate to a pesticidal claim or pesticidal activity (see *FIFRA § 3(c)(9)*)

Please note that registrants may no longer add or change advisory label statements by notification. (See *PR Notice 2000-5*). Please also note that there is a separate process for antimicrobials (*See FIFRA 3(h)(3)(f)*).

E. Amendments

1. No Data Review Required

   This type of submission involves an application for an amendment to a currently registered pesticide where no data is required for review of the action. 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 must be previously approved for all of the a.i.'s. For certain pests, such as public health pests, quarantine pests, and structural pests, data are required to demonstrate efficacy.

2. Data Review Required

   This type of submission involves an application for amendment of a currently registered pesticide where the request involves the need to review data. For example, the request may involve a new use, a new application rate, or a change in precautionary statements. A data review is also required to be expanded when there is a new public health claim (such as control of a human pathogen or control of mosquitoes) or when the environmental or human exposures are changed (e.g., a residential assessment is needed when turf/lawns are added to a label that has sod grass as a use site). This is an action not previously approved by the Agency, and a data submission and review is necessary. Review of the label will be based upon the conclusions of the data reviews. 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.

F. Identical or Substantially Similar Products

For identical or substantially similar product (formerly known as "me-too") submissions, the pesticide product and the proposed use must be identical or substantially similar to a currently registered pesticide or may differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment. *FIFRA 3(c)(7)(A)*. Identical or substantially similar products may be a "repack", if the product is manufactured by simply repackaging from another registered product, with no changes to its composition. As a "repack," a product may not include use sites that are merely similar to use sites on the

label of the product being repackaged. For example, if the product being repackaged includes directions for use on commercial apple orchards, it would not be acceptable for the new product to include directions for use on apple trees in residential areas. The sites must be the same. The label does not necessarily have to have all the uses but the repacked product cannot have more uses on the label than the product from which it is repacked**.**

The applicant must cite the currently registered pesticide product by EPA registration number. The Agency must first ensure that the two products *are* substantially similar or identical in formulation before the label review can begin.

The label reviewer must also ensure that the new product's use patterns, including any public health claims, are the same as those of the cited product. 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.

G. Products for Which Efficacy Data Must Be Submitted

Efficacy studies document how well pesticide products 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).

Although the Agency routinely waives the submission (but not the requirement to conduct the study) of efficacy data for most 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 request that the data be submitted at any time, either during initial review or subsequent to registration. The 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 that 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.

1. Some Types of Products Requiring Submission of Efficacy Data

a. Antimicrobials. Pesticide products intended to control microorganisms infectious to humans or animals.

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 with Public Health Uses or New Public Health Uses.** Formulated products that either contain new active ingredients or have proposed use patterns that differ from any previously accepted for a similar formulation, and that 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).

2. Product Team Structures/Roles Regarding Efficacy Data

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).

The Antimicrobial Division has developed guidance documents 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 Product Science 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.

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.

Within the Biopesticides and Pollution Prevention Division (BPPD) science reviewers evaluate efficacy and may consult other efficacy reviewers in other parts of OPP as needed.

H. Special Local Needs (SLN)

States have authority under *FIFRA Section 24(c)* to register additional uses for a federally registered pesticide. 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 ingredients must have an established tolerance associated with the crop, or be exempted from the requirement of a tolerance for that crop. *FIFRA 24(c)(3)*. 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.

SLN registrations are effective unless EPA takes action to disapprove such registrations. If the Agency determines the SLN must be disapproved, EPA must provide notice of the disapproval, in writing, to the state within 90 days of the effective date of the registration. See disapproval process at *40 CFR 162.154*. SLN registrations that are issued without following the procedures laid out in 40 CFR 162.152 may be invalidated by the Agency. *40 CFR 162.156(a)(3)*. In such cases, EPA will attempt to provide this information to the state no later than 90 days from the effective date of the registration.

Special Local Need labels are not stamped "Accepted", but are reviewed for the required, pertinent information. EPA sends the State an acknowledgement letter. If there is a problem with the SLN (e.g., no established tolerance), a notice of intent to disapprove or invalidate, if appropriate, 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 for science review depending on the use pattern.

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

I. Experimental Use Permits

Experimental Use Permits (EUP) authorize testing (such as greater than ten acres terrestrial; one acre aquatic; or on a case-by-case basis as EPA determines that an EUP is required) of unregistered pesticides or registered pesticides unregistered use. See *40 CFR 172.3* for a description of the types of tests that generally require a permit. The EUP label follows the standard label format, except that the label must also include:

- The EPA Experimental Use Permit No. *40 CFR 172.6(a)(2)*.
- The statement: *"Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use program"*, *40 CFR 172.6(a)(3)*.
- The statement *"For Experimental Use Only"*. *40 CFR 172.6(a)(1)*.

- The name and address of the permittee, producer or registrant. *40 CFR 172.6(a)(5)*.

  Refer to *40 CFR 172.6* for additional labeling 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. *40 CFR 172.5*.

J. Re-registration

The 1988 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorized EPA to conduct a comprehensive pesticide reregistration program in order to completely review the human health and environmental effects of pesticides first registered before November 1, 1984, and make decisions about these pesticides' future use. The goal of the reregistration program is to mitigate risks associated with the use of older pesticides while preserving their benefits. Pesticides that meet current scientific and regulatory standards may be declared "eligible" for reregistration. The results of EPA's reviews are summarized in Reregistration Eligibility Decision (RED) documents. Products undergoing reregistration receive a product-specific data call-in (PDCI) that requires product chemistry and acute toxicity data on that product. Compliance with RED label changes is required during reregistration, and companies have to submit copies of labels with the changes required in the RED with the PDCI responses for review.

IV. When a use is deleted

Use deletions are published in the Federal Register according to the requirements of *FIFRA 6(f)(1)(B)*. When a use is voluntarily deleted from the label, the label is not stamped accepted even if it is found to be acceptable upon review until the use cancellation FR notice comment period has concluded with no substantial comments. Registrants that intend to delete uses must submit a request to voluntarily terminate the use as described in section 6(f)(1) of FIFRA, an application for amended registration and five copies of revised labeling requesting the deletion of uses. 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.

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Label Review Manual

Chapter 5: Ingredient Statement

http://life.nbii.gov, National Biological Information Infrastructure, Library of Images From the Environment, Elizabeth A. Sellers

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 sub statements including, but not limited to: the acid equivalent, elemental equivalent, toxic ingredients, petroleum distillates, sodium nitrite, and corrosivity.

Format

The label must have a clear and prominent ingredient statement that contains the name and the percentage of each active ingredient, and the total percentage of all "inert" or "other" ingredients, in the pesticide. The ingredient statement must be presented clearly, and be neither obscured nor crowded by surrounding text. See *40 CFR 156.10(a)(2)*. 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)(1)*

II. What is included in an ingredient statement

A. 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).

1. **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. Additional 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".

2. **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 should be aligned by the decimal point.

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 section 2(a), except as provided in *40 CFR 174.3*.

C. Other Ingredient (Inert)

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 provided by *40 CFR 174.3*, as it relates to Plant-Incorporated Protectants. Some examples of ingredients that may be inert ingredients include: solvents, stabilizers, spreaders or stickers, preservatives, surfactants, defoamers, etc.

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."

III. Location of ingredient statement

A. Front Panel

The ingredient statement is normally required to appear on the front panel of the label, preferably immediately below the product name, unless doing so is impracticable and the Agency grants permission to place it elsewhere. *40 CFR 156.10(g)(2)(i)*. (Refer to the sample label formats in chapter 3.) 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.

B. For Outside Containers/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. *40 CFR 156.10(g)(2)(i)*.

IV. Names to be used in the ingredient statement

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.

A. Common Name

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. See section C, below for further information.

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).

An alphabetical listing that contains some of the common/chemical names may also be found in the *Alphabetical Listing of Pesticide Chemicals* at the beginning of *40 CFR Part 180*. Because this list only includes names for ingredients with tolerances, it is only a secondary source. Similarly, a list of some common/chemical names can be found in *PR Notice 97-5*.

B. Chemical Name

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)

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.)

C. 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.

D. Microbial Name

If the active ingredient is a microbial agent, the Agency prefers 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 OPPIN.

E. 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 OPPIN, and the name shown on the proposed label must be identical to the name found in OPPIN.

F. 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)*. *40 CFR 156.10(g)(3)*.

V. Criteria for determination of pesticidal activity

A. Is the Ingredient Considered to Be Active?

The criteria for determination of an ingredient's active or inert status are located in *40 CFR 153.125*. 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.

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 1chemicals with some other non-pesticidal use.

B. Active Related Compounds

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. Inert Related Compounds

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 158.130(2)*. 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.**
See *40 CFR 158.320*.

B. Expressions of Ingredients

1. 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.
2. 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.

3. If wider limits for active and inert ingredients were justified as per the regulations *40 CFR 158.350*, 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 ingredient statement on the label is the nominal concentration, which must be a value between the upper and lower certified limits, not equal to either value.
4. The sum of the percentage by weight of the active ingredient and intentionally added inert/other ingredients in a formulated product must equal 100%. *40 CFR 156.10(g)(4)*.
5. 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, per *40 CFR 156.10(g)(1)*:

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%
Total	100.0%

6. 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. *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 for Certain Inert/Other Ingredients

Based on historical practice, EPA prefers 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. Sodium Nitrite

EPA has historically required, based on *40 CFR 156.78(a),* that products containing >0.1% sodium nitrite add the following statement to the ingredients statement:

"This product contains sodium nitrite".

VIII. Deterioration

A. Required Statement

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). See PRN 70-16.

"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

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

A. 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.

1. Viability. For 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. The OPPTS Harmonized Test Guidelines, *Series 885 Microbial Pesticide Test Guidelines* address 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 syringae strain ESC-10	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

* Contains a Minimum of 4.5 million colony forming units (CFU) per pound (454 grams)

** Contains a Minimum of 14 thousand colony forming units (CFU) per pound (454 grams)

2. For *Bacillus thuringiensis* (Bt) products, the percentage of active ingredient for the ingredient statement will be calculated using the dry weight of the fermentor solids and solubles, including the spores and toxins as the amount of the active ingredient. For liquid products, a representative sample of the technical material is to be dried down to determine the dry weight for the purpose of expressing the percentage of active ingredient on the label. The weight of the water is to be included in the inert ingredient percentage on the label. Strain variety 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 not allowed except when standards are obtained from an EPA-recognized international authority. Instead of International Units, company-maintained target insect assay units are acceptable when named after the insect. (e.g. "cabbage looper units") If potency units are used, the designation should appear on the label immediately below the ingredient statement and should be followed by the statement *"the % active ingredient does not indicate product performance and potency measurements are not federally standardized*". For example:

ACTIVE INGREDIENTS:	
Bacillus thuringiensis subspecies *kurstaki* strain AB1*	.5.0% w/w
OTHER INGREDIENTS	95.0% w/w
Total	100.0% w/w

* Potency: 10,000 cabbage looper units per mg of product or 4540 cabbage looper units per a pound of product
The % active ingredient does not indicate product performance and potency measurements are not federally standardized

B. 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, should be stated in an acceptable and generally recognized bioassay unit. For example:

ACTIVE INGREDIENT:	
Cytokinin*	3.0%
OTHER INGREDIENTS	97.0%
Total	100.0%

*equivalent to 200 ppm kinetin activity

C. 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

D. 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:

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:

ACTIVE INGREDIENTS:	
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%

E. Salts, Amine or Ester of Acids

If the active ingredient is a salt, amine or ester of an acid, the label should 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%

F. Metal Salts or Complexes

Pesticide products for which the active ingredients are readily soluble metal salts or complexes (e.g., copper, zinc, manganese, magnesium, iron) should declare the chemical name of the metalcomplex as active ingredient and the equivalent metallic elementdeclared in a substatement. For example:

ACTIVE INGREDIENT:	
Copper naphthenate*	93.2%
OTHER INGREDIENTS:	6.8%
Total	100.0%

*Metallic copper equivalent, 22%

G. Halide Compounds

Certain halide compounds (e.g., bromine, chlorine, iodine) have historically been required to have a reference in the ingredient statement to the available halide in water. Such a reference is applicable when a halide product's directions for use specify that a certain concentration of the halide (e.g., ppm free chlorine) be achieved in water by dilution or by testing. An example of the ingredient statement follows:

ACTIVE INGREDIENT:	
1-Bromo-3-chloro-5,5-dimethylhydantoin	86.4%
1-3 dibromo-5,5-dimethylhydantoin	8.6%
OTHER INGREDIENTS:	5.0%
Total	100.0%

Provides:	66.8% Available Bromine
	25.4% Available Chlorine

H. Metal Ion Exchange Resins:

Any metal (e.g., Ag or Cu) used as pesticide, when bound to an ion exchange resin, should 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.

I. Sodium Chlorate Products:

Because sodium chlorate is extremely flammable, all pesticide products containing sodium chlorate should 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).

J. Arsenic Containing Products:

Pesticide products which contain arsenic in any form should 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%"

K. Fertilizer-pesticide Combinations:

Pesticides that are formulated in combination with fertilizers bear an ingredient statement the same as any other pesticide. The fertilizer composition is shown separately from the pesticide ingredient statement and may not detract from or obscure the required pesticide labeling statements.

L. Complexing Agents:

In products containing an active ingredient bound with other agents as a complex, the active ingredient should 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

Pesticide products with food use sites do not contain List 1 inerts. Reviewers need to ensure that food use products only contain inert ingredients that have a tolerance or tolerance exemption and that any limitations on the use of the inert ingredients are followed. See *40 CFR 180*.

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 156.10(g)(7)*. This statement must be placed in close proximity to the ingredient statement in a type size comparable to other front panel text. 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, announced the revision and modification of 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 has not registered any new products containing a List 1 inert. EPA's inert list is available on the Web: *Inert Ingredients in Pesticide Products | Office of Pesticide Programs | US EPA*.

B. Listing 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 should list **all** inert ingredients directly below the ingredient statement in descending order by weight. A partial listing on the label could be misleading.

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. For example:

Other Ingredients 92.8%

monochlorobenzene, glycerin, 8-hydroxyquinoline sulfate and dimethylpolysiloxane

Other Ingredients 92.8%

Diluent, emulsifier, defoamer, preservatives and stabilizer

XI. Alternate formulations

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. *40 CFR 152.43(b)(3)*. The Agency will not approve an alternate formulation if the alternate formulation requires a change in the label text.

The alternate formulation must have the same certified limits for each active ingredient as the basic formulation. *40 CFR 152.43(b)(1)*. 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. *40 CFR 152.43(b)(2)*.

The analytical method required under *40 CFR 158.355* must be suitable for use on both the basic formulation and the alternate formulation.

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.

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

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Chapter 6: Use Classification

http://en.wikipedia.org, public domain

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. *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, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects, the Agency will classify the pesticide as an RUP. *FIFRA 3(D)(1)(c)*.

It is the Agency's policy 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 meet the regulations set out at *40 CFR 152.167*, or those restrictions established 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. *FIFRA 3(d)(1)(C)(i)&(ii)*; *40 CFR 152.175*. Users of unclassified products are not limited in any manner unless the labeling limits use to a specific definable group, (e.g., veterinarians). See *Chapter 11* for further explanation of this issue.

II. Unclassified products

A. Criteria

If the label under review meets any of the criteria below, then the product may remain unclassified.

1. **Identical or Substantially Similar.** The product under review is an identical or substantially similar 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.

(d) 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.

3. **Manufacturing Use Products.** 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. **Active Ingredients Have not Previously Been Classified 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: *http://www.epa.gov/opprd001/rup/*.

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 an identical or substantially similar 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 RUPs"*.

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 *40 CFR 152.170*. Even if the RUP criteria are triggered, the Agency must determine if the potential risk can be adequately mitigated through additional labeling restrictions. The label reviewer should check with the Product Manager/team leader to determine if this is the case. See *40 CFR 152.170(e)*. If not, the product must be classified as an RUP. Go to Section B. below on *"Labeling Requirements for RUPs"*.

MITIGATION OPTION: 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, place it in the registration jacket, and ensure 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 in *40 CFR Part 156*, including the requirements set out in *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)(A)*. No other wording or symbols should appear above the RUP statement. *PR Notice 93-1*. The phrase "Restricted Use Pesticide" on the front panel must meet the minimum type size requirements of the human hazard signal words. *40 CFR 156.10(j)(2)(i)(A)*. 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 156.60(b)(1)* for the signal word.

2. A briefly stated reason for the restricted use classification should directly follow "Restricted Use Pesticide". *PR Notice 93-1*.

3. A summary statement of the terms of the restrictions must follow. *40 CFR 156.10(j)(2)(i)(B)*. (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". *40 CFR 156.10(i)(2)(i)*.

7. 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 should seek a separate registration only for those unrestricted uses. *40 CFR 156.10(j)*.

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. Following is an example of an RUP statement.

   "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.

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Label Review Manual

Chapter 7: Precautionary Statements

USDA NRCS, Jeff Kramer

I. Introduction

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 Precautionary Statements on Labels

The Code of Federal Regulations specifies both the acute toxicity category (*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.

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 Reregistration Eligibility Decision (RED) Documents

During Reregistration, the 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 156.64(b)(1)*)

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. 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

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 in concentrations of 4% or more. If so, the Signal Word, regardless of the toxicity categories noted in the acute toxicity review, is DANGER.

3. **Location and Prominence.** The Signal Word is required to appear on the front panel of the label, and must appear on a separate line from the required Child Hazard Warning statement, Keep Out of Reach of Children (KOROC). 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 signal word must also appear together with the heading for the human precautionary statement section of the labeling. 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 (*40 CFR 156.60(b)*). See Chapter 3 for the Minimum Type Size requirements for the Signal Word, Child Hazard Warning statement and the sample label format. The Signal Word must appear in all capital letters and should 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"). If the Prop 65 term conflicts with the EPA signal word, then registrants should use "Notice" or "Attention" for the Prop 65 statement so that it does not conflict with the EPA signal word. . However, 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 also required if the inert,

methanol, is present at 4% or more in the subject product because of the well-known possible risk of causing blindness..

Table 2. Examples of Signal Word Determination

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

*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 must bear the additional labeling because it contains a special inert (methanol) at greater than 4%, as described in paragraph B.1. above.

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".

C. Child Hazard Warning Statement

1. **When Required.** The Child Hazard Warning statement, "Keep Out of Reach of Children" (KOROC) 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*). The Child Hazard Warning must appear on a separate line above the Signal Word. Also make sure that the Child Hazard Warning statement is oriented in the same direction as other label text.

3. **Additional Information.** 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.

   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. 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 156.70*) The phrase "and Domestic Animals" may be omitted from the heading if domestic animals will not be exposed to the product. *(40 CFR 156.70(a))*

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. This organization is strongly preferred by the Agency.

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.** Statements from the tables 3-8 can be selected 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. 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.

7. **Products that contain greater than 4% Methanol.** If the product contains 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 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, using tobacco or using the toilet.
II	WARNING	May be fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.
III	CAUTION	Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.
IV	CAUTION (optional)	No statements are required. However, the registrant may choose to use category III labeling.

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, using tobacco or using the toilet. 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, using tobacco or using the toilet. 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, using tobacco or using the toilet. 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 5, 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 5, 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, using tobacco or using the toilet. 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, using tobacco or using the toilet. 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, using tobacco or using the toilet.
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, using tobacco or using the toilet. 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, using tobacco or using the toilet. 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, using tobacco or using the toilet. 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.

*A positive dermal sensitization study for a category IV product does not trigger a PPE requirement.

E. Personal Protective Equipment (PPE)

PPE 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 (Industrial/Commercial) Uses.** While there are no regulatory requirements that demand PPE for non-WPS products, many states test applicators for their comprehension regarding what types of PPE are used and how to use it correctly, however, this training and testing is normally only done for users of RUPs, not unclassified pesticides. Label reviewers should ensure that adequate, understandable language regarding the types of PPE that should be worn for the product's hazards is included in any label, whether RUP or unclassified. In cases where the reviewers determine PPE would be necessary, the various PPE tables in Chapter 10 provide information about which PPE is protective in specific circumstances. If there is an applicable regulatory document which specifies PPE requirements based on concerns

specific to the active ingredient then those PPE requirements must be placed on the label.

2. **For Products used by Residents/Consumers.** In order to protect human health, label reviewers should review the toxicity data and the product's uses to determine whether PPE would be necessary to meet the standards for registration. In cases where the reviewers determine PPE would be necessary, 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 regulatory document which specifies PPE requirements based on concerns specific to the active ingredient then those PPE requirements must 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, but not required, for the registrant to include First Aid statements for products that are classified as category IV.

2. **Appropriate Headers.** The first aid statements appear under either of the following headings: "First Aid" or "Statements of Practical Treatment". (*PR Notice 2001-1*). The heading "First Aid" is preferred by the Agency. In addition, EPA historically has not allowed the heading "Antidote" in conjunction with the first aid statements unless a specific antidote is necessary.

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 First Aid statement 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. First Aid statements should be organized so that the most severe routes of exposure, as demonstrated by the toxicity classification, are listed first. This organization is strongly preferred by the Agency.

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. (*PR Notice 80-2*).

   (a) Content and Clarity. First Aid statements should be brief, clear, simple and in straightforward language so that the average person in an emergency can easily and quickly understand the instructions. First Aid statements should apply to all ages or when necessary, 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. First aid statements for ingestion may be more appropriate for products with some potential for ingestion, such as liquid concentrates, but less so for products with low potential, such as aerosol sprays. For Toxicity Category I skin and eye irritants, the Agency has used the statement: "Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage." (PRN 2001-1).

6. **Products that contain 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). If the product contains either chemical, the following phrase should be included in the First Aid statement (*PRN 2001-1*):

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

7. **Products that contain zinc phosphide.** If the product contains zinc phosphide, the following First Aid statement is recommended (*PRN 2001-1*):

   "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".

8. **Products that contain petroleum distillates.** If the product contains ≥10% petroleum distillates, the following First Aid statement should be used (*PRN 2001-1*):

   *"If swallowed: Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give **any** liquid to the person. Do not give anything by mouth to an unconscious person".*

   However, if registrants have data to show there is benefit in drinking water or milk after ingesting their product(s), they may submit alternate wording via amendment.

9. **Telephone numbers.** EPA encourages, but does not require, registrants to include a company telephone number or toll-free hotline number for emergency information in the first aid section. If a number is included, confusion can be avoided by placing emergency numbers with the "First Aid" or "Hot Line Number" text. If a number is included, it should include a phrase or statement indicating the kinds of information the number should be used for and it may include hours of service. For example:

   "Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For non-emergency information on product usage for example,, call (1-XXX-XXX-XXXX), Monday through Friday, 9 a.m. to 5 p.m. For medical emergencies call your poison control center at 1-800-222-1222".

   If a registrant does not have its own number, the registrant may use the National Pesticides Information Center (NPIC) 800 number (see below). However, NPIC does not provide emergency information.

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.

Route of Exposure and Toxicity Category	First Aid Statement
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. – For general information on product use, etc.), call the National Pesticides Information Center at 1-800-858-7378. For medical emergencies, call the poison control center 1-800-222-1222.

10. **National Pesticides Information Center.** Regarding the General Information provided under the First Aid statements section (Table 9), the emergency phone number could be the National Pesticides Information Center's 800 number. The section could read:

    "Have the product container or label with you when calling a poison control center, doctor, or going for treatment. For non-emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time (NPIC Web site: www.npic.orst.edu*)".*

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 ≥ 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 statements, but should be clearly distinguished from it. In other words, it should not be placed within the First Aid statements, 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 must be sent 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 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. (*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. The following are some examples (in italics) of how use dilution labeling could 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. Optional Labeling/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 156.70(c)*) 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. **Identical or Substantially Similar Product Deviations.** If an identical or substantially similar product is citing a product that has optional use dilution hazard statements on the label, those statements are not required on the identical or substantially similar product if the acute toxicity data results are available. Questions about the availability of the acute studies should be referred to the precautionary labeling reviewers.

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Label Review Manual

Chapter 8: Environmental Hazards

http://life.nbii.gov, National Biological Information Infrastructure, Library of Images From the Environment, Charles H. Warren

I. Introduction

The Environmental Hazards statement provides the precautionary language informing users of the potential hazards to the environment from transport, use, storage, or spill of the product. These hazards may be to water, soil, air, beneficial insects, plants, and/or wildlife as identified in risk assessments performed by the Environmental Fate and Effects Division. Generally, the information contained in this section is based upon the results of eight basic acute toxicity studies performed on the technical grade of the active ingredient(s) in the formulation. These eight 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), (7) honeybee contact LD_{50}, and (8) mammalian acute oral LD_{50}. For specific data requirements: *40 CFR Part 158*.

In addition, data concerning a product's potential to be transported to groundwater, surface water, aquatic sediment, to drift, to adversely affect non-target plants and bees provide important information. Data include, but are not limited to, results from hydrolysis, batch equilibrium, aerobic soil metabolism, field dissipation, and prospective groundwater studies.

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.

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

II. Reviewing the statements

A. When Required

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 assume that any pesticide product used outdoors must include the Environmental Hazards statement on the label. However, the reviewer should also look at the proposed statement with a critical eye towards its applicability. Does it make 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. **Exclusively Indoor Products.** 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 in most cases 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 such a product. Thus it is important for reviewers to carefully evaluate the use pattern 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, MPs may require some Environmental Hazard statements text because MPs may be highly concentrated and could pose a serious hazard if a spill occurred. A discharge statement may also be required; see section VII. A. below for recommended language.

3. **Outdoor Use Products.** The Agency has typically required products labeled for use outdoors to have Environmental Hazards statements on their labels. 40 CFR 156.80 – 156.85. 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.

B. Statement Location

The Environmental Hazards section of the label should be located under the general heading "Precautionary Statements". It *must* have the heading "Environmental Hazards" (not "Environmental Precautions", "Environmental Protections", or anything similar). (*40 CFR Part 156.80(b)*).

C. Support for Statements

The text of the proposed Environmental Hazards statements is then reviewed according to the type of product. If the action represents a submission accompanied by data, 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, and assure that the changes are in accordance with mandatory/advisory guidance. (*Chapter 3* and *PR Notice 2000-5*)

1. **Technical/End-Use Products.** 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 *40 CFR Part 158*. Generally, 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 a Reregistration Eligibility Decision (RED) Document has been issued, it may contain appropriate Environmental Hazards statements, but the reviewer should evaluate whether the decision document specifically addresses the use at issue and then make appropriate changes to the label statement.

2. **Identical or Substantially Similar Products.** If the label reviewer is working on an application for registration for an identical or substantially similar product, 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 identical or substantially similar product Environment Hazard language should be the same as the currently registered product. If there are no similar products, route the application 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.

   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.

   If an error is discovered in the Environmental Hazards section of the cited identical or substantially similar product label, the reviewer should send a letter informing the registrant of the cited identical or substantially similar product label of the error(s) and request an application for amendment be submitted within a reasonable time, such as 30 days.

III. General statements

A. Outdoor, Terrestrial Uses

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".*

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., aquatic uses such as mosquito larvicides, aquatic herbicides, piscicides, etc.,or greenhouse and indoor uses.

Aerial Forestry Application Statement. If a pesticide product is aerially applied to forests, the above statements should be preceded with the phrase:

> "For terrestrial uses, except when applying aerially over 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. that are not under the forest canopy.

B. *Bacillus thuringiensis* (Bt)

For Bt products that are intended for forestry treatments or aquatic uses (e.g. mosquito control with *Bt israelensis*), variations of the above Environmental Hazards statements may be required.

1. **Forestry Uses.** For forestry uses, the statement should read:

   "Do not contaminate water when disposing of equipment washwaters or rinsate".

2. **Aquatic Uses.** For aquatic uses, the statement should read:

   "Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption".

C. Outdoor, Residential Consumer Products

For outdoor residential consumer products (except for lawn care products applied by a Pest Control Operator which use the same statement as outdoor terrestrial uses), the statements preferred by the Agency to meet risk/benefit concerns are as follows (See *PR-Notice 2008-1*).

Table 1. Outdoor Residential Consumer Product Statements

Formulation type	Preferred Language
Liquid Concentrate	To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems.
Broadcast Granular	To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Sweeping any product that lands on a driveway, sidewalk, or street, back onto the treated area of the lawn or garden will help to prevent run off to water bodies or drainage systems.
Dust	To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area.
Liquid Ready-to-Use (RTU)	To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area.

These statements provide the basic use instructions for avoiding water and other environmental contamination; they are used in addition to other required environmental

statements, such as wildlife hazard statements determined by the toxicology data (e.g., specific precautionary statements concerning bees, fish or aquatic organisms).

The reviewer must also 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 statements may be inappropriate as written.

D. Outdoor, Terrestrial Products Requiring Fish or Aquatic Invertebrate Statements

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".*

E. Groundwater Label Advisories

There are two groundwater label advisory options available. The need for a groundwater label advisory is based on the environmental fate properties of the chemical and/or detections of the chemical in groundwater. One option is for chemicals with little or no monitoring data that have environmental fate properties similar to pesticides that have been found in groundwater. The other option is for chemicals that have actually been found in groundwater.

1. **Based on Laboratory/Field Data.** If no detections are reported in groundwater (for example, a new chemical) but the chemical (or a major degradate) has a combination of environmental fate properties similar to other pesticides found in groundwater as a result of normal label uses:

   - mobility characteristics (e.g. K_d less than 5, or field dissipation results that indicate the chemical leaches)
   - persistence characteristics (e.g., hydrolysis half-life greater than 30 days at any pH or aerobic soil metabolism half-life greater than 2 weeks)

   then the Agency has generally required the following label language:

   *"**Groundwater Advisory***

   This chemical has properties and characteristics associated with chemicals detected in groundwater. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow".

2. **Based on Groundwater Monitoring.** If detections are reported in groundwater in a prospective groundwater study or other monitoring study conducted for registration, or

other reliable monitoring data in the publicly available literature, then the Agency has generally required the following label language:

*"**Groundwater Advisory***

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

F. Surface Water Label Advisories

When appropriate, after the environmental assessment, the Agency requires the following statement to be added to outdoor household/residential, agricultural, and other outdoor labels modified for the specific pesticide characteristics and targeted audience.

"This product may impact surface water quality due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water.

This product is classified as having [insert phrase 1.a., 1.b., or 1.c., according to the pesticide's "mean" soil partition coefficient (K_d)] for [insert phrase 2.a., 2.b., or 2.c. according to the pesticide's aerobic soil metabolism half-life]. [insert phrase 3.a or 3.b depending on whether the product is intended for the household user or farmer]",

1. Soil Partition Coefficient Phrases

(a) K_d less than 15 – "*high potential for reaching surface water via runoff*"

(b) K_d between 15-300 – "*a medium potential for reaching both surface water and aquatic sediment via runoff*"

(c) K_d greater than 300 – "*high potential for reaching aquatic sediment via runoff*"

2. Aerobic Soil Metabolism Half-Life Phrases

(a) $t_{1/2}$ less than 8 days – "*several days after application"*

(b) $t_{1/2}$ between 8 and 30 days – "*several weeks after application*"

(c) $t_{1/2}$ greater than 30 days – "*several months or more after application*"

3. Targeted User Community

(a) Household/Residential Label

See Table 1 on page 8-4.

(b) 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 loading of [Name of chemical] [A degradate

of (name of chemical)] from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall or irrigation is expected to occur within 48 hours.. [For pesticides with a soil partition coefficient greater than 300 add the following, *"Sound erosion control practices will reduce this product's potential to reach aquatic sediment via runoff".*]

IV. Non-target organism statements

A general requirement for products to bear environmental hazard statements, including hazards to non-target organisms, is stated at 40 CFR Part 156.80. In Part 156.85, examples are given of statements the Agency typically requires when data indicate certain acute toxicity levels for mammals, birds, fish, etc., or there is other information such as accident history indicating significant risks to non-target wildlife. Other statements than those listed may be required if more appropriate to the formulation or use.

A. Hazard Statements for Birds, Mammals, Fish, Aquatic Invertebrates and Estuarine Organisms

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

1. **Bird and Mammal Hazard Statement.** The following statement has typically 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:

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

2. **Fish/Aquatic Invertebrate Statement.** The following statement has typically 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]".

3. **Incident Data Statement.** 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 typically been required:

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

B. Pollinating Insect Hazard Statements

If a pesticide is used outdoors as a foliar application, and is toxic to pollinating insects, a "Bee Hazard" warning has generally been required to be included in the Environmental Hazards. See *40 CFR § 156.85(a)*. The following table sets out the toxicity groupings and examples of label statements for honey bees and other pollinating insects. Crop-specific use instructions would optimize bee and other pollinating insect safety. There may be other options for mitigating risk that may be considered (i.e. applications at night for continuously blooming crops).These instructions could be placed in the Directions for Use.

Table 2. Pollinating Insect Acute Toxicity Groups and Precautionary Statement Examples

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 and other pollinating insects 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 or other pollinating insects are visiting the treatment area.*	*This product is highly toxic to bees and other pollinating insects 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 or other pollinating insects 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 moderately toxic to bees and other pollinating insects exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product if bees or other pollinating insects are visiting the treatment area.*	*This product is toxic to bees and other pollinating insects exposed to direct treatment. Do not apply this product while bees or other pollinating insects are actively visiting the treatment area.*
III All others.	No bee or pollinating insect caution required.	No bee or pollinating insect caution required.

Potential chronic hazards to honey bees, and other pollinating insects, and the resulting label language will be dealt with on a case-by-case basis. The Agency is in the process of developing chronic toxicity label statements for pollinator protection. When the proposed language has been thoroughly vetted, the appropriate conditions and statement will be included.

C. Aquatic Weed Control Label Statement

If a pesticide product is used to control aquatic weeds, the Environmental Hazards section generally is required to 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 ⅓ 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".*

D. Irrigation Water Label Statement

If a pesticide product is applied to irrigation water and contains an ingredient requiring an aquatic organism toxicity statement, the Environmental Hazards section generally 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 sorbed by the soil or not released for (number) days after application".*

V. Mosquito control label statements

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 adverse effects to water quality. Products with aquatic toxicity concerns between these extremes should have the following recommended statement, as appropriate:

A. 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".*

B. Adulticides

PR Notice 2005-1 lays out seven specific adult mosquito control label recommendations and details Agency rationale for these statements. Pesticide manufacturers are being requested to incorporate these statements in the labeling of any new products seeking registration for adult mosquito control use, or to request amendments of existing labels with this use pattern.

These recommendations apply only to products labeled for wide-area application as Ultra Low Volume (ULV) sprays or fogs, and not to home and garden use products which list mosquitoes on the label, or to coarse non-ULV sprays intended for residual treatment of vegetation or other surfaces. Control of mosquito larvae in water is a completely different use pattern from adult mosquito control, and is not included in the scope of *PR Notice 2005-1*.

1. Adult mosquito control applications should be limited to trained personnel. It is the Agency's position that the following statement should appear on the label of non-restricted use products for wide-area adult mosquito control:

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

2. Products labeled for wide-area adult mosquito control should not bear container labeling for uses unrelated to adult mosquito control. The standard terrestrial use water hazard statement should not appear on product containers labeled solely for mosquito control. If a container label includes non-mosquito control use directions, those directions and associated precautions should be clearly distinguished from those applicable to mosquito control. The terrestrial use statements on a mixed-use label should be followed by the statement:

   "See separate directions and precautions for mosquito control applications".

3. Label statements intended to protect bodies of water and aquatic life should be harmonized, as well as improved to assist effective mosquito control applications. The Agency recommends the following statement to appear on mosquito adulticide labels:

   "This pesticide is [toxic/extremely toxic] to aquatic organisms, including [insert general types of organisms]. Runoff from treated areas or deposition of spray droplets into a body of water may be hazardous to [insert general types of organisms]. [If appropriate, insert any additional wildlife hazard statements]. [Bee precaution can be inserted here or as a third paragraph of this section of the label]. [Insert consultation with state/tribal agency statement].

   Do not apply over bodies of water (lakes, rivers, permanent streams, natural ponds, commercial fish ponds, swamps, marshes or estuaries), except when necessary to target areas where adult mosquitoes are present, and weather conditions will facilitate movement of applied material away from the water in order to minimize incidental deposition into the water body. Do not contaminate bodies of water when disposing of equipment rinsate or washwaters".

4. Users should consult with the State or Tribal agency for pesticide regulation to determine if permits or other regulatory requirements exist. The Agency concludes that the following statement is appropriate for all wide-area mosquito control product labels:

   "Before making the first application in a season, it is advisable to consult with the state or tribal agency with primary responsibility for pesticide regulation to determine if other regulatory requirements exist".

5. Labels should specify a spectrum of spray/fog droplet sizes, and indicate that droplet size should be determined according to directions from equipment manufacturers or other appropriate sources. The following language is recommended as a model for droplet size calibration instructions on adulticide labels:

   "Ground-based application:

   Spray equipment must be adjusted so that the volume median diameter is less than [X = value to be provided by registrant] microns (Dv 0.5 < X µm) and that 90% of the spray is contained in droplets smaller than [Y = value to be provided by registrant] microns (Dv 0.9 < Y µm). Directions from the equipment manufacturer or vendor, pesticide registrant or a test facility using a laser-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated".

   "Aerial Application:

   Spray equipment must be adjusted so that the volume median diameter produced is less than (A = value to be provided by registrant] microns (Dv 0.5 < A µm) and that 90% of the spray is contained in droplets smaller than [B = value to be provided by registrant] microns (Dv 0.9 < B µm). The effects of flight speed and, for non-rotary nozzles, nozzle angle on the droplet size spectrum must be considered. Directions from the equipment manufacturer or vendor, pesticide registrant or a test facility using a wind tunnel and laser-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated".

6. Precautionary language to protect bees should have a provision to allow mosquito control applications in order to respond to threats to public health which are identified by health or vector control agencies on the basis of evidence of disease organisms or disease cases in animals or humans. The following language should be added to the last sentence of the bee precaution statement on the labels of mosquito adulticide products:

   "... (do not apply to blooming crops or weeds when bees are visiting the treatment area), except when applications are made to prevent or control a

threat to public and/or animal health determined by a state, tribal or local health or vector control agency on the basis of documented evidence of disease-causing agents in vector mosquitoes or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort".

7. Mosquito adulticide labels should include limits on timing and number of applications to the same location. Exceptions to these limits may be allowed in order to respond to threats to public health which are identified by health or vector control agencies on the basis of evidence of disease organisms or diseases cases in animals or humans. The following language should be included in the directions for use section of the label:

   "Do not re-treat a site more than once in [X hours/days]; no more than [Y] applications should be made to a site in any [Z weeks/months] or [one year]. More frequent treatments may be made to prevent or control a threat to public and/or animal health determined by a state, tribal or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort".

   In addition to the label language recommended in *PR Notice 2005-1*, the following information is recommended to add to the labels for adult mosquito control products, based on label requirements issued in REDs for these products:

   - Maximum amount of active ingredient per acre/year
   - Wind speeds
   - Flight altitude- minimum and maximum

VI. Endangered species protection requirements

To protect endangered species, some products require Endangered Species Protection Bulletins that will contain geographically specific use limitations. Users will be directed to these Bulletins through a standard label statement. This statement may only be placed on a label after the completion of a risk assessment and determination that it is necessary. For complete endangered species labeling information, refer to *Chapter 11, Section IV, subsection J.*

VII. Miscellaneous statements

A. Point Source Discharge

For certain registered end-use products, technical grade products and other manufacturing use 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.

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".*

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*. This policy applies to any pesticide product that may be contained in an effluent discharged to the waters of the United States or municipal sewer systems. Such products include but are not limited to: (a) technical grade and manufacturing use products; (b) end-use products registered for industrial preservative, water treatment, or other industrial processing use such as in cooling tower water systems, pulp and paper mill water systems, secondary oil recovery injection water systems, food processing operations, leather tanning, and wood protection and textile treatment; and (c) large scale commercial and institutional end use (such as hospitals).

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.

B. Seed Treatment or Granule/Pellet/Treated Bait Products

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 when appropriate:

> *"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".*

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Label Review Manual

Chapter 9: Physical or Chemical Hazards

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I. Introduction

This chapter covers the Physical or Chemical Hazards statements that are required for certain pesticide products set out in the regulations, *40 CFR 156.78*. Such hazard statements address flammability, explosive potential and precautions. In addition, special hazard statements are required for certain fumigants. The reviewer should refer to the regulations and look through the guidance set out in the following sections to evaluate labels.

II. Placement of the physical or chemical hazards statement

Placement of the Physical or Chemical Hazards section should be immediately below the Hazards to Humans & Domestic Animals and Environmental Hazards statements in the Precautionary Statements section of the label. The physical or chemical hazards section must bear the subheading "Physical or Chemical Hazards".

III. Labeling for flammable products

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.

A. Data Requirements for Flash Point/Flame Extension

Data requirements for flammability are covered in the regulations set out in *40 CFR 158.310* and *40 CFR 161.190*. 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.

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. Typical Statements for Flammable Products

Criteria	Required Text
(A) Pressurized Products	
Flash point at or below 20°F (-7°C) 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 (-7°C)to 80°F (27°C) or if the flame extension is greater 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 products	**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 Products	
Flash point at or below 20°F (-7°C)	**Extremely flammable.** Keep away from fire, sparks, and heated surfaces.
Flash point greater than 20°F (-7°C) to 80°F (27°C)	**Flammable.** Keep away from heat and open flame.
Flash point greater than 80°F to 150°F (66°C)	**Combustible.** Do not use or store near heat or open flame.

[40 CFR 156.78]

B. Terms to Avoid

In order to avoid confusion with the product's overall signal word, the terms, CAUTION, WARNING, and DANGER (human hazard signal words based on toxicity data) 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)*).

C. Total Release Fogger Products

If the product is a total release fogger containing a propellant with a flash point at or below 20°F, the following label statement must be included in the Physical or Chemical Hazards 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 Hazards 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

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 that 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 appears in the Physical or Chemical Hazards section, the claim of non-flammability CAN NOT be used.

A. Criteria for Declaring Non-Flammability

If the proposed label bears a claim of non-flammability, it should meet the following criteria:

1. **Gases/Mixtures of Gases.** If a gas or mixture of gases (under pressure), the product must not ignite when a lighted match is placed against the open cylinder valve.

2. **Liquids.** If a liquid, the product must have a flash point greater than 350°F (177°C). Refer to the CSF for the flash point.

3. **Pressurized Products. Pressurized products (aerosols) may be classed as non-flammable if they meet the following criteria:**

   a. The flame extension is zero inches, using the method designated in the Guidelines.

   b. There is no flashback.

   c. The flash point of the non-volatile liquid component is greater than 350°F (177°C).

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.

B. 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*)

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. (*40 CFR 158.310(d)*). (OPPTS Test Guidelines Series 830, Product Properties, #830-6321)

If the proposed label **is** for a liquid product, review the criteria below:

A. Criteria for Determining the Requirement of the Shock Hazard Statement

1. The use directions permit use of the product near electrical equipment or electrical outlets (transformers, cable TV pedestals, conduits, etc.); and
2. the data matrix does not provide a dielectric breakdown voltage; or
3. the dielectric breakdown voltage is less than 5,000 volts.

B. 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".

VI. Labeling for explosive potential

A. When Required

When data submitted in accordance with *40 CFR Part 158* demonstrates 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
- 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". (*PR Notices 84-5* and *85-6*)

A. 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 "Compatibility with Other Products", for more information on this issue.)

IX. Requirements 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, (IX)(I) Sodium Chlorate Products*, 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 158.310* and *40 CFR 161.190* 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. For example, EPA has historically required a warning statement for oxidizing agents such as "Do not use with or store near any oxidizing or reducing agents." These decisions are made on a case-by-case basis. Check with other documents, such as REDs and registration review documents, to see if other wording is required.

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Label Review Manual

Chapter 10: Worker Protection Label

National Garden Bureau

I. Introduction

This chapter provides guidance for reviewing statements required for the protection of occupational users of pesticides, including agricultural workers and handlers. While much of this chapter focuses on the requirements 40 CFR 156 (Labeling Requirements for Pesticides and Devices) Subpart K (Worker Protection Statements) designed to implement the protections of the Worker Protection Standard (WPS)(40 CFR 170), it includes protections required for non-WPS occupational users of pesticides as well. The portions of the label discussed 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). To the extent possible, label reviewers should ensure that all products with occupational exposure have appropriate risk mitigation measures equivalent to those measures contained in this chapter.

II. Background

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 that fall into this category.

A. The Worker Protection Standard

The Labeling Requirements for Pesticides and Devices, Worker Protection Statements (*40 CFR 156, Subpart K (156.200 -212)*) were published in *the Federal Register* on August 21, 1992, as was The Worker Protection Standard (WPS) (*40 CFR 170)*. Together these regulations establish standards and labeling requirements for worker protection. Further, *PR Notices 93-7* and *93-11* provide Agency guidance for complying with the WPS. The correct product specific WPS labeling can be found in the Acute Toxicity Data Evaluation Records (DER) for any given product.

B. Worker Risk Assessment

As part of the pesticide registration, reregistration, and registration review processes, a comprehensive worker risk assessment is performed. The worker risk assessment is based on toxicological criteria and potential for dermal, ocular, 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 regulatory assessment 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 regulatory assessment documents (Reregistration Eligibility Decision (RED), Registration Review Documents, etc.).

C. Evaluating the Regulatory Assessment Document and the Acute Toxicity Review

To determine the correct worker protection labeling for a given product, the label reviewer must consider the chemical specific worker protection labeling defined by the RED, the most current regulatory risk assessment 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 to derive the final handler PPE statements for the labeling.

III. Determination of products subject to the WPS

A. Scope of WPS

Review the criteria below 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. A summary table of the scope of WPS is also provided in Appendix A of this chapter to assist label reviewers in determining if a product is subject to WPS.

B. Criteria for Determining WPS Applicability

Does the product bear directions for use on an agricultural establishment (defined at *40 CFR 170.3* as "any farm, forest, nursery, or greenhouse") or 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 is not limited to, food, feed, and fiber plants; trees; turf grass; flowers, shrubs; ornamentals; and seedlings"). See *40 CFR 170.102*. Or does the product bear labeling that could reasonably permit such a use?

NO, the product does not bear directions for use on an agricultural establishment or involving the production of an agricultural plant. The product is not subject to the WPS. The requirements in this chapter do not apply.

YES, the product does bear directions for use on an agricultural establishment or involving the production of an agricultural plant. Does the product meet any of the exceptions listed below?

Exceptions: The WPS contains exceptions for certain uses. WPS does not apply when any pesticide is applied on an agricultural establishment or involving the production of an agricultural plant in the following circumstances (*40 CFR 170.103*):

- For mosquito abatement, Mediterranean fruit fly eradication, or similar **area-wide public pest control programs** sponsored by governmental entities (area-wide programs are those where large swaths of public, private, residential, commercial and/or agricultural land/property is sprayed and a land owner has no control over

the spraying; this does not include the boll weevil and gypsy moth eradication programs or other similar program where specific areas of forests or agricultural land (e.g., cropland, Christmas tree nurseries, managed forests, etc.) are sprayed under arrangements with the land owner);

- 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", "drill 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 non-managed pasture and rangeland use **(i.e., 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 around agricultural premises (vertebrate pest control applications for the purposes of crop protection is covered);
- As attractants or repellents in traps;
- Post harvest treatments on the harvested portions of agricultural plants or harvested timbers; and
- For research uses of unregistered pesticides.

If the product's directions for use allow for any uses that are not in the above exceptions, the product IS subject to the WPS. Keep reading.

If the product's directions for use contain only uses that fall under one or more of the above exceptions, the product is NOT subject to the WPS. The WPS-specific requirements in this chapter do not apply. Other non-WPS user protections, which may apply, are discussed later in this chapter.

1. **Exceptions for Seed Treatments:** The WPS does apply when pesticide products contain directions for use which allow treating seed at an agricultural establishment at or immediately before planting (such as through use of hopper boxes, planter boxes, slurry boxes, or tractor-mounted treaters). If seed treatment is only allowed off-farm (for example treating seed in a plant where seed is bagged to be used by growers) the WPS does not apply.

For further details, see *PR Notice 93-11, Supplement F*, and information at the following Website: (*http://www.epa.gov/pesticides/safety/workers/wpsinterpolicy.htm*)

Remember, in some cases it may not be clear whether or not a product is "within-scope" of the WPS if the product could be used on agricultural plants such as vegetables or ornamentals, but the registrant intends the product for an exempted use. **If the registrant's intention is to remove the product from the scope of the WPS, then clear language should be required on the label that limits or prohibits where this product can be applied (i.e., on WPS covered agricultural establishments), rather than who may apply it. This can be done by using exclusionary labeling statements such as the following:**

"*Not for use in commercial or research nurseries or greenhouses",*

or

"Not for use on agricultural establishments covered by the WPS (40 CFR Part 170)",

or

"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 residential lawns."

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. See *40 CFR 156.206(e)*. 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 (the signal word Aviso and the statement are optional for toxicity categories III and IV):

"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 non-WPS products

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 should be used to contain all non-WPS worker related restrictions. In either case, the registrant should submit a master label that clearly distinguishes between the two separate sub-labels. The registrant should not provide the WPS labeling merely as a supplemental label to a non-WPS product. See *PR Notice 93-7*.

Many pesticide products also contain residential consumer uses along with WPS and non-WPS 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 uses, and the other containing the residential consumer uses.

VI. Precautionary statements

There are four types of worker protection statements that generally appear in the Precautionary Statements of a label. They are as follows:

A. Handler Personal Protective Equipment (PPE)

B. Statements for Contaminated PPE

C. Engineering Controls

D. User Safety Recommendations

Certain precautionary statements are required by Part 156 Subpart K (Worker Protection Statements (*40 CFR 156.200-212*) for products subject to the WPS. These statements may also be needed on non-WPS products if required by a regulatory assessment 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)

- **Determining the Correct Product-Specific PPE Requirements.** The correct handler PPE to be specified on the product labeling is determined by comparing the product-specific handler PPE requirements specified in the Acute Toxicity Review for a product with the chemical-specific handler PPE requirements specified in the regulatory assessment document. In most cases, the reviewer uses a combination of the most protective PPE requirements given in the regulatory assessment document and the Acute Toxicity Review to determine the correct handler PPE labeling statements.

  As noted above, the correct product specific handler PPE should be specified in the Acute Toxicity Review for a given product. The process used to derive the correct product-specific handler PPE is described in sections 1 through 4 below. In some cases the reviewer may need to use this process to determine the correct product-specific handler PPE labeling statements if the required handler PPE information isn't specified

in the Acute Toxicity review or if there are questions about the specified PPE requirements.

- **Compare Product-Specific PPE with PPE Required by the Regulatory Assessment Document.** After completing sections 1 through 4 below and identifying the correct handler PPE based on the product-specific acute toxicity data (or based on the Acute Toxicity Review), the reviewer should consider the handler PPE required by the regulatory assessment document for the active ingredient (such as a RED), if one has been published. A combination of the most protective PPE specified in the Acute Toxicity Review (or derived from sections 1 through 4 below) and the regulatory assessment document must be used to determine the appropriate product labeling. For guidance on which PPE is considered more protective, consult Table 7 below.
- Note: All end-use **occupational use products** (WPS or non-WPS) need to have the minimum baseline label-required work clothes for handlers consisting of long-sleeved shirt, long pants, socks and shoes. Technically these work clothes items are not considered PPE, but they can be required on labels (see 40 CFR 170.240 (b)).

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	Coveralls worn over short-sleeved shirt and short pants	Long-sleeved shirt and long pants	Long-sleeved shirt and long pants
	Socks	Socks	Socks	Socks
	Chemical-resistant footwear	Chemical-resistant footwear	Shoes	Shoes
	Waterproof or Chemical-resistant Gloves[2]	Waterproof or Chemical-resistant Gloves[2]	Waterproof or Chemical-resistant Gloves[2]	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 2 below to determine if additional PPE is required beyond that specified in Table 1

[2] Refer to Section 3, Table 3 to determine the specific type of waterproof or 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, unless the assessment requires a specific type of eyewear for adequate protection.

2. **Identifying Additional Product-Specific Handler Protective Clothing (Apron and Headgear).** In addition to PPE listed in Table 1, additional, more protective 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 (See *40 CFR 156.212(i)*)

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 WPS Handlers.** The specific glove or gloves that are acceptable to meet the requirements for handler PPE must be listed on the label. See *40 CFR 156.212(f)*. Table 3, the EPA Chemical Resistance Category Selection Chart for Gloves, lists the types of waterproof or chemical-resistant gloves for products classified as toxicity category I, II, or III for acute dermal toxicity or primary skin irritation. See *40 CFR 156.212(e)*. It is EPA's current view that the Chemical Resistance Category Selection Chart for Gloves should not be placed or referenced on the product label. The chart is intended for EPA and registrant guidance only to determine the required glove type and glove statement for the label. Do not list the solvent category (A-H) on the product label.

   - **Determining the Correct Product-Specific Glove Requirements for WPS Handlers.** The correct glove type(s) to be specified on the product labeling for WPS-defined handler activities is determined based on the solvent in the product formulation. Table 4 below lists the solvent category for common solvents. The glove(s) selected must be rated as providing a "high" level of chemical resistance for the solvent category found

in Table 4 in order to be listed as an acceptable glove type on the product labeling for WPS handling activities.

Table 4 provides a listing of solvents that EPA believes are likely to be contained in pesticide products that are subject to the Worker Protection Standard. The appropriate chemical resistance category is listed for each solvent. IMPORTANT NOTE: If the chemical resistance category for a solvent is listed as "F or G", then the correct category is: "F" if the solvent constitutes less than 40 percent of the end-use product; or "G" if the solvent constitutes 40 percent or more of the end-use product. For those solvents not listed, the label reviewer should contact the Health Effects Division's Chemistry and Exposure Branch (CEB-I).

- **Glove Requirements for WPS Handlers for Products in Solvent Category A (Dry and Water-Based Formulations).** Products in solvent category A (i.e., those with dry or water-based formulations) DO NOT require chemical-resistant gloves. Waterproof gloves provide the necessary handler protection. For category A, listing of specific gloves types is not necessary. The correct glove statement for solid and aqueous-based product formulations in solvent category A is indicated below:

  (a) Solid Formulations: For those products which are applied as solids or formulated as solids and diluted solely with water for application, the glove statement shall specify: "**Wear waterproof gloves**". See *40 CFR § 156.212(f)(2)*.

  (b) Aqueous-Based Formulations: For those products which are applied as formulated, and/or diluted solely with water for application, the glove statement shall specify: "**Wear waterproof gloves**" . See *40 CFR 156.212(f)(3)*.

- **Glove Requirements for WPS Handlers for Products in Solvent Categories B – H (Other Liquid Formulations).** For all other liquid formulation products which are not aqueous-based, and applied as formulated or diluted with liquids other than water, (constitutes more than 5% of the end-use product), the glove statement shall direct users to wear the chemical resistant gloves specified, and the label statement shall specify **ALL** of the acceptable glove types from Table 3 that provide a **"high"** level of chemical resistance for the solvent category of the product in question.

  Based on Table 3, the correct glove statement for handlers for a product in solvent category B would be, "Wear butyl rubber or barrier laminate gloves". The correct glove statement for handlers for a product in solvent category H would be, "Wear barrier laminate or viton gloves". *40 CFR 156.212(f)(4)*.

- **NOTE: It is important that ONLY glove types rated as providing a "high" level of chemical resistance for the product's solvent category found in Table 4 are selected as acceptable glove types for listing on the product labeling for mixing, loading, or application.**

- **NOTE: It is important that ALL glove types that provide a high level of chemical resistance for the solvent category be listed on the label as acceptable glove types so users have flexibility to select the most cost-effective glove option that will provide the required protection.**

- **Glove Requirements for WPS Handlers for Gaseous Formulations or Formulations Applied as Gases.** For products that are applied or formulated as gases, any existing glove statement established before 10/20/1992 including any glove prohibition statement will continue to apply. If no glove statement or glove prohibition currently exists on the label, then the glove statement shall be "wear nitrile or butyl rubber gloves". *40 CFR 156.212(f)(5)*

- NOTE: Registrants 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 needs to justify why the alternative glove should be used. The label must indicate the specific type of chemical-resistant glove(s) that must be worn (for example, Wear nitrile or butyl rubber gloves; statement would be appropriate for the category of solvent). See *40 CFR 156.212(f)(1)*.

Table 3. EPA Chemical Resistance Category Selection Chart for Gloves

(For use when selecting glove types to be listed in the PPE section on pesticide label. Only select glove(s) that indicate a high level of chemical resistance.)

Solvent Category (see Table 4)	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)	high	high	high	high	high	high	high	high
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 within an hour or two of contact
SLIGHT: Slightly chemical-resistant. Clean or replace within 10 minutes of contact
NONE: No chemical-resistance.

NOTE: The EPA Chemical Resistance Category Selection Chart for Gloves should never be placed or referenced on the product label; it is intended for EPA and registrant guidance only.

Table 4. Solvent List (PRN 93-7, Supplement 2)

Solvent (chemical name or Trade name)	Chemical Resistance Category	Solvent (chemical name or Trade name)	Chemical Resistance Category
Acetone	B	Isopar L	E
Amyl Acetate	D	Isopar M	E
Aromatic 100	F or G	Isopar V	E
Aromatic 150	F or G	Isophorone	B
Aromatic 200	F or G	Isopropanol	C
Aromatic Petroleum	F or G	Kerosene	E
Butoxypolypropylene glycol	C	Methanol	C
Butyl acetate	D	Methyl amyl ketone	B
Cyclohexanone	B	Methyl Carbitol	C
Diacetone alcohol	C	Methyl isobutyl ketone	B
Diethanolamine	C	Mineral oil	E
Diesel fuel	E	Mineral spirits	E
Dipropylene glycol monothylether	C	Naphtha	E
Ethanol	C	N-methyl pyrrolidone	B
Ethylene glycol	C	Penreco 2251 oil	E
Exxon 589	E	Petroleum Distillate (aliphatic)	E
Heavy Aromatic Naphtha	F or G	Petroleum oil	E
Hexylene glycol	C	Propylene glycol	C
Isopar B	E	T 500-100	F or G
Isopar C	E	Tetrahydro-furfuryl alcohol	C
Isopar E	E	1,1,1-Trichloroethane	H
Isopar G	E	Water	A
Isopar H	E	Xylene	F or G
Isopar K	E	Xylene range solvents	F or G

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. See *40 CFR 156.212(g)*. Review the RPD types in Table 5 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 5 would not provide adequate protection or could pose an increased risk to the user.

   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 Part 84 regulation created a total of nine classes of particulate filters; these classes apply only to nonpowered, air-purifying, particulate filter respirators.

Table 5. Respirator Language

Pesticide Type	Vapor Pressure (mmHG)	Respirator Language	
		Oil in Application Mix	No Oil in Application Mix
Non-Organic Gaseous Products: Products that are formulated or applied as a gas that are not organically based such as phosphine	1×10^{-3} or lower	Case by case basis	Case by case basis
Organic 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	1×10^{-3} or lower	For handling activities in enclosed areas, use either a NIOSH approved supplied-air respirator with NIOSH approval number prefix 19C; or a self-contained breathing apparatus (SCBA) with NIOSH approval number prefix TC-13F.	For handling activities in enclosed areas, use either a NIOSH approved supplied-air respirator with NIOSH approval number prefix 19C; or a self-contained breathing apparatus (SCBA) with NIOSH approval number prefix TC-13F.
Organic Gaseous Products Applies Outdoors: products that are formulated or applied as a gas (space and soil fumigants) and that may be applied outdoors must bear labeling specidying the following RPD requirements and statement:	1×10^{-03} or lower	A NIOSH-approved respirator with an organic vapor (OV) cartridge with a combination R or P filter, with NIOSH approval number prefix TC-84A; or NIOSH approved gas mask with an organic vapor canister with NIOSH approval number prefix TC-14G; or a NIOSH approved powered air purifying respirator with organic vapor (OV) cartridge and combination HE filter, with NIOSH approval prefix TC – 23C.	A NIOSH-approved respirator with an organic vapor (OV) cartridge with a combination N, R, or P filter with NIOSH approval number prefix 84A; or NIOSH approved gas mask with an organic vapor canister with NIOSH approval number prefix TC – 14G; or a NIOSH approved powered air purifying respirator with organic vapor (OV) cartridge and combination HE filter with NIOSH approval number prefix TC 23C.

Solid Products: Products that are formulated and applied as solids.	**NA**	**A NIOSH approved particulate respirator with any R or P filter with NIOSH approval number prefix TC-84A; or a NIOSH approved powered air purifying respirator with HE filter with NIOSH approval number prefix TC-21C.**	**A NIOSH approved particulate respirator with any N, R or P filter with NIOSH approval number prefix TC-84A; or a NIOSH approved powered air purifying respirator with HE filter with NIOSH approval number prefix TC-21C.**
Liquid Products in Toxicity Category I: Products that are formulated or applied as liquids:	**Lower than 1 x 10^{-05}**	**A NIOSH approved particulate respirator with an R or P filter with NIOSH approval number prefix TC – 84A.**	**A NIOSH approved particulate respirator with any N, R, or P filter, NIOSH approval number prefix TC-84A .**
	Greater than 1 x 10^{-05}	**A NIOSH approved respirator with an organic vapor (OV) cartridge with a combination R or P filter, with NIOSH approval number prefix TC – 84A; or a NIOSH approved gas mask with an organic vapor canister with NIOSH approval number prefix TC – 14G.**	**A NIOSH approved respirator with an organic vapor (OV) cartridge with any combination N, R or P filter with NIOSH approval number prefix TC – 84A; or a NIOSH approved gas mask with an organic vapor canister with NIOSH approval number prefixTC – 14G.**
Liquid Products in Toxicity Category II: Products that are formulated or applied as liquids	**Lower than 1 x 10^{-04}**	**A NIOSH approved particulate respirator, with any R or P filter with NIOSH approval number prefix TC-84A.**	**A NIOSH approved particulate filter with any N, R, P filter with NIOSH approval number prefix TC-84A.**
	Greater than 1 x 10^{-04}	**A NIOSH approved respirator with an organic vapor (OV) cartridge with a combination R or P filter, with NIOSH approval number prefix TC – 84A; or a NIOSH approved gas mask with a canister with NIOSH approval number prefix TC – 14G; or a NIOSH approved powered air purifying respirator with organic vapor**	**A NIOSH approved respirator with an organic vapor (OV) cartridge with a combination N, R or P filter with NIOSH approval number prefix TC – 84A; or a NIOSH approved gas mask with a canister with NIOSH approval number prefix TC – 14G; or powered air purifying respirator with organic vapor (OV) cartridge and**

		(OV) cartridge and combination HE filter with NIOSH approval number prefix TC – 23C.	**combination HE filter with NIOSH approval number prefix TC – 23C.**

(a) Selection Criteria. 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. 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. See *PR Notice 98-9*.

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 product chemistry reviewer.

(b) Respirator types for which label language changes are not required at this time. The following are types of respirators which are NOT subject to change per *PR Notice 98-9*:

- Powered air purifying respirator equipped with a high efficiency particulate air (HEPA) filter (NIOSH approval number prefix TC-21C).
- Powered air purifying respirator equipped with an organic-vapor (OV) removing cartridge plus a high efficiency (HE) filter (NIOSH approval number prefix TC-23C).
- Powered air purifying canister-type respirator (gas-mask) equipped with an organic vapor canister that incorporates HE filters (NIOSH approval number prefix TC-14G).

Table 6. Oil Resistance and 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).

Table 7. 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	Waterproof or 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	Particulate filtering facepiece respirator[1]	Respirator with a vapor removing cartridge or canister with a particulate prefilter[2]	Air Supplying Respirator

[1] Can be used only for filtering particulates: it is not adequate if vapor pressure indicates a vapor-removing filter is needed.
[2] Can be used when it is necessary to filter both particulates.

5. **Required Location for Handler PPE.** Handler PPE statements for applicators and other handlers must appear in the PRECAUTIONARY STATEMENTS section of the labeling in the "HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)" section. See *40 CFR 156.212(c)(1)*.

6. **States May Require the Use of Additional PPE.** The Agency will approve additional state-required language if it is clear that it applies only in that state.

B. Statements for Contaminated PPE

The statements for contaminated PPE must appear in the PRECAUTIONARY STATEMENTS section of the labeling. The preferred location is directly below the Personal Protective Equipment. Remember to check the regulatory assessment document, if one has been completed, for specific User Safety and PPE requirements such as engineering controls. All occupational use products must bear the following statements:

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

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".*

C. Engineering Controls

Engineering Controls (eg. closed systems, enclosed cabs, lock and load containers) may be required by the regulatory assessment document or by the Acute Toxicity profile of a given product. The following statement should appear on the label in the Precautionary Statement section unless supplemented or superseded by a regulatory assessment document:

> *"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".*

1. **For Toxicity I and II Products packaged in water soluble package.** If a product is in Toxicity Category I or II (signal word Danger or Warning) for either acute dermal toxicity or skin irritation potential, then the following statements shall appear on the label unless supplemented or superseded by a regulatory assessment document:

   "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.

   [*insert "NOTE" here that would be added to any WSP engineering control statement that specifies the correct use (mixing/loading) procedures that must be followed for a WSP product to be allowed closed system status.*]

   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. **For Toxicity III and IV Products Packaged in Water Soluble Packages or other similar devices (e.g., gel packs).** If a product is in 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 may appear on the label unless supplemented or superseded by a regulatory assessment document:

   "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.

   [*insert "NOTE" here that would be added to any WSP engineering control statement that specifies the correct use (mixing/loading) procedures that must be followed for a WSP product to be allowed closed system status.*]

   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".

D. User Safety Recommendations

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 regulatory assessment 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 regulatory assessment documents or found on many products.

Example of a User Safety Recommendations Box showing sample language:

"User Safety Recommendations"

"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

For products subject to the WPS, there are four types of worker protection statements that generally appear in the Directions for Use of a label. They are as follows:

A. Required Statements;

B. Agricultural Use Requirements Referral Statement for Supplemental Labeling;

C. Agricultural Use Requirements Statement; and

D. Statements for Products with both WPS and Non-WPS Uses.

A. Required 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.

"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 the additional language presented in section C (2) below 40 CFR 156.206(a).

"For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation". 40 CFR 156.206(d).

B. Agricultural Use Requirements Referral Statement for Supplemental Labeling

This statement should be used if you put the Agricultural Use Requirements Box in Supplemental Labeling. It must appear on the product label near the statement referring users to the supplemental labeling and must be placed IN A BOX under the heading AGRICULTURAL USE REQUIREMENTS.

"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".

C. Agricultural Use Requirements Statements

1. **Required Statements.** The following statements must also appear on all labeling for all WPS products. 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.

   "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 the label (in this labeling) about (use any of the following that are applicable) personal protective equipment, restricted-entry interval, and notification to workers." 40 CFR 156.206(b)(2).

2. **Restricted Entry Statements.** An REI is the time period immediately following a pesticide application during which entry into the treated area is restricted. REIs can be determined by referencing Supplement Three-A of *PR Notice 93-7*, the regulatory assessment document or by using the guidelines listed below. If the REI established by the regulatory assessment document is different from the guidance below, the REI established by the regulatory assessment document must be required on the label. Some labels may have several different REIs for different crops. The label must include the following statement under the "AGRICULTURAL USE REQUIREMENTS" heading (*40 CFR 156.208(a)*):

   "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)".

   (a) 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/m3 is reached." 40 CFR 156.208(b)(1).

   (b) Crop- or use-specific REI(s): If different REI's exist for 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". 40 CFR 156.208(b)(2).*

(c) 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. *40 CFR 156.208(c)(2)*.

3. **Early Entry PPE.** All products subject to the WPS should 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:"

   (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 hander requirement for gloves, then the early-entry requirement shall be *"chemical resistant gloves (made of any waterproof material)"*.

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

   (a) **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".

   (b) **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".

   To identify the toxicity category follow the steps below:

   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 for all active ingredients (a.i.(s)) in the product;

b. If acute dermal data are missing for any a.i., consider acute oral data for 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 for any a.i. in the product, consider the signal word of the end-use product.

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.

(c) Location of Statement. All notification statements must be located in the DIRECTIONS FOR USE section in the box with the heading AGRICULTURAL USE REQUIREMENTS. If notification is not required (because the product meet the toxicity criteria or is not a fumigant), the reviewer should make sure that the statement about notification to workers is not included in the Agricultural Use Requirements box.

A. Statements for Products with both WPS and Non-WPS Uses

If the label contains only uses within the scope of the WPS, skip this section. If the label contains or the regulatory assessment document 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.

This box may be placed anywhere in the Directions for Use section of the label after the Agricultural Use Requirements box and must contain the following statements (*PR Notice 93-7, Supplement 3*):

"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".

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 regulatory assessment document. If a regulatory assessment 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

REI(s) will be retained.

C. All Other REI(s).

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

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

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

Table 8. 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.

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

Table 9. Determining the REI (See 156.208)

Most Severe Tox Category Usedto 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 10/20/1992, 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. If a product is reduced risk, the REI may be 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) The active ingredient has not been the subject of a Reregistration Eligibility Decision (RED) document or other risk assessment which concluded that a longer REI was necessary to protect workers. Active ingredients with REIs established during reregistration activities are NOT eligible for reduced REIs.

4. 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)

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

NO: No action is necessary.

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 (from *PR Notice 93-7*, Supplement 3, page 39)

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

NO: No action is necessary.

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)

If the current product labeling or risk assessment does not contain any requirements or recommendations for the use of closed systems, enclosed cabs, or open or enclosed cockpits, then the following paragraph may be added 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".

1. 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)

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

1. If the product does not have any PPE requirements, do nothing.
2. 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:"

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

   (b) 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

– 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.

APPENDIX A. Summary Table of the Scope of WPS

CRITERIA	Subject to WPS?
Product is a manufacturing use product, or an unregistered pesticide used under an experimental use permit issued under *FIFRA section 5*, or under an exemption issued under *FIFRA section 18*.	NO
Product bears directions for use on an agricultural establishment or 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; turf grass; flowers, shrubs; ornamentals; and seedlings). Or the product bears labeling that could reasonably permit such a use.	YES
EXCEPTIONS: The use sites below are not subject to WPS	
Mosquito abatement, Mediterranean fruit fly eradication, or similar area wide public pest control programs sponsored by governmental entities.	NO
Use on livestock or other animals, or in or around animal premises.	
Plants grown for other than commercial or research purposes, which may include plants in habitations, home fruit and vegetable gardens, and home greenhouses.	
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.	
Use 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.	
Control of vertebrate pests.	
Use as attractants or repellents in traps.	
Post harvest treatments on the harvested portions of agricultural plants or harvested timbers.	
Research uses of unregistered pesticides.	
Commercial seed treatment that is only allowed to be conducted off-farm. (e.g. Seed treated at factories that are placed in containers/bags.)	

Revised October 2013

Label Review Manual

Chapter 11: Directions for Use

USDA NRCS

I. Introduction

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

II. Purpose of directions for use

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

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

Special Reminder to Reviewers

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

The directions for use reflect the Agency's determination that the use of the product in such a manner does not cause unreasonable adverse effects on the environment under FIFRA. The Directions for Use section should be organized and carefully worded so that the directions are understood by the person expected to use or to supervise the use of the pesticide. Sentences should be written to indicate whether any actions are mandatory or advisory. Other sentences in the use directions may be used only to convey background information.

III. Enforceability of directions for use

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

- **Any direction or precaution that is necessary to achieve effective, safe use of the product must be stated in mandatory terms (e.g., must, will, do not)** Do not allow the use of terms such as "can", "should" or "may" if the statement is intended to be mandatory. See *PR Notice 2000-5* and *Chapter 3* of this manual for more information on mandatory versus advisory language.
- **Any direction that is not truly necessary for effective, safe use of the product, or which is too vague or subjective for a user to clearly follow**, must NOT be stated in mandatory terms. Such informational or advisory statements should be factual and provide a reason for the desired behavior, as described in Chapter 3 discussion of mandatory versus advisory language.
- **Use terms with specific definitions whenever possible.** Terms that are defined in FIFRA, by Federal Agencies, or give clear instruction are preferable. For example, terms such as "near", "around", and "windy" do not have clear definitions and may cause confusion. A clear statement, such as "in winds strong enough to move spray away from treatment area", would be preferable to "windy". To define a soil type use of USDA standard terminology, such as "sandy loam", is appropriate. (For soil classifications see *http://websoilsurvey.nrcs.usda.gov/app/* or *Soil Properties: Texture*)
- **Clearly separate advisory and mandatory statements.** Intermingling advisory and mandatory language can cause confusion and make the intent of the statement(s) or an entire section unclear. If separation is not practical, the intent of each statement as mandatory or advisory needs to be clear.
- **Ensure that section headings are appropriate to all material contained beneath it**. For example, if a heading includes the term "recommended", everything in that section must be intended to be purely advisory and need not be followed for safe and effective use of the product. If we believe a statement is necessary for proper use, the term "recommended" would not be accepted.
- **"For Use Only by" statements should not be approved unless it refers to a group that can be clearly defined by FIFRA, an applicable regulation or an EPA policy which has defined an identifiable group of users—such as persons licensed by the state for termite control** (*PR Notice 96-7*) or employees of mosquito control agencies (*PR Notice 2005-1*). For example, statements such as "For professional use only" or

"For commercial use only" do not have accepted definitions, and the apparent "limitation" is meaningless and unenforceable, and may be considered misleading.

- **Avoid "avoid".** The term "avoid" poses particular problems. The Agency views the term as mandatory, however it also recognizes that some users may perceive the term as advisory, or may see it as a weaker statement than the clear prohibition of "do not". Reviewers should strongly discourage the use of the word "avoid" for this reason.

IV. Review strategy for directions for use

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

A. General Strategy for All Labels

1. **Charts, Tables, and Formats.** Labels should be presented so they are easy to read and understand by the user. The *Consumer Label Initiative (CLI)* research, as well as other label research done around the world, shows that in many cases graphics (charts, graphs, symbols, or pictures) can be used to help convey information and may be useful in the Directions for Use portion of the label. However, care needs to be taken that the graphics do not contain or imply false or misleading information and they provide accurate information in a clear, concise and complete manner.

   Subheadings, like paragraph headings in a book, help to organize the information and also make it easier to find. Information presented in a "bulleted" format is easier to read and understand than longer narrative paragraphs, even when the same type size is used. When more lengthy and complicated information is required, a tabular format may be easier to follow.

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

   The following are some suggested formats:

   (a) Bulleted Format. When using the bulleted approach, the intent is not to leave information out, but to make it visually easier to follow. Either partial, or complete, sentences can be used. Any type of character could be used as the "bullet".

Example of Bulleted Format:

DIRECTIONS FOR USE

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

Precautions

- Use may damage marble surfaces.

Restrictions

Do not apply to porous surfaces

Application Instructions

- Turn nozzle to "Spray" or "Stream".

For Cleaning:

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

To Control Mildew:

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

To Disinfect:

1. For heavily soiled surfaces, pre-clean according to Cleaning Directions.
2. Spray until thoroughly wet.
3. Let stand 10 minutes before wiping or rinsing.

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

Examples of Modified Paragraph Format:

Application Instructions:

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

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

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

Table 1. Tabular format

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

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

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

- Some labels may be very old.
- Previously accepted uses and language may no longer be recommended.
- Agency guidance such as PR Notices may have been updated or clarified.

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

3. **Consult Essential Document References.** Various policy documents including Pesticide Registration Notices provide guidance on particular issues. Label reviewers should use the guidance along with the applicable laws to make case-by-case determinations on the acceptability of label language. In addition, reviewers should consult:
   - Applicable documents and guidance policies for the active ingredient(s) including: Registration Review Decision documents, Reregistration Eligibility Decisions (RED, IRED, TRED) Biopesticide Registration Action Documents (BRAD), Science assessments, etc.
   - Applicable product-specific data evaluation records and assessments,
   - Labels of substantially similar or identical products,
   - The Registration Standard (if there is one not superseded by a RED),
   - For new or revised uses, available science/technical reviews, or the efficacy reviewer,
   - The *40 CFR, Part 180* for published tolerances supporting food/feed uses, and
   - Current Pesticide Registration (PR) Notices.

   Pesticide Registration (PR) Notices are issued by the Office of Pesticide Programs to inform pesticide registrants and other interested persons about important policies, procedures and regulatory decisions. PR notices are important resources to help the label reviewer stay informed about current regulatory policies in OPP. These documents are available at: *Pesticide Registration (PR) Notices | Pesticides | US EPA*.

   If a Reregistration Eligibility Decision (RED) Document has been issued for the active ingredient in the product undergoing review, the reviewer must ensure that:
   - All of the use sites on the label are in Appendix A of the RED (or have been evaluated and approved by OPP in a subsequent regulatory document);
   - The site(s)/pest(s) are all eligible for Reregistration; and
   - If any of the uses have been declared ineligible for reregistration, the use may not be reregistered.

Further, if the product contains more than one active ingredient, *all uses* on the label must be acceptable for *all* of the active ingredients. If there is more than one a.i. in the product and a RED is available for each, all sites on a label must be listed in each RED.

4. **Consult Subject Matter Experts.** The "Directions for Use" portion of a label can become very complex depending on the number of sites, pests claimed and application methods. If a label seems to present problems of clarity, organization, enforceability or consistency with EPA policy, reviewers should seek advice.

   Reviewers should first consult PM/team leaders or efficacy reviewers. PM/team leaders may raise more difficult questions to their branch chief, or, in cases of "mandatory or advisory" issues or other enforceability questions, may directly contact staff in the Office of Enforcement and Compliance Assurance for advice.

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

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

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

   Note that it is allowable to say "intended for use by (type of user), but not with the word "only". "Intended for use" statements are recognized by state regulators as advisory and not enforceable. The terms "maintenance applicator" and "service technician" are defined in FIFRA section 2 (jj) and (kk) respectively, but these terms do not seem to be in use by pesticide registrants. Several specific user groups that can be identified as the

only allowable users for non-RUP products in certain situations are described in Section V. D, E and F of this chapter.

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

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

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

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

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

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

   Assuming that the "100 to 200 gals." refers to diluted spray mix, improved instructions would be:

   "To make spray solution, mix 1/2 to 2 pints of this product in 100 gals. of water. Apply 100 to 200 gals. of diluted spray solution per acre to trees

depending on tree size and the coverage obtained with the spray equipment used".

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

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

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

Target pests or use sites found on the registered product's label may be omitted from the identical or substantially similar product's labeling. For example, an identical application is made for an insecticide formulation to add structural perimeter treatments for crickets, ants, and sowbugs. The registered product referenced in the identical application must be labeled for this site, and its label must claim crickets, ants, and sowbugs; although other species (earwigs, millipedes) also may be claimed on the registered label. While the pending submission need not have all the pests listed on the registered label, no *new use sites or pests* may appear on the label for the pending identical or substantially similar product. The format for the presentation of use information on the identical or substantially similar label need not be identical to the format on the registered (cited) label as long as the critical information as described above remains the same and the identical product meets applicable legal requirements on labeling.

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

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

When a registrant's application is not for an identical or substantially similar product as when a registrant proposes a new use, new application rate, preharvest interval (PHI) change, or another action not previously approved by the Agency, a more extensive review than the simple comparison is necessary. Such applications usually must be accompanied by relevant data and/or data citations, and should be sent for technical review. The "Directions for Use" on the proposed label may need to be altered due to the outcome of the science/technical review (i.e., use rates on crops, PHIs, reentry intervals, restrictions such as

bee hazard warning statements, application rates and methods may have to be added or modified). The use rate, or application rate, may be the most difficult part of this section to interpret and review. Application rates and number of applications per season for agricultural products may be affected by the residue data submitted or cited by the registrant. Approval of most agricultural uses requires that an appropriate tolerance be established because of the pesticide chemical residue on food.

V. Additional review strategies for specific products

A. Manufacturing-Use Product (MP)

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

1. "Directions for Use" heading;
2. Misuse Statement(s);
3. The statement "For Formulation Into A (type of pesticide)" followed by a continued statement of the uses (crops/sites or other uses) for which the end-uses product (EP) may be registered and uses for experimental purposes that are in compliance with FIFRA.

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

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

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

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

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

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

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

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

B. Typical End-Use Pesticide Products

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

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

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

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

C. Experimental Use Permits

In general, the directions for use on experimental use permit labels must follow the same label requirements as products registered under FIFRA Section 3. The directions for use must be consistent with section G of the permit. The label reviewer should ensure that the

site, pests, and application method on the submitted label match those listed in their permit. Refer to *Section III.(I) of Chapter 4* for more information on Experimental Use Permits.

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

"For Experimental Use Only".

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

"For Experimental Use Only

For use only at an application site of a cooperator or participant and in accordance with the terms and conditions of the Experimental Use Permit. Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Permit program. This label must be in possession of the user at the time of pesticide application. For use in the following states only: (insert states listed on permit)".

D. Pesticide Product Intended for Use Only By Physicians, Veterinarians or Pharmacists

Directions for Use sections on labels for products of these types may be very limited in content. However, this provision applies only when the product is also classified as a drug and regulated as such under the provisions of the *Federal Food, Drug and Cosmetic Act (FFDCA)* (see *40 CFR 156.10(i)(1)(iii)(B)(3)*).

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

"This product may only be used by veterinarians/physicians".

E. Termiticides

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

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

Termiticide products already classified for "Restricted Use" will remain so classified and must bear the required restricted use statements on product labeling. Consult *PR Notice 96-7* for further guidance on termiticide labeling.

F. Adult Mosquito Control Products

If the product is an adult mosquito control product, applications should be limited to trained personnel. (See *PR Notice 2005-1*.)

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

VI. Standard elements

All standard elements and language required by FIFRA and the applicable regulations to appear in the Directions for Use must be placed on the label in the locations specified for them if FIFRA or applicable regulations do specify a location; however, not all elements have such a specified location. These elements should be presented on the label:

- "Directions For Use Heading"
- Use Classification Statement
- Misuse and Related Statements
- Worker Protection Standard (WPS) Requirements (if applicable)
- l Instructions and Information Subheading (if applicable)
- Use Restrictions (if applicable)
- Chemigation Information (If applicable)
- Spray Drift Language (if applicable)
- Endangered Species Statement (if applicable)
- Storage and Disposal Statements

A. Directions for Use Heading

The heading of the Directions for Use section of the label must be **"*Directions for Use*". It may not have any other title.** Headings such as "General Directions", "Use Directions", "Recommendations for Use", "Recommended Uses", "How to Use", or any other similar wording are not acceptable.

The heading "Directions for Use" may be capitalized, put in bold type, and/or underlined to give it proper emphasis. The heading must be of such prominence and placement on the label that it is clear that all subsequent components of the section fall under the main

heading "Directions for Use". Such prominence can be assured by putting the heading in the largest, most conspicuous type that is used in the section and by centering the heading on the label panel while left-justifying all subheadings within the section.

B. Use Classification Statement

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

C. Misuse Statement

Experimental Use Permits and all registered pesticides, including all end-use and manufacturing use products, must bear labeling which has the following statement immediately below the Use Classification:

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

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

"STOP! Read the label before using".

"Use only as directed on this label".

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

"Failure to follow all precautions and directions is illegal".

D. Worker Protection Standard (WPS)

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

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

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application". (For wide-area treatments, see section 3c below under Directions for Use)

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

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

E. Instructions and Information Subheading

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

F. Use Restrictions

Non-site- specific precautions, restrictions or limitations of the product comprise another important type of use restriction information in the Directions for Use section. Such a restriction may consist of an imperative sentence—practically any sentence that begins with a verb and ends in a period—or any other sentence which requires or forbids certain action (See Section III of *Chapter 3* for discussion of mandatory labeling statements). Use restrictions may also be phrased as requirements by using words such as "must", "never", and "always". Any precautions and restrictions that apply to specific site(s) and pest(s) must be included in the directions specific to that combination. Use restrictions may be required by the Agency to meet the unreasonable adverse effects standard or proposed by the registrant or applicant. Such restrictions may include, but are not limited to, the following categories:

- User Restrictions;
- Rate Restrictions or Limitations;
- Site, Pest, Timing, Weather, Soil, Geographic Restrictions;
- Equipment, or Application Method Restrictions;
- Miscellaneous Precautions such as Staining, Phytotoxicity, Incompatibility with Other Products, etc.; and
- PHIs or Rotational Crop Restrictions (unless site-specific).

1. **Appropriateness of Precautions and Restrictions.** The reviewer must carefully assess each restriction or limitation to make sure that it does not place on the product obligations that the user cannot reasonably carry out.

   For example, an aquatic herbicide for use in ponds and lakes might have a restriction like:

   "POTABLE WATER: Delay the use of treated water for domestic purposes for a period of three weeks or until such time as an approved assay shows that the water contains no more than 0.1 ppm (herbicide active ingredient)".

Because any number of applicators could be using the product in public ponds or lakes used by many households or municipalities, the applicator may have no reasonable way of complying with such a restriction. Either another risk mitigation measure must be developed, or the product should be given restricted use status.

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

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

2. **Use-Related Restrictions.** Any other appropriate information (precautions or restrictions) should be presented in the restrictions subsection unless such statements apply only to some of the uses permitted by the label, in which case the statements belong with directions for specific site and pest groupings. Use related information can include restrictions regarding the timing of application, weather, soil conditions, geography, or other relevant considerations. This information should be appropriate for the intended user(s), site(s), and pest(s) listed on the label.

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

G. Resistance Management Labeling Considerations

The Office of Pesticide Programs (OPP) of the EPA has developed voluntary pesticide resistance management labeling guidelines based on target site/mode of action (MOA) for agricultural uses of herbicides, fungicides, bactericides, insecticides, and acaricides. MOA refers to the biochemical mechanism by which the pesticide acts to control the pest and should not be interpreted to imply that these chemicals share a common toxicological mechanism for purposes of cumulative human health risk assessment under FIFRA and the Federal Food, Drug, and Cosmetics Act (FFDCA).

Rotation of MOA action was selected as a primary pest/pesticide resistance management strategy for this voluntary regulatory initiative rather than metabolic resistance, because it is the easiest for reducing the likelihood of resistance, especially monogenic resistance, and it

will help reduce the likelihood of resistance caused by other mechanisms. The rotation of MOA is a scientifically-sound, flexible, and practical resistance management strategy. Other management practices that will reduce resistance include application timing, crop rotation and other cultural practices, and application equipment cleaning. The voluntary resistance management guidelines based on rotation of MOA are found in *Pesticide Registration Notice 2001-5.* These guidelines were developed under the auspices of the North American Free Trade Agreement (NAFTA) by both the U.S. and Canada. Canada published similar guidelines to those of the U.S. in October 1999 as *Regulatory Directive 99-06.* Both countries agreed that uniform labeling guidance across North America would encourage adoption of resistance management strategies and help reduce the development of pest resistance.

In support of these goals, the resistance management guidelines based on rotation of MOA provide guidance to users about pesticide classes and pesticide management strategies. Adoption of these guidelines will provide users with easy access to information regarding target site/mode of action resistance.

The objective of the voluntary resistance management labeling guidelines (*PR Notice 2001-5*) is to include pesticide mode of action symbols and resistance management recommendations on the labels of all new and existing pesticide products for agricultural uses. The management of pesticide resistance is an important part of sustainable pest management and this, in conjunction with alternative pest management strategies and Integrated Pest Management (IPM) programs, can make a significant contribution to reducing pesticide risk to humans and the environment. When used, the mode of action (MOA) numerical classification symbol(s) are recommended to be placed in the upper right hand corner of the front-panel of end-use product labels, although the numerical classification symbol can be placed elsewhere on the label. The numerical MOA classifications are found in the Appendices of PR Notice 2001-5. A sample of this is:

GROUP	1	HERBICIDE

In addition to the MOA classification symbols, a registrant may choose to have resistance management statements on the label. If used, these statements should be included in the "Use Directions" for end-use products for the control of weeds, plant pathogens (diseases), insects and mites under the heading "Resistance Management Recommendations". These statements should be clearly distinguished from mandatory statements (see *PR Notice 2000-5*, "Guidance for Mandatory and Advisory Labeling Statements") on the pesticide label to avoid confusion to the users.

Pesticide Registration Notice 2001-5 provides examples of standard resistance management labeling statements that focus on the following areas: (1) avoid repeated or sequential use of products in the same MOA class through rotation of MOA; (2) if tank mixes or premixes are legally allowed, makes sure each compound is from a different MOA class; (3) use an effective IPM program; (4) monitor for loss of product performance; (5) contact your

extension specialist, certified crop consultant, or manufacturer for the latest resistance management information; and (6) contact the pesticide producer to report loss of efficacy. Alternatively, registrants may supply their own resistance management labeling statements that address these same areas. Registrants may also choose to have specific mandatory statements regarding resistance management, but these statements would not fall under "Resistance Management Recommendations".

H. Chemigation Information

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

"Do not apply this product through any type of irrigation system".

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

- Types of irrigation systems to be used;
- Consequences of improper chemigation;
- To whom questions about chemigation can be directed;
- Warnings against connecting irrigation equipment to public water supplies without safety mechanisms;
- Personnel required for adjustment of chemigation equipment;
- Statements required for Toxicity Category I products.

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

I. Spray Drift Labeling

Generic label language for Spray Drift prevention is still pending. In the meantime, OPP is developing spray drift management label language on a case-by-case basis. Typically, risk from potential spray drift, based on the use patterns for any given product will be identified in the risk assessment. The label reviewer should check the relevant RED or reregistration documents for required spray drift language as well as work with the risk assessors to craft appropriate spray drift risk mitigating label language.

J. Endangered Species Label Statement

To address Endangered Species Act and FIFRA obligations, some products are required to carry a statement informing the user of potential risk to endangered species. This language

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

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

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

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

VII. Where the product is 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 presenting specific application directions.

A. Consistency of Listed Sites

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

B. Complete Site Information

Treatment sites must be clearly identified. For example, if residential sites are listed as an application site, exactly where the pesticide is applied must be specified, for example, bathrooms or kitchens. Reviewers should require the use of the most specific site terminology reasonable. If possible, refer to site indices in OPPIN to identify appropriate site terminology but avoid the use of site categories (e.g., "domestic dwellings") that would

be awkward or confusing on a label. The use of uniform site terminology is useful for the purposes of exposure reviews. The label reviewer may need to inform the registrant that the application sites need to be identified more specifically, for example, cracks and crevices in kitchen areas of residences instead of "dwellings".

C. Site Groupings

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

D. Site-Pest Considerations

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

E. Sites and the Intended User

The listed sites should be appropriate for the intended end-user. For example, sites listed on the labels of residential use products should be typical household/garden sites and not commercial agricultural sites such as cotton, tobacco, or cranberries.

VIII. The pests being claimed

The term pest is defined by 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 (*FIFRA 2(ee)*). Pest claims may be made in the Use Restrictions section or with specific application instructions. In addition, pest claims often may appear on the front panel as part of the name of the product or in promotional statements appearing under the product's name or elsewhere on the label.

A. Consistency of Listed Pests

Wherever the pests are listed on the label, they must be consistent with pests listed elsewhere on the label. For example, if the front panel lists fire ants as a target pest, then the directions for use must include the appropriate treatment directions for fire ants. If the front

panel lists several pests and then references other pests controlled by using phrases like “and more”, or “plus others” or “and many more”, these phrases will only be acceptable if they are followed by a direct reference to the Directions for Use section for the complete listing of pests controlled, i.e., “and more listed on the back panel”. The reviewer must make sure that the directions for use are actually included and are applicable to all pests listed anywhere else on the labeling. This consistency is necessary to ensure that the product is not considered misbranded.

B. Pest Groupings

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

C. Product Formulation and Pests

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

D. Pests and Use Sites

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

IX. How the product is prepared and handled

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

A. Formulation Type

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

B. Mixing Instructions

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

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

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

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

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

C. Compatibility with Other Products.

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

X. Application information

What goes in this subsection will vary considerably according to the type of pesticide product and the intended user. However, this subset of the Directions for Use section should indicate use precautions and restrictions that apply to *all* sites and pests claimed on the label. For products with many registered uses, it may be useful and efficient to provide separate directions which pertain to specific sites and pest combinations claimed for the product. In such cases, each site and pest would have its own subsection which would be further divided into subsections such as "USE RESTRICTIONS" and the other elements specific to that grouping.

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

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

A. Timing

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

1. **Regulatory Intervals to Mitigate Risk.** The label reviewer should check the residue chemistry assessment and RED to determine if any regulatory intervals were recommended for the product's label. The residue chemistry assessment for a given product or active ingredient may specify the following intervals:
   - Pre-harvest Interval (PHI)
   - Pre-slaughter Intervals
   - Pre-grazing Intervals
   - Pre-feeding Intervals
   - Pre-silage Intervals

   If required to meet the FIFRA standard, the PHI should be indicated as numbers of weeks or days. Preslaughter intervals and pregrazing intervals should be expressed similar to the PHIs.

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

B. Application Methods

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

   The label reviewer should make sure that the methods of application and equipment recommended are appropriate for the product formulation, the intended user, and the site and pest to which the pesticide product is being applied. Complete information on how to apply the product should be included. For example, the statement "Apply this product to

the soil" is not sufficient. Labels which state that the pesticide must be applied to the soil and immediately incorporated must specify what kind of equipment must be used.

2. **Liquid Spray Instructions.** Labels for liquid formulations generally refer to "spraying" the product as the method of application. Labels that have directions which instruct users to mix a spray solution should provide special instructions devoted to preparing spray mixes and should indicate the spray volume to be applied per acre or per unit area. For some applications it may be acceptable for the label to indicate, "apply sufficient volume for thorough coverage" or similar language. The following types of spray applications are generally used:

   (a) *Space Spray*. Dispersal of the product into the air by foggers, misters, aerosol devices or vapor dispensers for control of flying pests and exposed crawling pests.

   (b) *General Area Spray*. Application to broad surfaces, such as walls, floors and ceilings.

   (c) *Spot Spray*. Application to small areas on which pests are likely to occur. These areas may be on floors, walls, bases or undersides of equipment. To limit potential exposure in a commercial food area, a "spot" should not exceed two square feet.

   (d) *Crack and Crevice*. Application of small amounts of pesticide into cracks and/or crevices in which pests hide or through which they may enter a building. Such openings commonly occur at expansion joints, between elements of construction and between equipment and floors.

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

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

4. **Aerial Applications.** For aerial applications, spray volumes should be stated.

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

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

   "DO NOT use more than one fogger per room. DO NOT use in small, enclosed spaces such as closets, cabinets, or under counters or tables. DO NOT use in a room 5 ft. x 5 ft. or smaller. Instead, allow fog to enter from other rooms. Turn off ALL ignition sources such as pilot lights (shut off gas

valves), other open flames or running electrical appliances that cycle off and on (e.g., refrigerators, thermostats, etc.). Call your gas utility or management company if you need assistance with your pilot lights".

C. Application Rate

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

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

3. **Net Contents and Application Rate.** The directions for use should not call for use of *more than* the net contents of the product's container (i.e., if a granular product is packaged as a 1 lb. unit, its application rate should not require 200 lbs. of product). If the product is a liquid, the specified treatment rate should be fl. oz. or gal. per unit area. If a solid, the rate should be expressed oz. or lb. per unit area. Note: Many labels of liquid formulations incorrectly omit the "fluid" (fl.) with the oz. when specifying application rate.

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

   (a) When there is a risk that reduced application of the product may result in increased pest resistance to the active ingredient; or

   (b) When there is documentation that a product's efficacy is substantially compromised under a certain application rate.

D. Frequency of Applications

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

E. Other Information Pertaining To Specific Applications

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

XI. Additional application information

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

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

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

XII. Storage and disposal instructions

Labels for pesticide products are required to bear labeling instructions for the storage and disposal of pesticides and pesticide containers in the Directions for Use section of the label . It is preferred that the Storage and Disposal instructions appear at the end of the Directions for Use section. Information about and requirements for Storage and Disposal instructions are given in *Chapter 13*.

Appendix A—Directions for Use Checklist

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

Technical Elements
Elements to Consider
2. Is the product subject to the guidance set out in PR Notice 87-1 (chemigation)? If so, is there adequate chemigation information or a chemigation prohibition statement?
3. Is the product subject to the Worker Protection Standard (WPS)? If so, does the proposed label contain all the required, accurate WPS information as set forth in the regulations and the guidance in Chapter 10 Is the Re-entry Interval in the Agricultural Use Requirements box correct?
4. Are the following elements (*if applicable*) adequately expressed: Instructions and Information Subheading? Use Restrictions? Spray Drift Language? Endangered Species Statement? Pollinator Protection Statement?
Sites and Pests
5. Are the sites and pests identified?
6. Are there appropriate tolerances or exemptions from tolerance for all of the ingredients in the product to cover all the food use sites listed?
7. If peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, milk, Crustacean, or wheat commodities are listed on the confidential statement of formula, do the use sites and application methods comply with 40 CFR 180.1071?
8. Is the formulation acceptable for this site/pest combination?
9. If a RED has been issued, is the site eligible for Reregistration?
10 If the product contains more than one active ingredient, are all the uses acceptable for all the active ingredients (AI)?
Application Instructions
11. Are adequate preparation and handling instructions included?
12. Are the application rates indicated?
13. Are the rates appropriate and calculated correctly?
14. Does the product density (eg. lbs of AI/gallon) times the application rate agree with the tables that list the weight of AI applied to a given area?
15. Do the rates deviate from a standard use pattern?
16. Is the rate of application consistent with the packaging of the product?

Application Instructions	
17.	Is the application frequency acceptable?
18.	Is all equipment (e.g. for mixing, loading or application) identified/specified and is the equipment practical for the user?
19.	Are all methods of application appropriate?
20.	Is the timing of the applications appropriate?
Use Restrictions	
21.	Should there be a Use Restrictions sub-heading and section?
22.	Is the Pre-harvest Interval, Pre-grazing, Pre-feeding, Pre-silage or Pre-slaughter Interval correct?
23.	Are site specific precautions and restrictions clearly listed with each site/pest combination?

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

Check *40 CFR 156.10* for further guidance.

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Label Review Manual

Chapter 12: Labeling Claims

USDA NRCS, Joe Larson

I. Introduction

This chapter provides guidance for reviewing claims made on proposed labels. A label claim is a statement of something as a fact or an assertion on the label open to challenge. 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

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:

- A false or misleading statement concerning the composition of the product;
- 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);
- A false or misleading statement about the value of the product for purposes other than as a pesticide or device;
- A false or misleading comparison with other pesticides or devices;
- Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by an agency of the Federal Government;
- 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;
- A true statement used in such a way to give a false or misleading impression to the purchaser;
- Label disclaimers or warranty statements which negate or detract from labeling statements required under FIFRA and EPA's regulations;

- 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.
- Non-numerical and/or comparative statements on the safety of the product, including but not limited to:
  - "Contains all natural ingredients"
  - "Among the least toxic chemicals known"
  - "Pollution approved"

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.

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.

EPA's policy does *not* permit the use of the terms "natural", or "naturally" in the labeling of any registered product, including biopesticide products, both microbials and biochemicals. These terms cannot be well defined, and may possibly be misconstrued by consumers as a safety claim.

If a label reviewer is in doubt as to whether a claim or statement is false or misleading, he or she should consult their division's Ombudsperson or OGC representative 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 unacceptable claims

- Statements that imply or suggest that the product can or will prevent or control disease or offer health protection.
- "Commercial Line," "Commercial Size", "Institutional Size", "Garden Center Size": The use of these terms for products clearly intended for consumer household use is misleading.

- "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.

- Claims about the *Absence* of an Ingredient: Statements or claims that express the absence of certain ingredients may be misleading statements prohibited by *40 CFR 156.10 (a)(5)*. 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 or was likely to contain the substance in the first place.

- "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 Child Resistant Packaging" be made due to the use of CRP.

- "Organic", "For Organic Lawns", "Organic Disease Control", "An Organic Alternative to _____", and "Your Organic Solution" are all examples of misleading label claims as to safety. Under the National Organic Program (NOP), the phrase, *"For Organic Production",* and "*For Organic Gardening*" located on the front panel of the label in close proximity to the product name are examples of acceptable labeling statements relating to the term "organic". The phrase should not appear above the product name (in the location normally reserved for a Restricted Use Statement). See the next section for more information on organic claims.

- 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.

- 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.

- The term "steri-" implies sterilant activity and is not acceptable as a product name or on a product label unless it is a sterilant.

- Statements that imply indefinite or all encompassing protection against bacteria, fungi or algae such as “germ-free”, or “algae-free” are not acceptable.

IV. Pesticides exempted from registration

Certain information on the pesticide label assists organic growers in knowing which products meet the requirements of the National Organic Program (NOP) Rule. If the criteria described in *Pesticide Registration (PR) Notice 2003-1* are met, a pesticide product may bear the following phrases

“For Organic Production”,

“For Organic Gardening”,

“For Organic Lawn Care”, and

“For Use in Organic Production”.

Label language and/or logos from other groups that review materials proposed for organic agriculture may also be considered (E.g. OMRI). The reviewer needs to determine if this information is false or misleading. Label reviewers should consult with the National Organic Program Liaison in the Biopesticides and Pollution Prevention Division for an evaluation of the product’s proposed labeling before approving any organic claims.

V. Claims made about the active ingredient

A product label may include the statement “contains [name of active ingredient], the active ingredient used in [Brand Name (™ or ®)]”, if the following criteria are met:

A. Placement

The claim may be placed anywhere on the label, however the preferred location is in close proximity to the Ingredient Statement.

B. Presentation

The claim should not be presented in an overly large font, such that the claim is set in a font type no larger than that of the Signal Word on the label. Furthermore, the claim should not be presented with heavily bolded or highlighted type or use coloring to cause the claim to excessively stand out over the rest of the labeling text. The format of the claim should not be in such a way that is causes greater attention than other required precautionary labeling on the label.

C. Appropriate Comparison

If the subject product is a single active ingredient product, the claim should only refer to another similar single ingredient product. If the subject product is a multiple active ingredient product, the claim should only refer to another similar mutli-ingredient product

with the same active ingredients. Appropriate disclaimers stating that the generic product is not manufactured or distributed by the maker or marketer of the brand-name product as well as the trademark of the brand may be cross reference by use of a footnote.

VI. Product names

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*.

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. Following is the Agency's current guidance on false or misleading product names:

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 ™ or ® 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)*.

The exact same name cannot be used for different products registered by any registrant. *40 CFR 156.10(b)(2)(ii)*. 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. See *40 CFR 152.132(d)*.

VII. Efficacy-related claims

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 158.400*. 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.

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 non-public-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 that go beyond mere control of claimed pests. *PR Notice 93-6*.

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 when data supports their use. *PR Notice 93-6*.

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” *PR Notice 93-6*.

6. 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. *PR Notice 93-6*.

7. 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". Other statements such as "typhoid rooms", which imply efficacy against *Salmonella typhi*, but are not supported by efficacy data that has been reviewed and accepted by the Agency are not allowed. 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.

8. 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 two-minute contact time for efficacy.

9. 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.

VIII. Instructions to label reviewers for efficacy issues

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 that differ significantly from existing claims.

As mentioned earlier, do not allow any claim that would render the product misbranded under FIFRA or false and misleading under *40 CFR part 156.10(a)(5)*.

IX. Warranty and disclaimer statements

Most, if not all, pesticide labels contain some type of warranty disclaimer language. It is important, as always, that the Agency be consistent in reviewing such language when it is first submitted or subsequently amended. 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 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 that explain how the product is 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.

The reviewer should check the proposed label for warranty/disclaimer/liability language statements (like those above) that 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).

The following are examples of problematic warranty statements. The problematic portions of the label statements are stricken, and necessary language is added in red.

EXAMPLE 1

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and ~~should~~ must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of XXXX. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, XXX makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of XXX is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, XXX disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at XXX's election, the replacement of product.

Reasons for Corrections

The phrase "should follow directions" could mislead users to believe that the directions for use are only suggestions and not enforceable restrictions on how the product may be used; therefore, all statements relating to using the product in accordance with its labeling will be required to be mandatory (i.e., "must").

The phrase, "to the extent consistent with applicable law" has been added to the disclaimers of liability and damages to avoid the statements being false or misleading. Some states or localities may not allow certain disclaimers of liability or damages; therefore, the user/buyer may have a remedy under other law governing warranties.

EXAMPLE 2

Warranty and Disclaimer Notice

Warranty

The directions for use of this product are believed to be adequate and ~~should~~ must be followed carefully, it is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result due to such factors as weather conditions, presence or absence of other materials, or the manner of use or application, all of which are beyond the control of XXX, the manufacturer, or the seller.

To the extent consistent with applicable law, the products sold to you are furnished "as is" by XXX. The manufacturer and the seller are subject only to the manufacturer's warranties, if any, which appear on the label of the product sold to you. Except as warranted by this label ~~expressly provided herein~~, XXX, the manufacturer, or the seller makes no warranties, guarantees, or representations of any kind to the buyer or the user, either express or implied, or by usage of trade, statutory or otherwise, with regard to the product sold or use of the product, including, but not limited to, merchantability, fitness for a particular purpose or use, or eligibility of the product for any particular trade usage. ~~Except as expressly stated herein, XXX., the manufacturer, or the seller makes no warranty of results to be obtained by use of the product~~. To the extent consistent with applicable law, Buyer's or user's exclusive remedy, and XXX, the manufacturer's or the seller's total liability shall be limited to damages not exceeding the cost of the product. No agent or employee of XXX, or the seller is authorized to amend the terms of this warranty disclaimer or the product's label or to make a presentation or recommendation different from or inconsistent with the label of this product.

To the extent consistent with applicable law, XXX, the manufacturer, or the seller shall not be liable for consequential, special, or indirect damages resulting from the use, handling, application, storage, or disposal of this product or for damages in the nature of penalties, and the buyer and the user waive any right that they may have to such damages.

Reasons for Corrections

Prior to legal use of a pesticide product it must be registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA). Registration of a pesticide requires, in part, that the product be effective in controlling the pest(s) for which it is registered. In registering the product under FIFRA, the product must perform as purported when used in accordance with its labeling. The phrase, "Except as expressly stated herein, XXX., the manufacturer, or the seller makes no warranty of results to be obtained by use of the product", is

overly broad and could be misleading to the consumer. Overly broad statements, which negate or detract from the Directions for Use, must be qualified by a phrase such as "Except as warranted in this label". Statements such as those used in the example above ("Except as expressly provided herein" and "Except as expressly stated herein") are not adequate qualifiers because they are misleading in that they do not clearly incorporate the warranty offered through the act of registration.

State and local laws may not allow the manufacturer to limit its liability by offering its product "as is". In addition, the same laws may not allow certain limitations of liability or remedy. Therefore "to the extent consistent with applicable law" has been added in appropriate places.

More examples of Warranty and Disclaimer Statements can be found on EPA's *Labeling Committee Projects* Web site. If, after reviewing the examples, a label reviewer is still in doubt as to the acceptability of any warranty or disclaimer statement, the statement should be referred to the Office of General Counsel.

X. Claims made in advertising

Advertising and collateral literature or verbal claims for the product must not substantially differ from any claims made on the label or labeling. See *FIFRA § 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:

Branch Chief
Agriculture Branch
Agriculture Division
Office of Compliance (2225A)

Revised January 2012

Label Review Manual

Chapter 13: Storage and Disposal

http://life.nbii.gov, National Biological Information Infrastructure, Library of Images From the Environment, Elizabeth A. Sellers

I. Introduction

This chapter discusses the storage and disposal instructions for pesticides and pesticide containers. Label reviewers should use this chapter as well as information presented in PR Notices *83-3*, *84-1*, *84-5*, *94-2*, *2007-1*, and *2007-4*; in the regulations at *40 CFR §156.10(i)(2)(ix)* and *§§156.140–156.159*; and in *Reregistration Eligibility Decision (RED)* documents or *Registration Review Decisions* for active ingredients. In addition, chemical-specific storage and disposal statements have been provided by the Agency for certain pesticides, as stated in *PR Notice 84-1* (and an errata sheet dated April 12, 1984), and in PR Notice *84-5*. These chemical-specific statements are described in detail in this chapter.

According to *40 CFR §156.10(i)(2)(ix)*, pesticide products must have label instructions for the storage, residue removal and disposal of pesticides and pesticide containers. For many years, the content of these Storage and Disposal instructions has been established in PR Notices. The labels of pesticide products "released for shipment"1 after August 16, 2011 must bear Storage and Disposal instructions that also conform with the requirements in Subpart H – Container Labeling, *40 CFR §§156.140 – 156.159*.

II. Reviewing the statements

A. Determining Storage and Disposal Labeling

The Storage and Disposal section of the label **must have** instructions on how to:

- Store a product
- Dispose of leftover pesticides
- Clean an empty container (for certain types of pesticides and containers)
- Dispose of an empty container if recycling or reconditioning is not an option.

In addition, the Storage and Disposal section of a label **may have** instructions on how to:

- Dispose of pesticide rinsate
- Return the container for refilling (for sale or distribution), if it can be reused.

1 The definition of "released for shipment" in *40 CFR* §152.3 is: "…A product becomes released for shipment when the producer has packaged and labeled it in the manner in which it will be distributed or sold, or has stored it in an area where finished products are ordinarily held for shipment. Products stored in an area where products are ordinarily held for shipment, but which are not intended to be released for shipment must be physically separated and marked as not yet released for shipment. Once a product becomes released for shipment, the product remains in the condition of being released for shipment until subsequent activities, such as relabeling or repackaging, constitute production."

B. Statement Location

Storage and Disposal instructions *(except for batch codes)* must be ***grouped*** together under the heading "Storage and Disposal" and should be ***within*** the "Directions for Use" section ***at the end***, while **c**learly ***set apart*** (as blocked or in a box) from the rest of the "Directions for Use". *(See §156.10(i)(2)(ix) and PR Notice 83-3)*

EXCEPTION:

All but one of the container statements required by *40 CFR 156.140 – 156.159* can be placed on the actual container (not on the closure) itself. Specifically, the container type, container reuse and container recycling or reconditioning statements can be on the container, but not the cleaning instructions. Cleaning instructions must always be on the label itself. When statements are on a container the label must have an appropriate statement under "Storage and Disposal" that directs the user where to find the information. *Examples* are: "See container for recycling [*or other descriptive word*] information" or "Refilling limitations are on the container."

Any container statement required by *40 CFR 156.140 – 156.159* and put directly on the actual container itself must be durably marked such as by (but not limited to) etching, embossing, ink jetting, stamping, heat stamping, mechanically attaching a plate, molding, or marking with durable ink. *(See §156.140)*

C. Format

If it is a nonrefillable container and the container handling statements are placed on the label (or labeling), registrants must use an appropriate subheading under the heading "Storage and Disposal". *(See §156.140(a))* For refillable containers it is suggested (not required) that there be a subheading under the heading "Storage and Disposal". One subheading commonly used, but not required to be used, is "Container Handling".

The example below shows the order and subheadings of a typical storage and disposal section of a label for a non-residential/household use product.

DIRECTIONS FOR USE

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

Storage:
[Where and how to store the product.]

Pesticide Disposal:
[What to do with product that is left over and not going to be used.]

Container Handling:
[Whether the container is nonrefillable or refillable; if it can be reused, recycled or reconditioned; how to dispose of it if recycling or reconditioning is not an option; and how to clean it if cleaning is required.]

D. Type Size Requirements

The heading "Storage and Disposal" must be in type of the same minimum sizes as required for the child hazard warning by 40 CFR 156.60(b). *(See §156.10(i)(2)(ix))*

III. General storage and disposal statements

The Agency historically has required the following sentence for non-residential/household use products:

"Do not contaminate water, food, or feed by storage and disposal".

Preferably, registrants should place this statement immediately under the heading "Storage and Disposal" since it concerns both storage and disposal. However, it may be placed elsewhere within the Storage and Disposal section. *(See PR Notice 83-3)*

IV. Pesticide storage statements

Registrants must have instructions for proper storage of pesticide products. *(§156.10(i)(2)(ix))* Safe storage is essential to protect against accidental exposure to children, bystanders and workers, environmental contamination due to leaks and spills, and intentional exposure due to vandalism or terrorism. EPA has preferred storage instructions for certain active ingredients (Section A); suggested statements for other products (Section B); and guidelines for registrants developing their own storage instructions (Section C).

A. Preferred Storage Statements (for products with certain active ingredients)

As mentioned above, the Agency has preferred storage statements for products with the following active ingredients:

- Calcium hypochlorite - liquid and solid
- Chloropicrin
- Ethylene oxide
- Etridiazole
- Sodium hypochlorite - liquid
- Sulfuryl fluoride
- Methyl bromide and methyl bromide plus 2% or less chloropicrin
- Phosphide – aluminum and magnesium
- Sodium cyanide

For products with one of these active ingredients, see Attachment A for the appropriate storage statement(s).

B. Suggested Storage Statements (for products with active ingredients not included in the list above)

A list of EPA-suggested storage statements for all other products (not listed above in A) is provided in Attachment B.

C. Developing Other Storage Statements

For products that do not have active ingredients listed above in Section A, *PR Notices 84-1* or *84-5*, or that do not have storage statements provided by an Agency decision document (e.g., a RED) registrants may use the suggested storage statements in Attachment B, or develop storage instructions for each product based on the following considerations:

1. Whether the composition or usefulness of the pesticide could be altered by: temperature extremes, excessive moisture or humidity, heat, sunlight, friction, contaminating substances or media that may affect the product.

2. Physical requirements of storage that could affect the container and its ability to function properly: container type, positioning of the container in storage, storage temperature, crushing or damage by stacking, penetration of moisture, and ability to withstand shock or friction.

3. Handling the container: movement within storage area, proper opening and closing procedures (particularly if the container has been opened), and how to minimize exposure while opening or closing the container.

4. 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.

5. General precautions, such as:
   - Lock the storage area, store product in the original container only, or separate products during storage to prevent cross-contamination with other pesticides, fertilizer, food and feed.

   - If it is a residential/household use product, emphasize keeping the pesticide in the original container and in a locked storage area, and not using an empty container for other uses or substances. *(See PR Notice 83-3)*

D. Additional Guidance on Storage Statements

Websites of state extension services, state and federal agencies and industry associations may offer guidance that is useful for developing storage instructions. Common features include the need for:

- Security - locks, restricted access, frequent inspections for tampering, signage in appropriate languages;

- Recordkeeping - inventory, deliveries, employee licenses, contact and emergency numbers posted;

- Spill prevention and cleanup - emergency response plan, cleanup and first aid supplies; and

- Site integrity - ventilation, lighting, pallets and protection from weather and run on, secondary containment, etc.

V. Pesticide disposal statements

Registrants must provide appropriate instructions on how to dispose of leftover or unused pesticides *(40 CFR 156.10(i)(2)(ix)* and *40 CFR part 156*, Subpart H). Pesticide disposal statements are specific to the uses of the product (e.g., residential/household or non-residential/household use) and the type of container.

Listed below are pesticide disposal statements for:

A. Residential/household use **only** products (including non-antimicrobial residential/household use) that are not hazardous waste or highly toxic;

B. **Not solely** residential/household use products that are hazardous waste or are highly toxic; and

C. **Non-**residential/household use products that are not hazardous waste and are not highly toxic

In Sections A, B and C below, language in quotation marks may generally be used verbatim by registrants making label changes by notification.

For non-antimicrobial residential/household use products, pesticide disposal and container handling instructions are combined and should appear under the subheading "Pesticide Disposal and Container Handling." These statements were originally provided by *PR Notice 2001-6* (superseded by *PR Notice 2007-1*), have been updated to reflect the container-containment regulations and *PR Notice 2007-4*, and are presented in Section A below.

For antimicrobial products that are residential/household use, the pesticide disposal and container handling instructions which were provided in PR Notices *83-3* and *84-1* are still valid, have been updated to reflect the container-containment regulations, and are also presented in Section A below. In addition, antimicrobial products that are residential/household use can voluntarily use the pesticide disposal and container handling instructions for non-antimicrobial residential/household use products.

A. Pesticide container and handling instructions for residential/household use only products (including non-antimicrobial residential/household use) that are not hazardous waste or highly toxic

Description of Containers and Products	Pesticide Disposal and Container Handling Statements	Description of Residential/ Household Use Product
Pressurized container for any residential/household use product *(PR Notices 94-2, 2007-1 & 2007-4; 40 CFR 156.140(a))* *Note: Because we assume that pressurized containers are aerosol cans, the "Nonrefillable container" and "Do not reuse or refill this container." statements are not required for these containers.* *(40 CFR 156.140(a)(5)(i))*	"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 for disposal instructions." **Or** "Do Not Puncture or Incinerate! **If empty:** 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 label (DO NOT PUNCTURE!). If recycling option is not available, wrap the container and discard in trash. **If partly filled:** Call your local solid waste agency for disposal instructions."	A pesticide product is considered to be a residential/ household use product if it meets one or both of the following2: The intended end use of the product is in or around a residence or household by a resident; **and/or** The product is regularly available to household consumers for purchase, and of a size and type practicable for household use, regardless of whether it is also marketed for agricultural use. *(PR Notice 2007-1)*
Non-pressurized container for any residential/ household use product (PR Notices *2007-1* & *2007-4*; 40 CFR *156.140(a)*)	"Nonrefillable container. Do not reuse or refill this container.3 **If empty:** Place in trash or offer for recycling, if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain."	

2 Previously, this referred to "a non-antimicrobial pesticide product". However, PRN *84-1* which has not been superseded for antimicrobial products (section IIB clarification of PRN *83-3* pesticide storage and disposal instructions) says "EPA intended to include under the household use section of the PR Notice, those products which have 'domestic uses,' as defined in 40 CFR 162.3(m)(1-4) and products whose use patterns and container sizes are similar to those defined as 'domestic use'. Thus, for the purposes of this PRN, the definition for household use patterns includes products which are marketed in container sizes similar to products intended for household use and are used in public areas such as office buildings, retails stores, hotels and schools, and hospital patient care areas, as well as products intended for use in home gardens and lawns." In this case, the definition for "household use patterns" could include antimicrobial use pesticides. Therefore, EPA has deleted "a non-antimicrobial pesticide product" so that the definition applies to antimicrobial and non-antimicrobial products.

3 The statements "Nonrefillable container. Do not reuse or refill this container." are not required for certain container types (See Section IV C below). Also, there are other options for the statement "Do not reuse or refill this container." that can be found in *156.140(a)(2)*. Those options are: 1) "Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state." and 2) if the product is ready-to-use and the directions for use allow a different (similar but concentrated) product to be poured into the container and

Description of Containers and Products	Pesticide Disposal and Container Handling Statements	Description of Residential/ Household Use Product
Pressurized or non-pressurized container for **antimicrobial residential/ household use products** *(PR Notices 83-3, 84-1 & 2007-4; 40 CFR 156.140(a))*	"Nonrefillable container. Do not reuse or refill this container.3 Securely wrap original container in several layers of newspaper and discard in trash or offer for recycling if available." **Or** "Nonrefillable container. Do not reuse or refill this container.[3] Wrap [container] and put in trash or offer for recycling if available."	

Alternative statement for the "If partly filled:" instructions found in Section A above

Registrants who voluntarily use a toll-free number or website should:

(1) Put "Call your local solid waste agency or" in front of the toll free number or website address and "for disposal instructions" after, so the statement is "Call your local sold waste agency or (insert toll free number or web site) for disposal instructions.";

(2) Use a service that is available between 18 – 24 hours per day, free to users, available nationally, gives advice agreeable to the local solid waste authority for the location of the user, and/or provides a direct phone number for the appropriate local or state authority;

and

(3) Reasonably assure that the service will continue to exist at a level that meets user demand.

(PR Notice 2007-1)

diluted by the end user: "Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container."

B: Pesticide disposal instructions for products not solely for residential/household use that are hazardous waste; or are highly toxic

Description of containers and products	Pesticide disposal statements	When a pesticide is a hazardous waste or highly toxic
For products that are **not** solely for residential/ household use and meet any of the criteria in the **far right hand column**.	"Pesticide wastes may be 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."	A pesticide product should bear one of the pesticide disposal instructions in this section if the product: 1) Contains active ingredients that, when discarded, are hazardous waste under the Resource Conservation and Recovery Act (RCRA), *40 CFR 261.33(e) and (f);* 2) When discarded, meets the criteria in *40 CFR 261*, Subpart C for a characteristic waste under RCRA; 3) Is in Toxicity Category I *[DANGER]* on the basis of oral or dermal toxicity, or skin or eye irritation potential; ***or*** 4) Is in Toxicity Category I *[DANGER]* or II *[WARNING]* on the basis of acute inhalation toxicity.
For products that are **not** solely for residential/ household use and the active ingredient **is an acute hazardous waste** per *40 CFR 261.33(e)* *(PR Notice 83-3)* *See the text box below for alternative container handling instructions for pesticides that are acute hazardous waste when disposed.*	"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."4	
For products that are **not** solely for residential/ household use and if either: (1) the active ingredient **is a toxic hazardous waste** per *40 CFR 261.33(f)*; or (2) the product meets any of the criteria in *40 CFR Part 261* Subpart C for a **characteristic hazardous waste** *(PR Notice 83-3)*	"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."	

4 PR Notice *83-3* offers this statement for products assigned 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). However, this statement is misleading for these products since they may not be acute hazardous waste upon disposal.

Alternative Container Handling Instructions for Pesticide Products that are Acute Hazardous Waste When Discarded

Pesticide container handling instructions are described in detail in Section IV and Attachment C of this chapter. The following statements can be used (as described below) on the labels of pesticide products that contain active ingredients that, when discarded, are acute hazardous wastes under the RCRA, *40 CFR 261.33(e).* These statements were originally developed for Furadan 3G and Furadan 4F, but are also appropriate for any pesticide products that are acute hazardous wastes when discarded.

For nonrefillable bags of granular or dry formulation:
Use the appropriate container handling statements as described in Attachment C, Tables A.4 (*for nonrefillable paper & plastic bags)* and A.8 *(for other non-rigid nonrefillable containers)*, but change the how to clean statement (in e) and the recycling statement (in f1)

from: "…Completely empty bag into application equipment. Offer for recycling if available or…"
to: "…Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed of in accordance with local, state and federal regulations. When completely empty, offer for recycling if available or…"

For nonrefillable or refillable plastic or metal containers with a dry flowable or liquid formulation:
Use the appropriate container handling statements as described in Attachment C, Tables A.1 (*for nonrefillable metal containers, non-aerosol)*, A.3 *(for nonrefillable plastic containers)*, A.7 *(for other rigid nonrefillable containers),* B.1 *(for refillable metal containers, non-aerosol),* B.2 *(for refillable plastic containers), and* B.5 *(for other refillable containers),* **but add the following language after the recycle, reconditioning and disposal instructions** (in f):

"…If rinsate cannot be used, follow pesticide disposal instructions. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations. DO NOT cut or weld metal containers."*

*(*The last sentence should be used for metal containers, but not for plastic containers.)*

C. Pesticide disposal instructions for products that are not solely for residential/household use and are not hazardous waste or highly toxic

Description of containers and products	Pesticide disposal statements
For products not specifically identified in a RED or a PR Notice, that are **not solely** residential/household use, are **not hazardous wastes**, and are **not highly toxic** (as described above in Section B) *Note: The second option may be preferred in some states.* *(PR Notice 83-3)*	"Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility." ***or*** "To avoid waste, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry)."

VI. Container handling statements

A. Subheading

Labels for products in nonrefillable containers must have the appropriate subheadings under the heading "Storage and Disposal" for the statements required by *§156.140(a)* regarding "Nonrefillable container.", reuse/refill and recycling/reconditioning. If placed on the label of a nonrefillable container, these three statements must be under an appropriate subheading. "Container Handling" is a subheading that is most commonly used, but registrants may use a different subheading that is appropriate. Although a subheading is required only for nonrefillable containers and not refillable containers, EPA recommends using a similar subheading for the container instructions for refillable containers. *(See §156.140(a))*

B. Location

Most container handling instructions are put on the label. However, the container statements required by *§156.140* (identifying the container type, reuse/refill limitations, and information on recycle/reconditioning) can be on the actual container itself as long as the user knows where to find it. For example, under the heading "Storage and Disposal" registrants may put "See container for information on reusing the container" or another appropriate statement. If statements are placed directly on the actual container itself they must be durably marked. Durable marking includes, but is not limited to, etching, embossing, ink jetting, stamping, heat stamping, a mechanically attached plate, molding, or marking with durable ink. *(See §156.140)* Alternatively, the residue removal instructions and container disposal instructions *must be* on the label under the heading "Storage and Disposal." (PR Notice *83-3*, *§156.10(i)(2)(ix)* and *§156.144*) The batch code can be on the label or the container. (*See §156.140*)

C. Instructions

Container handling instructions should be appropriate for the container type. For example, users should *not* be instructed to puncture or incinerate a pressurized container. In Sections C1a through C1f below, language in quotation marks may generally be used verbatim by registrants making label changes by notification. (Exceptions to this are explained on a case-by-case basis.) Optional guidance is provided in brackets. *(See PR Notice 2007-4)*

Is it a "*refillable*" or "*nonrefillable*" container? *The registrant decides based on how the container is intended to be used*	
A "refillable container" is one that is intended to be refilled for sale or distribution.	A "nonrefillable container" may **not** be refilled for sale or distribution, but in some cases the end user can refill it for use only.

The registrant determines whether a container is "refillable" or "nonrefillable." A refillable container is intended to be filled with pesticide more than once for sale or distribution. A "nonrefillable container" is designed and constructed for one-time use and is not intended to be filled again with a pesticide for sale or distribution. *(See §165.3)*

Products registered solely for residential/household use are usually sold in *nonrefillable* containers, although occasionally the label instructions allow an end user to refill the container for his/her own use. For example, if a consumer buys a spray bottle filled with a ready-to-use product, uses all of the pesticide up, and buys a 1-gallon bottle with product to refill the spray bottle, then the spray bottle is a "nonrefillable container" because it is being filled again *for use*, not for sale or distribution. For this to be legal, the instructions on the label of the spray bottle cannot specifically prevent it, e.g., the label of the spray bottle cannot say "Do not reuse or refill this container." and must allow this practice, e.g. "Do not reuse or refill this container except as allowed in the directions for use."

The remainder of this section describes the statements that are required or recommended by EPA regulations or policies. Attachment C shows the full set of appropriate container handling instructions for different types of containers.

1. If it is a *nonrefillable* container, the label must have:	2. If it is a *refillable* container, the label must have:
A subheading such as "Container Handling" on the label under the heading "Storage and Disposal"; and: a. The nonrefillable container statement b. Reuse limitations c. When to clean (for dilutable pesticides) d. How to clean (for dilutable pesticides) e. Recycle or recondition (and should also have how to dispose) f. Batch code *(See Section 1 below)*	a. The refillable container statement b. Reuse limitations c. Who is responsible for cleaning & when d. How to clean The label *should have* container return or disposal instructions. EPA *recommends* that these instructions appear on the label under a subheading such as "Container Handling". *(See Section 2 on Refillable Containers)*

1. NONREFILLABLE CONTAINERS

If the pesticide is distributed or sold in a nonrefillable container, the label must have the statements described below unless otherwise exempted, modified or waived with EPA approval. If EPA requires a different statement or approves a modification or waiver, label changes would be made by amendment. Registrants can use notification if the exact wording is used from the regulations in 40 CFR §§*156.140* – 156.156 or if otherwise allowed by EPA.

1a Nonrefillable container and 1b Reuse limitations

The phrase "Nonrefillable container." and one of the reuse limitations are required on the label ***except if:***

- The product is a plant-incorporated protectant, pesticidal article not already exempted under *§152.25(a)* or distributed only in a transport vehicle *(See §156.140*, and *§156.140(d)&(e)).*
- EPA requires a different statement or approves a modification or waiver requested by the registrant.
- The product and/or container type is listed in Table 1. *(See §156.140(a)(5))*

Table 1. Exemptions to the Requirement for "Nonrefillable container" Statement and Reuse Limitations on the Label

Exemption *(§156.140(a))*	Example
(i) Aerosol can	Bug spray (insecticide) in aerosol can
(ii) Device as defined in *§152.500*	Mouse trap
(iii) One-time use caulking tube or other one-time use squeezable tube container for paste, gel or other similar substance	Crack & crevice treatment gel in syringe applicator; Pet product gel in squeezable tube
(iv) Foil packet for water soluble packaging, repellent wipes, or other one-time use products	Foil or plastic pouches around water-soluble film holding a dose of pesticide; Foil packet with gel strip for wood treatment; Pouch around mosquito repellent coils
(v) One-time use portion control packet, such as a polyethylene sleeve package or rodenticide place pack	Portion pack with sanitizer; Plastic pouch for swimming pool tablet; Plastic pouch for disinfecting wipes (and refill pack for user); Plastic pouch for toilet bowl cleaner tablet
(vi) One-time use bait station	Bait station for rodenticide product
(vii) One-time use cage for repellent or trapping strip	Cage containing sticky strip with insecticide
(viii) Pet collar or animal ear tag, such as for cattle	Flea collar for pets
(ix) One-time use semiochemical dispersion device	A polymeric dispenser (2 tubes fused together) that can be hung from a tree branch and contains a pheremone
(x) Any container that is destroyed by the use of the product contained	Shrink wrap on block of cattle feed
(xi) Any container that would be destroyed if reuse of the container were attempted	Roll-on fly repellent; Cassette containing sterilant for hospital equipment

Registrants should consult with the EPA Product Manager if they are uncertain whether a product fits into one of the categories in Table 1 above.

1a. The phrase "Nonrefillable container." and 1b. Reuse limitations on nonrefillable containers *(See §156.140(a)(1)&(2))*

When the "Nonrefillable container." phrase and a reuse limitation statement are both required for a pesticide in a a nonrefillable container, registrants must use one of the following options:

i. "Nonrefillable container. Do not reuse or refill this container."

ii. "Nonrefillable container. Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state."

iii. For a ready-to-use product that has directions for use that allow a different product (that is a similar, but concentrated formulation) to be poured into the container and diluted by the end user: "Nonrefillable container. Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container." (*Note: In some situations, EPA has waived the requirement to include the phrase "Nonrefillable container." if this set of reuse limitations is used.*)

iv. An acceptable variation of 1.b.iii. is: "Nonrefillable container. Do not reuse or refill this container except as allowed in the directions for use." In this case, the directions for use must describe how to refill the container and with what product(s). *(Note: In some situations, EPA has waived the requirement to use the phrase "Nonrefillable container." if this set of reuse limitations is used.*)

1c and 1d Cleaning instructions

Cleaning instructions are required on the label if the nonrefillable container is rigid and the product is dilutable EXCEPT if the product is a:

- Residential/household use only;
- Gas at atmospheric conditions;
- Pesticidal article that is not already exempted by *§152.25(a)*; and
- Pesticide distributed only in transport vehicles.

(Exempt by regulation. See 40 CFR 156.144)

In addition, EPA may require a different statement or approve a modification or waiver requested by the registrant.

Note: PR Notice *83-3* gives instructions for how to clean certain containers with dry non-dilutable pesticides, such as "Completely empty bag into application equipment." for paper and plastic bags. These "how to clean" instructions are included in the appropriate tables in Attachment C.

What is a "dilutable" pesticide?

For the purposes of the container-containment regulation, a dilutable pesticide is one for which "…the pesticide product's labeling allows or requires the pesticide product to be mixed with a liquid diluent prior to application or use." *(§156.3)*

A pesticide applied directly to swimming pool water is ***not*** a dilutable pesticide because it is not mixed with a diluent before it is added to pool water.

Similarly, many manufacturing use products are ***not*** dilutable because they are not mixed with a diluent before they are used to formulate a product, although it depends on the specific directions for use on the label.

Labels must bear the label statements described in section (1c) and (1d) about when and how to clean rigid, nonrefillable containers of dilutable pesticides ***except for***, pesticidal articles not already exempted under *§152.25(a),* products that are gases at atmospheric conditions, residential/household use products or pesticides distributed only in transport vehicles or if EPA requires a different statement or approves a modification or waiver requested by the registrant. *(§156.144(c) through (g))* Note: If a nonrefillable container is not rigid or the product is not dilutable, or both, cleaning instructions (both when and how) are not required. *[If EPA requires a different statement or approves a modification or waiver, label changes would be made by amendment. Registrants can use notification if the exact wording is used from the regulations in 40 CFR §§156.140 – 156.156 or if otherwise allowed by EPA. (See PR Notice 2007-4)*

1c. When to clean rigid, nonrefillable containers of dilutable pesticides
The options are:

i. "Clean container promptly after emptying."

ii. "Triple rinse or pressure rinse container (or equivalent) promptly after emptying."

iii. "Triple rinse container (or equivalent) promptly after emptying."

(See §156.146(a))

Registrants using option 1.c.ii (above) must give triple rinse instructions immediately followed by pressure rinse instructions.

1d. How to clean rigid, nonrefillable containers of dilutable pesticides

For dilutable pesticides in rigid nonrefillable containers, the label must include triple rinse instructions unless EPA waives the requirement. The options for **triple rinse** instructions for rigid, nonrefillable containers with dilutable pesticides are:

i. For liquid dilutable pesticides in rigid, nonrefillable containers small enough to shake (i.e., with capacities equal to or less than 5 gallons), "Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."

ii. For solid dilutable pesticides in rigid, nonrefillable containers small enough to shake (i.e., with capacities equal to or less than 5 gallons or 50 pounds), "Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."

iii. For any dilutable pesticides in rigid, nonrefillable containers too large to shake (i.e., with capacities more than 5 gallons or 50 pounds): "Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times."

(See §156.146(b))

iv. For antimicrobial products with public health claims that are dilutable pesticides in rigid, nonrefillable containers EPA has approved the following alternative rinsing instructions that are generally added by amendment, not notification:

"Triple rinse as follows: Fill container 1/4 full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times."

The options for **pressure rinse instructions** for rigid, nonrefillable containers of dilutable pesticides are:

v. For liquid dilutable pesticides in rigid, nonrefillable containers, "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."

vi. For solid dilutable pesticides in rigid, nonrefillable containers, "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank.

Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."

(See §156.146(c))

Registrants who want to use a non-water diluent must submit a request to EPA explaining why a diluent other than water is necessary, what the diluent is, and the instructions that would be used for cleaning the container and disposing of the rinsate.

Registrants may not distribute or sell the pesticide with modified residue removal instructions (using a non-water diluent) until EPA approves the request in writing.

(See §156.146(d))

1e. Recycle, recondition, or dispose

The label of a pesticide product in a nonrefillable container must have instructions on whether to recycle or recondition nonrefillable containers *except for* plant-incorporated protectants, pesticidal articles not already exempted under *§152.25(a),* and pesticides distributed only in transport vehicles, or if EPA requires a different statement or approves a modification or waiver requested by the registrant. In addition, the label should include instructions for disposing of the container if recycling or reconditioning is not an option. *(See §156.140(a)(3)* and *PR Notice* 83-3*)*

The options for **container recycling/reconditioning** *(§156.146(a)(3))* are:

i. "Offer for recycling if available or *[disposal statement]*."

ii. "Offer for reconditioning if appropriate or *[disposal statement]*."

iii. If it is an agricultural product: "Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact [*a pesticide container recycling organization*] at [*phone number*] or [*web site*] or *[disposal statement]*." *[An example of a pesticide container recycling organization, phone number or web site is: Ag Container Recycling Council at 1-877-952-2272 or* www.acrecycle.org*]*

iv. A recycling statement published in an EPA document, such as a PR Notice.

v. A recycling statement reviewed and approved by EPA.

The options for **disposing** of the container are: *[to follow one of the statements from i. through v above]*

…place [or put] in trash or in a sanitary landfill.

…dispose of in trash or in a sanitary landfill or by incineration.

…dispose of in trash or in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

…dispose of in trash or in a sanitary landfill or by incineration. Do not burn, unless allowed by state and local ordinances.

…dispose of in trash or in a sanitary landfill or by incineration. In most states, burning is not allowed.

1f. Batch code

The batch code is required on all nonrefillable containers ***except for*** plant-incorporated protectants, pesticidal articles not already exempted under *§152.25(a)* and pesticides distributed solely in transport vehicles. It may be a lot number, or other code used by the registrant or producer to identify the batch of the product distributed or sold. *(See §156.140(a)(4))*

2. REFILLABLE CONTAINERS

If the pesticide is distributed in a refillable container the label,	
MUST HAVE:	2a. The refillable container statement 2b. Reuse limitations 2c. Who is responsible for cleaning and when 2d. How to clean
AND SHOULD HAVE:	2e. Return and/or disposal insructions

If the pesticide is distributed or sold in a refillable container, the label must have the statements described below unless otherwise exempted, modified or waived with EPA approval. If EPA requires a different statement or approves a modification or waiver, label changes would be made by amendment. Registrants can use notification if the exact wording is used from the regulations in 40 CFR §§*156.140* – 156.156 or if otherwise allowed by EPA.

2a Refillable container and 2b Disposal instructions

2a. The statement "Refillable container" and **2b.** Reuse limitations are required on the label of all refillable containers ***except for*** plant-incorporated protectants, pesticidal articles not already exempted under §152.25(a), and pesticides distributed only in transport vehicles. Also, EPA may require a different statement or approve a modification or waiver requested by the registrant.

The options are:

i. "Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose."

ii. "Refillable container. Refill this container with [common chemical name] only. Do not reuse this container for any other purpose."

Unlike nonrefillable containers, the labels of refillable containers must have cleaning instructions whether or not the container is rigid and/or the product is dilutable.

2c and 2d Cleaning instructions

2c. Statements about who is responsible for cleaning a refillable container & when are required on the label of all refillable containers ***except for*** pesticidal articles not already exempted under §152.25(a), pesticides that are gases under atmospheric conditions, residential/household use products and pesticides distributed only in transport vehicles. Also, EPA may require a different statement or approve a modification or waiver requested by the registrant. *(See §156.144(c) through (g))*

The options are:

i. "Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller." *(Triple rinsing or pressure rinsing instructions follow.); or*

ii. "Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller." *(Pressure rinsing instructions follow.)*

(See §156.156(a))

2d. Instructions on **how to clean a refillable container are** required ***except for*** products that are pesticidal articles not already exempted under §152.25(a), gases under atmospheric conditions, residential/household use or pesticides distributed only in transport vehicles. Also, EPA may require a different statement or approve a modification or waiver requested by the registrant. *(§156.144(c) through (g))*

Instructions for removing residue from refillable containers prior to disposal must be appropriate for the characteristics and formulation of the pesticide product and must be adequate to protect human health and the environment. *(See §156.156(b))*

The options are:

i. For pesticides that require dilution prior to application, the following statement can be used: "To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times."

ii. A procedure developed by the registrant for that product;

iii. Standard industry practices for refillable containers;

iv. Any other statement the registrant considers appropriate and EPA accepts.

2e. Instructions on how to **return or recycle/dispose of refillable containers should be on refillable containers.**

The options for the return of **refillable containers are:**

i. When empty, return to point of sale.

ii. Call 1-800-XXX-XXXX for instructions on returning the empty container.

iii. Any other statement reviewed and approved by EPA.

The options for disposal of **refillable containers depends on the product and type of container.**

One example is:

…or puncture or dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

See Tables B1 through B5 below for appropriate disposal instructions.

3. **Multiple container disposal statements on one label**

Each pesticide product must bear storage and disposal statements appropriate for its container. The registrant may submit separate labels for each container type and/or size, or may submit a single label with alternative storage and disposal statements. A label submitted for EPA review that bears multiple statements must indicate the circumstances in which each statement would appear on a final container label. For example, a label may indicate in italics and/or brackets that one section of the

container handling and disposal instructions are for plastic containers with a capacity of 5 gallons or less while another section is for plastic containers greater than 5 gallons. The proposed labels will be reviewed by the appropriate EPA Product Manager or the Notification Team and approved if acceptable.

Example of Container Handling Instructions for Multiple Container Types, Sizes and Uses*

Container Handling
(*For Residential/Household Uses)*
Nonrefillable container. Do not reuse or refill this container. If empty: Offer for recycling if available or discard in a sanitary landfill. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

(For Commercial Uses)
For plastic containers less than or equal to 5 gallons: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

For plastic containers greater than 5 gallons: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Recap and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

**This example is for a dilutable product, distributed or sold in a rigid, nonrefillable container.*

Preferably, a label that appears on or is securely attached to the immediate container will have instructions only for that container. However, it may be acceptable for a pesticide product label to have container handling/container disposal instructions for multiple container types in which that product can be sold, provided that the presentation of the instructions is sufficiently clear to the end user. The end user must be able to read, understand, and identify which instructions to use under customary conditions of purchase and use, and not detract from other label provisions. If an end user cannot tell which set of container handling/container disposal instructions to follow, the pesticide would be misbranded.

Some labels have alternative handling/disposal statements that were approved under the assumption that end users knew that 1- and 2.5-gallon containers are not ordinarily intended to be refillable. Thus, those labels did not specifically identify the containers as non-refillable and did not specifically exclude 1- and 2.5-gallon containers from the refillable container instructions. However, in order to facilitate the use of 1- and 2.5-gallon refillable containers in the future, EPA intends to ask registrants to revise these labels to identify whether containers are refillable or non-refillable when other label changes are proposed. During the review of future label amendments, EPA will also look for situations and ask for clarification where multiple handling/disposal instructions might be confusing and appear to apply to only one container type and/or size.

ATTACHMENT A

Pesticide Storage Statements for Products with Certain Active Ingredients

Historically, EPA has developed specific storage instructions for certain active ingredients. Table 2 below shows some examples. However, these *may not be the complete **storage** instructions*. Registrants should check with EPA Product Managers and follow the guidance provided in this chapter for the complete the storage instructions. Examples of requirements that may not be provided in Table 2 for all active ingredients include, but are not limited to:

- All instructions must appear under the heading "STORAGE AND DISPOSAL".
- Products sold for uses other than residential/household use must have the statement: "Do not contaminate water, food, or feed by storage and disposal."
- Products distributed or sold in nonrefillable containers must use the subheading "CONTAINER HANDLING".

Although Table 2 contains mostly storage instructions, product disposal and container handling instructions may also be provided for some active ingredients. Registrants should check and the information provided in this chapter for the most recent and complete storage and disposal instructions. Statements in bold indicate language added to comply with the regulations at *40 CFR §156.140*.

Table 2. Preferred Active-Ingredient Specific Pesticide Storage Statements

Active Ingredient	Pesticide Storage Statements[5]	Source of Statement
Liquid sodium hypochlorite	"STORAGE AND DISPOSAL *For Household use products:* STORAGE: 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 DISPOSAL: Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer. CONTAINER HANDLING: **Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or reconditioning if appropriate** or place in trash. *For Institutional/Commerical Use:* Do not contaminate water, food, or feed by storage and disposal. STORAGE: Store in a cool, dry area away from direct sunlight and heat to avoid deterioration. In case of spill, flood area with large quantities of water. PRODUCT DISPOSAL: Products or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer. CONTAINER HANDLING: **Nonrefillable container. Do not reuse or refill this container. Fill the container ¼ full with water and recap. Shake for 10 seconds and dispose of rinsate in sanitary sewer. Offer container for recycling if available or reconditioning if appropriate** or place in trash."	*PR Notice 84-1 & errata sheet*, *40 CFR 156.140*, and *PR Notice 2007-4*
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. **CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available** or place in trash collection. Do not contaminate food or feed by storage, disposal, or cleaning of equipment."	*PR Notice 84-1 & errata sheet*, *40 CFR 156.140*, and *PR Notice 2007-4*
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. **CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container**. **Offer for recycling if available** or place in trash collection. Do not contaminate food or feed by storage, disposal, or cleaning of equipment."	*PR Notice 84-1 & errata sheet*, *40 CFR 156.140*, and *PR Notice 2007-4*

5 Not all instructions provided in this table are the complete storage and disposal instructions required for the active ingredient shown.

Active Ingredient	Pesticide Storage Statements5	Source of Statement
Etridiazole	Manufacturing use products must contain the statement "This product is corrosive to steel and many other metals. Do not transport or store in unlined metal containers." *(Note: these statements take precedence over the storage guidelines in the PR Notice for manufacturing use products only.)*	PR Notice 84-1
Methyl bromide and Methyl bromide plus 2% or less chloropicrin	"Store in dry, cool, well-ventilated area under lock and key. Post as a pesticide storage area. Do not contaminate water, food, or feed by storage. Store cylinders upright, secured to a rack or wall to prevent tipping. Cylinders should not be subjected to rough handling or mechanical shock such as dropping, bumping, dragging, or sliding. Do not use rope slings, hooks, tongs or similar devices to unload cylinders. Transport cylinders using hand truck, fork truck or other device to which the cylinder can be firmly secured. Do not remove valve protection bonnet and safety cap until immediately before use. Replace safety cap and valve protection bonnet when cylinder is not in use. When cylinder is empty, close valve, screw safety cap onto valve outlet, and replace protection bonnet before returning to shipper. Only the registrant is authorized to refill cylinders. Do not use cylinders for any other purpose. Follow registrant's instructions for return of empty or partially empty cylinders."	PR Notice 84-5
Aluminum phosphide and Magnesium phosphide	"Not for use or storage in or around inhabited areas. Protect from moisture, open flames, and heat. Store in a dry, cool, well-ventilated area under lock and key. Post as a pesticide storage area. Store container away from all liquids. Store so as to minimize hazards of tipping, spilling or accidental puncturing of the container. Keep container tightly closed when not in use. Do not contaminate water, food, or feed by storage or disposal."	PR Notices 84-5 and 84-1
Chloropicrin	"Store in dry, cool, well-ventilated area under lock and key. Post as a pesticide storage area. Do not contaminate water, food, or feed by storage or disposal. Persons moving or handling containers should wear protective clothing. Open container only in a well-ventilated area wearing protective clothing, and respiratory protection if necessary."	PR Notice 84-5
Sodium cyanide	"Store in dry, cool, well-ventilated area under lock and key. Post as a pesticide storage area. Store container away from all liquids. Store so as to minimize hazards of tipping, spilling or accidental puncturing of the container. Keep container tightly closed when not in use. Do not contaminate water, food, or feed by storage or disposal."	PR Notice 84-5

Active Ingredient	Pesticide Storage Statements5	Source of Statement
Ethylene oxide	"Do not contaminate water, food, or feed by storage. Store in dry, cool, well-ventilated area under lock and key. Post as a pesticide storage area. Store cylinders upright, secured to a rack or wall to prevent tipping. Cylinders should not be subjected to rough handling or mechanical shock such as dropping, bumping, dragging, or sliding. Do not use rope slings, hooks, tongs or similar devices to unload cylinders. Transport cylinders using hand truck, fork truck or other device to which the cylinder can be firmly secured. Do not remove valve protection bonnet and safety cap until immediately before use. Replace safety cap and valve protection bonnet when cylinder is not in use. When cylinder is empty, close valve, screw safety cap onto valve outlet, and replace protection bonnet before returning to shipper. Only the registrant is authorized to refill cylinders. Do not use cylinders for any other purpose. Follow registrant's instructions for return of empty or partially empty cylinders."	*PR Notice 84-5*
Sulfuryl fluoride	"Store in dry, cool, well-ventilated area under lock and key. Post as a pesticide storage area. Do not contaminate water, food, or feed by storage. Store cylinders upright, secured to a rack or wall to prevent tipping. Cylinders should not be subjected to rough handling or mechanical shock such as dropping, bumping, dragging, or sliding. Do not use rope slings, hooks, tongs or similar devices to unload cylinders. Transport cylinders using hand truck, fork truck or other device to which the cylinder can be firmly secured. Do not remove valve protection bonnet and safety cap until immediately before use. Replace safety cap and valve protection bonnet when cylinder is not in use. When cylinder is empty, close valve, screw safety cap onto valve outlet, and replace protection bonnet before returning to shipper. Only the registrant is authorized to refill cylinders. Do not use cylinders for any other purpose. Follow registrant's instructions for return of empty or partially empty cylinders."	*PR Notice 84-5*

ATTACHMENT B

Storage Statements Suggested by EPA

The following are examples of storage statements that registrants may use for products with active ingredients not listed in *Attachment A*. EPA provided these suggested statements as a result of a recommendation from the State FIFRA Issues Research and Evaluation Group. Some of these may not be appropriate for all pesticide products.

"Always store pesticides in the original container. If a leaky container must be contained within another, mark the outer container to identify the contents."

"Storage areas must be locked and secure from vandalism, with precautionary signs posted."

"The storage area must be dry, well-lit, and well-ventilated. Keep pesticide storage areas clean. Clean up any spills promptly."

"Store pesticides away from food, pet food, feed, seed, fertilizers, and veterinary supplies."

"Protect pesticide containers from extreme heat and cold."

"Store herbicides, insecticides and fungicides in separate areas within the storage unit."

"Place liquid formulations on lower shelves and dry formulations above."

"Maintaining a spill kit and fire extinguisher on hand and having emergency phone numbers posted will allow you to be prepared for emergencies."

"If spill cleanup PPE is stored nearby, but outside the pesticide storage area, it will be accessible when needed."

ATTACHMENT C

Container Handling Instructions by Container Type

The following tables show the full set of appropriate container handling instructions by different container types. In each table, the first column describes which of the statements, if any, are required and under what conditions. The second column describes the general category of the statements, using the categories described in Unit IV.C of Chapter 13. The last columns on the right show the specific language to include on the pesticide label. Areas shaded in gray indicate that the statement it is not required for that container type. In a situation where a specific container type is not listed, see the appendices to PR Notice *2007-4* and/or one of the following tables below for guidance: Table A7 (for other rigid nonrefillable containers); Table A8 (for other non-rigid nonrefillable containers); or Table B5 (for other refillable containers).

List of Tables

Table A1: Container Handling Statements for NONREFILLABLE METAL Containers (non-aerosol)

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required	***a. Subheading***	[a] "Container Handling" [*or other appropriate subheading]*
Required unless product and/or container type are exempt per *§156.140(a)(5) (See unit IV.C.1a or Table 1 of this chapter)* **Use** [b] followed by one option from c1, c2, c3 or c4	***b. Container type*** ***and*** ***c. Reuse limitations of container***	[b] "Nonrefillable container. "
		[c1] "Do not reuse or refill this container."
		[c2] "Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state."
		[c3] "Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container." *(May use if product is ready-to-use and directions for use allow a different product [similar but concentrated] to be poured into container and diluted by end user.)*
		[c4] "Do not reuse or refill this container unless allowed by the directions for use." *(May use if product is ready-to-use, directions for use allow it to be refilled with same pesticide, and EPA approves use of this language.)*
Required for non-residential/household use only if product is dilutable **Use** one option from d1, d2 or d3, followed by one option from e1, e2, e3 or e4 *A "dilutable" product is mixed with a diluent by the end user before use or application*	***d. When to clean***	[d1] "Clean container promptly after emptying."
		[d2] "Triple rinse or pressure rinse container (or equivalent) promptly after emptying." *(Registrants must give instructions for triple rinsing immediately followed by pressure rinsing instructions)*
		[d3] "Triple rinse container (or equivalent) promptly after emptying."
	e. How to clean	[e1] For liquid dilutables in containers small enough to shake (5 gallons or less) "Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."

Table A1: Container Handling Statements for NONREFILLABLE METAL Containers (non-aerosol)

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Registrants who wish to use a diluent other than water must contact EPA for approval		[e2] For solid dilutables in containers small enough to shake (5 gallons or 50 pounds or less) "Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."
		[e3] For any dilutable pesticides in containers too large to shake (larger than 5 gallons or 50 pounds) "Triple Rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times."
		[e4] For *antimicrobial products with public health claims for dilutable pesticide in rigid, nonrefillable containers]:* "Triple rinse as follows: Fill container 1/4 full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times."
Not required, but if d1 or d3 is used, registrants may add e5 or e6 after e1, e2, e3 or e4		[e5] For liquid dilutable pesticides "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."

Table A1: Container Handling Statements for NONREFILLABLE METAL Containers (non-aerosol)

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
		[e6] For solid dilutable pesticides "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."
Required **Use** one option from f1, f2 or f3	***f. Recycle + dispose***	[f1] "Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities."
		[f2] "Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities."
		[f3] "The offer for reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities."
Required anywhere on label or on container	***g. Batch code***	A lot number, or other code used by the registrant or producer to identify the batch.

Table A2: Container Handling Statements for NONREFILLABLE AEROSOL CANS

Registrants may request a waiver or modification from EPA for any of the requirements. Please note that while these statements are from PR notices that address household or residential use products, the Agency is recommending the same statements for all other aerosol products.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required	***a. Subheading***	[a] "Container Handling" [*or other appropriate subheading]*
Exempt per §156.140(a)(5) *(See unit IV.C.1a or Table 1 of this chapter)*	***b. Container type*** ***and*** ***c. Reuse limitations of container***	
Not required because product is not dilutable *(Also not required for residential/household uses or products that are gases)*	***d. When to clean*** ***and*** **e.** ***How to clean***	
Required **Use** f1 or f2	***f. Recycle or dispose and pesticide disposal***	[f1] 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 for disposal instructions."
		[f2] "Do Not Puncture or Incinerate! If empty: 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, discard in the trash. If partly filled: Call your local solid waste agency for disposal instructions."
Required anywhere on label or on container	***g. Batch code***	A lot number, or other code used by the registrant or producer to identify the batch.

Table A3: Container Handling Statements for NONREFILLABLE PLASTIC Containers

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required	***a. Subheading***	[a] "Container Handling" [*or other appropriate subheading]*
Required unless product and/or container type are exempt per *§156.140(a)(5)* *(See unit IV.C.1a or Table 1 of this chapter)* **Use** b followed by one option from c1, c2, c3 or c4	***b. Container type***	[b] "Nonrefillable container. "
	c. Reuse limitations of container	[c1] "Do not reuse or refill this container."
		[c2] "Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state."
		[c3] "Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container." *(May use if product is ready-to-use and directions for use allow a different product [similar but concentrated] to be poured into container and diluted by end user.)*
		[c4] "Do not reuse or refill this container unless allowed by the directions for use." *(May use if product is ready-to-use, directions for use allow it to be refilled with same pesticide, and EPA approves use of this language.)*
Required for non-residential /household use only if the product is dilutable **Use** one option from d1, d2 or d3 followed by one option from e1, e2, e3 or e4	***d. When to clean***	[d1] "Clean container promptly after emptying."
		[d2] "Triple rinse or pressure rinse container (or equivalent) promptly after emptying." *(Registrants must have instructions for triple rinsing immediately followed by pressure rinsing instructions.)*
		[d3] "Triple rinse container (or equivalent) promptly after emptying.

Table A3: Container Handling Statements for NONREFILLABLE PLASTIC Containers

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Registrants who want to use a diluent other than water must first get EPA approval *A "dilutable" product is mixed with a diluent by the end user before use or application*	e. ***How to clean***	[e1] For liquid dilutables in containers small enough to shake (5 gallons or less) "Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times." [e2] For solid dilutables in containers small enough to shake (5 gallons or 50 pounds or less) "Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times." [e3] For any dilutable pesticide in containers too large to shake (larger than 5 gallons or 50 pounds) "Triple Rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times." [e4] For *antimicrobial products with public health claims for dilutable pesticide in rigid, nonrefillable containers]:* "Triple rinse as follows: Fill container 1/4 full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times."

Table A3: Container Handling Statements for NONREFILLABLE PLASTIC Containers

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by 40 CFR §152.25(a) are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Not required, but if d1 or d3 is used, registrants may add e5 or e6 after e1, e2, e3 or e4		[e5] For liquid dilutable pesticides "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip." [e6] For solid dilutable pesticides "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."
Required **Use** one option from f1, f2, f3 or f4	***f. Recycle + dispose***	[f1] "Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by puncture and dispose of in a sanitary landfill, or by incineration."
		[f2] "Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration."
		[f3] "Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer, or contact [a pesticide container recycling organization] at [phone number] or [website], or puncture and dispose of in a sanitary landfill, or by incineration."
		[f4] "Then offer for recondition-ing if appropriate or puncture and dispose of in a sanitary landfill or by incineration."
Not required, but registrants may add f6, f7 or f8 after f1, f2, f3 or f4		[f6] …"or if allowed by state and local authorities, by burning. If burned, stay out of smoke."
		[f7] …"Do not burn, unless allowed by state and local ordinances."
		[f8] …"In most states, burning is not allowed."

Table A3: Container Handling Statements for NONREFILLABLE PLASTIC Containers

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required anywhere on label or on container	***g. Batch code***	A lot number, or other code used by the registrant or producer to identify the batch.

Table A4: Container Handling Statements for NONREFILLABLE PAPER and PLASTIC BAGS

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required	***a. Subheading***	[a] "Container Handling" [*or other appropriate subheading]*
Required unless product and/or container type are exempt per *§156.140(a)(5)* *(See unit IV.C.1a or Table 1 of this chapter)* **Use** b followed by one option from c1 or c2	***b. Container type***	[b] "Nonrefillable container. "
	c. Reuse limitations of container	[c1] "Do not reuse or refill this container."
		[c2] "Do not reuse or refill this container unless allowed by the directions for use." *(May use if product is ready-to-use, its directions for use allow it to be refilled with same pesticide, and EPA approves use of this language.)*
Not required because the nonrefillable container is not rigid *(Also not required for residential/household uses or products that are gases)*	***d. When to clean***	
Required except for residential/household use (PRN 83-3) **Use** [e1]	*e.* ***How to clean and Recycle +dispose***	[e1] "Completely empty bag into application equipment, then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration."
Not required, but registrants may add e2, e3 or e4 after e1		[e2] …"or if allowed by state and local authorities, by burning. If burned, stay out of smoke."
		[e3] …"Do not burn, unless allowed by state and local ordinances."
		[e4] …"In most states, burning is not allowed."
Required anywhere on label or on container	***f. Batch code***	A lot number, or other code used by the registrant or producer to identify the batch.

Table A4: Container Handling Statements for NONREFILLABLE PAPER and PLASTIC BAGS

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label

Table A5: Container Handling Statements for NONREFILLABLE FIBER DRUMS with LINERS

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required	***a. Subheading***	[a] "Container Handling" [*or other appropriate subheading]*
Required unless product and/or container type are exempt per *§156.140(a)(5) (See unit IV.C.1a or Table 1 of this chapter)* **Use** [b] followed by one option from c1, c2, c3 or c4	***b. Container type***	[b] "Nonrefillable container. "
	c. Reuse limitations of container	[c1] "Do not reuse or refill this container."
		[c2] "Do not reuse this container to hold materials other than pesticides or dilutable pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state."
		[c3] "Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container." *(May use If product is "ready-to-use" and directions for use allow a different product [similar but concentrated] to be poured into container and diluted by end user.)*
		[c4] "Do not reuse or refill this container unless allowed by the directions for use." *(May use if product is ready-to-use, directions for use allow it to be refilled with same pesticide, and EPA approves use of this language.)*
Not required because the nonrefillable container is not rigid	***d. When to clean***	
Required **Use** [e]	*e.* ***How to clean***	[e] "Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment."
Required **Use** f1 followed by f5	***f. Recycle + dispose***	[f1] "then offer for recycling if available or dispose of in a sanitary landfill or by incineration"...

Table A4: Container Handling Statements for NONREFILLABLE PAPER and PLASTIC BAGS

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Not required, but registrant may add f2, f3 or f4 in between f1 and f5		[f2] …"or if allowed by state and local authorities, by burning. If burned, stay out of smoke."
		[f3] …"Do not burn, unless allowed by state and local ordinances."
		[f4] …"In most states, burning is not allowed."
		[f5] "If drum is contaminated and cannot be reused*, dispose of it in the manner required for its liner." *(* A registrant may replace this phrase with one indicating whether & how fiber drum may be reused.)*
Required anywhere on label or on container	***g. Batch code***	A lot number, or other code used by the registrant or producer to identify the batch.

Table A6: Container Handling Statements for NONREFILLABLE FOIL OUTER POUCHES of WATER SOLUBLE PACKETS (WSP)

Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required	***a. Subheading***	[a] "Container Handling" [*or other appropriate subheading]*
Exempt per *http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title40/40tab_02.tplhttp://www.ecfr.gov/cgi-bin/text-*	***b. Container type and c. Reuse limitations of container***	
Not required because the nonrefillable container is not rigid	***d. When to clean and e. How to clean***	
Required **Use** f	***f. Recycle + dispose***	[f] "Offer foil pouch for recycling if available or dispose of empty pouch in the trash as long as WSP is unbroken."
Required anywhere on label or on container	***g. Batch code***	A lot number, or other code used by the registrant or producer to identify the batch.

Table A7 Container Handling Statements for OTHER RIGID NONREFILLABLE Containers

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required	***a. Subheading***	[a] "Container Handling" [or other appropriate subheading]
Required unless the product and/or container type are exempt per *§156.140(a)(5)* *(See unit IV.C.1a or Table 1 of this chapter)* **Use** [b] followed by one option from c1, c2, c3 or c4	***b. Container type***	[b] "Nonrefillable container."
	c. Reuse limitations of container	[c1] "Do not reuse or refill this container."
		[c2] "Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state."
		[c3] "Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container." *(May use if product is ready-to-use, directions for use allow a different product [similar but concentrated] to be poured into container and diluted by end user.)*
		[c4] "Do not reuse or refill this container unless allowed by the directions for use." *(May use if the product is ready-to-use, directions for use allow it to be refilled with same pesticide, and EPA approves use of this language.)*
Required for uses other than residential/household use **only if** the product is dilutable Use one option from d1, d2 or d3	***d. When to clean***	[d1] "Clean container promptly after emptying."
		[d2] "Triple rinse or pressure rinse container (or equivalent) promptly after emptying." *(Registrants must have instructions for triple rinsing immediately followed by pressure rinsing instructions.)*
		[d3] "Triple rinse container (or equivalent) promptly after emptying."

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Use one option from d1, d2 or d3 followed by one option from e1, e2, e3 or e4 *A "dilutable" product is mixed with a diluent by the end user before use or application* *Registrants who want to use a diluent other than water must first get EPA approval*	***e. How to clean***	[e1] For liquid dilutables in containers small enough to shake (5 gallons or less) "Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."
		[e2] For solid dilutables in containers small enough to shake (5 gallons or 50 pounds or less) "Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."
		[e3] For any dilutable pesticides in containers too large to shake (larger than 5 gallons or 50 pounds) "Triple Rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times."
		[e4] For *antimicrobial products with public health claims for dilutable pesticide in rigid, nonrefillable containers:* "Triple rinse as follows: Fill container 1/4 full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times."
Not required but if using d1 or d2, registrants may add e5 or e6 after e1, e2, e3 or e4		[e5] For liquid dilutable pesticides "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
		[e6] For solid dilutable pesticides "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."
Required **Use** one option from f1, f2 or f3	***f. Recycle, recondition or dispose***	[f1] "Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities."*
		[f2] "Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities."*
		[f3] "Then offer for reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities."*
Required anywhere on label or on container	***g. Batch code***	A lot number, or other code used by the registrant or producer to identify the batch.

Table A8 Container Handling Statements for OTHER NON-RIGID NONREFILLABLE Containers

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are not already exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required	***a. Subheading***	[a] "Container Handling" *[or other appropriate subheading]*
Required unless the product and/or container type are exempt per *§156.140(a)(5)* *[See unit IV.C.1a or Table 1 of this chapter]* **Use** [b] followed by one option from c1, c2, c3 or c4	***b. Container type***	[b] "Nonrefillable container."
	c. Reuse limitations for container	[c1] "Do not reuse or refill this container."
		[c2] "Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state."
		[c3] "Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container." *(May use if ready-to-use and directions for use allow a different product (similar but concentrated) to be poured into container and diluted by end user.)*
		[c4] "Do not reuse or refill this container unless allowed by the directions for use." *(May use if product is ready-to-use, its directions for use allow it to be refilled with same pesticide, and EPA approves use of this language.)*
Not required because the nonrefillable container is not rigid. *(Also not required for residential/household use)* (*§156.146*)	***d. When to clean***	
May be required except for residential/ household use (PRN *83-3*)	***e. How to clean***	*See the "How to clean" instructions for paper or plastic bags and fiber drums with liners for potentially applicable cleaning or emptying instructions from* PR Notice 83-3*.*
Required		[f1] "Offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities."*

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Use one option from f1, f2 or f3	***f. Recycle, recondition or dispose***	[f2] "Offer for recycling if available or reconditioning if appropriate or dispose of in a sanitary landfill or by other procedures approved by state and local authorities."*
		[f3] "Offer for reconditioning if appropriate or dispose of in a sanitary landfill or by other procedures approved by state and local authorities."*
		**Note that "or by other procedures approved by state and local authorities" is a basic container disposal statement that is likely to apply to many types of containers. For other options, see the specific container disposal statements for nonrefillable metal, plastic, paper/plastic bags, and fiber drums with liners.*
Required anywhere on label or on container	***g. Batch code***	A lot number, or other code used by the registrant or producer to identify the batch.

Table A8 Container Handling Statements for OTHER NON-RIGID NONREFILLABLE Containers

Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles that are already not exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required	***a. Subheading***	[a] "Container Handling" *[or other appropriate subheading]*
Required unless the product and/or container type are exempt per *§156.140(a)(5)* *[See unit IV.C.1a or Table 1 of this chapter]* **Use** [b] followed by one option from c1, c2, c3 or c4	***b. Container type***	[b] "Nonrefillable container."
	c. Reuse limitations of container	[c1] "Do not reuse or refill this container."
		[c2] "Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state."
		[c3] "Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container." *(May use if ready-to-use and directions for use allow a different product (similar but concentrated) to be poured into container and diluted by end user.)*
		[c4] "Do not reuse or refill this container unless allowed by the directions for use." *(May use if product is ready-to-use, its directions for use allow it to be refilled with same pesticide, and EPA approves use of this language.)*
Not required because the nonrefillable container is not rigid. *Also not required for residential/household use* (*See §156.146*	***d. When to clean***	
May be required except for residential/ household use (PRN *83-3*)	***e. How to clean***	*See the "How to clean" instructions for paper or plastic bags and fiber drums with liners for potentially applicable cleaning or emptying instructions from* PR Notice 83-3.
Required **Use** one option from f1, f2 or f3	***f. Recycle, recondition or dispose***	[f1] "Offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities."*
		[f2] "Offer for recycling if available or reconditioning if appropriate or dispose of in a sanitary landfill or by other procedures approved by state and local authorities."*

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
		[f3] "Offer for reconditioning if appropriate or dispose of in a sanitary landfill or by other procedures approved by state and local authorities."*
		**Note that "or by other procedures approved by state and local authorities" is a basic container disposal statement that is likely to apply to many types of containers. For other options, see the specific container disposal statements for nonrefillable metal, plastic, paper/plastic bags, and fiber drums with liners.*
Required anywhere on label or on container	***g. Batch code***	A lot number, or other code used by the registrant or producer to identify the batch.

Table B1 Container Handling Statements for REFILLABLE METAL Containers (non-aerosol)

Pesticidal articles that are not already exempted by *40 CFR §152.25(a)* and pesticides distributed only in transport vehicles are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Not required but recommended	***a. Subheading***	[a] "Container Handling" *[or other appropriate subheading]*
Required except for plant-incorporated protectants **Use** [b] followed by c1 or c2	***b. Container type***	[b] "Refillable container."
	c. Reuse limitations of container	[c1] "Refill this container with pesticide only. Do not reuse this container for any other purpose."
		[c2] "Refill this container with [*common chemical name*] only. Do not reuse this container for any other purpose."
Required except for products that are gases and for residential/ household use products **Use** d1 or d2 followed by one option from e1, e2, e3 or e4, where the statements from [d] and [e] must be consistent	***d. Who is responsible for cleaning and when***	[d1] "Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal"…
		[d2] "Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal"…
	e. How to clean	[e1] [*The refilling residue removal procedure developed by the registrant for the pesticide product.*]*
		[e2] *[Standard industry practices for cleaning refillable containers.*]*
		[e3] *[For pesticides that require dilution prior to application, the following statement*:]* …"empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times."
		[e4] *[Any other statement the registrant considers appropriate.*]*
		** The cleaning procedure must be appropriate for the characteristics and formulation of the pesticide product and must be adequate to protect human health and the environment.*
Not required but recommended	***f. Return, recycle or disposal***	[f1] "Return to point of sale."
		[f2] *[Any other return statement the registrant considers appropriate.]*

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Use f1 or f2 followed by f3 or f4		[f3] …"or offer for recycling if available or reconditioning if appropriate"… or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities." [f4] … "or offer for recycling if available"… "or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities."

Table B2 Container Handling Statements for REFILLABLE PLASTIC Containers

Pesticidal articles that are not exempted by *40 CFR §152.25(a)* and pesticides distributed only in transportation vehicles are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Not required but recommended	***a. Subheading***	[a] "Container Handling" *[or other appropriate subheading]*
Required except for plant-incorporated protectants **Use** [b] followed by c1 or c2	***b. Container type***	[b] "Refillable container."
	c. Reuse limitations of container	[c1] "Refill this container with pesticide only. Do not reuse this container for any other purpose."
		[c2] "Refill this container with [*common chemical name*] only. Do not reuse this container for any other purpose."
Required except for products that are gases or residential/ household use products **Use** d1 or d2 followed by one option from e1, e2, e3 or e4, where the statements from [d] and [e] must be consistent	***d. Who is responsible for cleaning and when***	[d1] "Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal,"
		[d2] "Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal,"
	e. How to clean	[e1] [*The refilling residue removal procedure developed by the registrant for the pesticide product.*]*
		[e2] *[Standard industry practices for cleaning refillable containers.*]*
		[e3] *[For pesticides that require dilution prior to application, the following statement:*]* "Empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times."
		[e4] *[Any other statement the registrant considers appropriate.*]*
		** The cleaning procedure must be appropriate for the characteristics and formulation of the pesticide product and must be adequate to protect human health and the environment.*

Not required but recommended **Use** f1 or f2 followed by f3 or f4, then f5	***f. Return, recycle or disposal***	[f1] "Return to point of sale." [f2] *[Any other return statement the registrant considers appropriate.]* [f3] "Then offer for recycling if available"… [f4] "Then offer for recycling if available or reconditioning if appropriate"… [f5] …"or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved state and local authorities."

Table B3 Container Handling Statements for REFILLABLE FIBER DRUMS WITH LINERS

Pesticidal articles that are not exempted by *40 CFR §152.25(a)* are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Not required but recommended	***a. Subheading***	[a] "Container Handling" [or other appropriate subheading]
Required except for plant-incorporated protectants **Use** [b] followed by c1 or c2	***b. Container type***	[b] "Refillable container."
	c. Reuse limitations of container	[c1] "Refill this container with pesticide only. Do not reuse this container for any other purpose."
		[c2] "Refill this container with [*common chemical name*] only. Do not reuse this container for any other purpose."
Required except for products that are gases and for residential/ household use products **Use** d1 or d2 followed by one option from e1, e2, e3 or e4, where the statements from [d] and [e] must be consistent	***d. Who is responsible for cleaning and when and*** ***e. How to clean***	[d1] "Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal"…
		[d2] "Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal"…
		[e1] [*The refilling residue removal procedure developed by the registrant for the pesticide product.*]*
		[e2] *[Standard industry practices for cleaning refillable containers.*]*

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
		[e3] "Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment or a mix tank."
		[e4] *[Any other statement the registrant considers appropriate.*]*
		** The cleaning procedure must be appropriate for the characteristics and formulation of the pesticide product and must be adequate to protect human health and the environment.*
Not required but recommended **Use** f1 or f2, followed by f3 or f4, followed by f5 or f6, then f9 *May insert f5 or f6 in front of f9*	***f. Return, recycle or disposal***	[f1] "Return to point of sale." [f2] *[Any other return statement the registrant considers appropriate.]* [f3] "or offer for recycling if available"… [f4] "or offer for recycling if available or reconditioning if appropriate"… [f5]…"or dispose of in a sanitary landfill, or by incineration, or if allowed by local and state authorities, by burning. If burned, stay out of smoke." If drum is contaminated and cannot be reused*, dispose of it in the manner required for its liner. [f6] …"or dispose of in a sanitary landfill, or by incineration." If drum is contaminated and cannot be reused*, dispose of it in the manner required for its liner. [f7] "Do not burn unless allowed by state and local ordinances." [f8] "In most states, burning is not allowed." [f9] "If drum is contaminated and cannot be reused*, dispose of it in the manner required for its liner. **A registrant may replace this phrase with one indicating whether and how the fiber drum may be reused.*

Table B4 Container Handling Statements for REFILLABLE COMPRESSED GAS CYLINDERS

Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements for REFILLABLE COMPRESSED GAS CYLINDERS	
Not required but recommended	***a. Subheading***	[a] "Container Handling" [or other appropriate subheading]	
Required Use [b] followed by c1 or c2	***b. Container type***	[b] "Refillable container."	
	c. Reuse limitations	[c1] "Refill this container with pesticide only. Do not reuse this container for any other purpose."	[c2] "Refill this container with [*common chemical name*] only. Do not reuse this container for any other purpose."
Contact the EPA Product Manager to determine whether cleaning instructions are needed	***d. Who is responsible for cleaning and when and e. How to clean***	To be determined on a product-specific basis.	
Required Use f1 or f2	***f. Return, recycle or disposal***	[f1] "Return empty cylinder for reuse."	[f2] [*Other wording similar to f1.]*

Table B5 Container Handling Statements for OTHER REFILLABLE Containers

Pesticidal articles that are not exempted by *40 CFR §152.25(a)* and pesticides distributed only in transport vehicles are exempt from all requirements below. Registrants may request a waiver or modification from EPA for any of the requirements.

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Not required but recommended	***a. Subheading***	[a] "Container Handling" [or other appropriate subheading]
Required except for plant-incorporated protectants **Use** [b] followed by c1 or c2	***b. Container type***	[b] "Refillable container."
	c. Reuse limitations	[c1] "Refill this container with pesticide only. Do not reuse this container for any other purpose."
		[c2] "Refill this container with [*common chemical name*] only. Do not reuse this container for any other purpose."

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Required except for products that are gases and for products that are residential/ household use products Use d1 or d2 followed by one option from e1, e2, e3, or e4, where the statements from [d] and [e] must be consistent	***d. Who is responsible for cleaning and when***	[d1] "Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal,"
		[d2] "Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal,"
	e. How to clean	[e1] [*The refilling residue removal procedure developed by the registrant for the pesticide product.*]*
		[e2] *[Standard industry practices for cleaning refillable containers.*]*
		[e3] [*For pesticides that require dilution prior to application, the following statement:*]* "To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times."
		[e4] *[Any other statement the registrant considers appropriate.*]*
		** The cleaning procedure must be appropriate for the characteristics and formulation of the pesticide product and must be adequate to protect human health and the environment.*
Not required but recommended **Use** f1 or f2 followed by f3 or f4, then f5	***f. Return, recycle or disposal***	[f1] "Return to point of sale." [f2] [Any other return statement the registrant considers appropriate.] [f3] "Or offer for recycling if available"… [f4] "Or offer for recycling if available or reconditioning if appropriate"… [f5] …"or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities."

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Label Review Manual

Chapter 14: Identification Numbers

USDA NRCS, Lynn Betts

I. Introduction

The EPA Registration Number and the Establishment Number are required on all pesticide products. *40 CFR 156.10(a)(1)(iv)-(v)*. 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 registration number must be preceded by either the phrase, "EPA Registration No.", or "EPA Reg. No." *40 CFR 156.10(e)*. This phrase will be followed by a company number then a dash (-), and then the product number. Instructions for obtaining a company number are available at http://www.epa.gov/pesticides/bluebook/chapter14.html

B. Assignment of Registration Number

Before a pesticide product is registered under *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.

R	E	G	U	L	A	T	I	O	N
1	2	3	4	5	6	7	8	9	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 must be stated on the label. Although no specific location is required, the preferred location is on the front panel 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. Distributor numbers

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 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. *40 CFR 152.132(d)*. No new claims may be added. Distributors may not make amendments to a product's master label. Only the basic registrant can amend the EPA-approved registered label.

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 label are identical to that of the basic product and that the distributor label meets all applicable regulatory requirements.

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. (see *Chapter 15, Company Name and Address*).

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. *40 CFR 152.132(d)(3)*. 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 the EPA-approved registered label.

IV. EPA Establishment Number

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 assigned by the Office of Pesticide Programs 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.

A. Purpose and Location of Establishment Number

The Establishment Number indicates the final establishment at which the product was produced. *40 CFR 156.10(f)*; see also *40 CFR 167.3*. This number must be 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*.) The final establishment where the product will be produced might not be known when the draft label is submitted, or the registrant may intend to place the Establishment Number directly on the container rather than the label, so the Establishment Number might not appear on the draft label submitted for review.

B. State Designation

As a matter of Agency practice, letters such as MO, AZ, or PA appear after the producer's company number in establishment numbers. These letters represent the state in which the product was produced.

Example 1: 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.

Example 2: 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.

C. Multiple Establishment Numbers

Some registrants may produce an identical product in more than one establishment. 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 number 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.

If a producer lists multiple establishment numbers, the establishment number for the actual production site of a particular product must be very obviously marked or highlighted, for example, with an arrow, a notch, a bullet, etc. For instance, a master label may list three establishments in two states, all of which produce the same product. The same label can be used at all three establishments by marking the site where individually labeled products are actually produced.

Products may also be produced in sequential steps at multiple establishments. Use of the word "last" implies that a product traveled through sequential establishments during its production. Only the establishment number of the last establishment at which a product is produced is required to be on the label. *40 CFR 156.10(f)*. If the product is changed as it moves from site to site, the required label would change at each site so that the establishment number of the final establishment up to that point is indicated on the product label at each site.

D. Foreign Establishment Numbers

Foreign producers of pesticides or devices must also have company and establishment numbers. Instructions for obtaining these numbers are included along with general guidance on company and establishment numbers provided in chapter 14 of the Agency's registration manual at http://www.epa.gov/pesticides/bluebook/chapter14.html

V. Special Local Need (SLN) registration number

The Special Local Need registration number (SLN number) is also known as a FIFRA Section 24(c) Registration Number. *40 CFR 162.153(e)*. These registrations are issued by the states to meet special local needs. See *40 CFR Part 162*. 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.

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.

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).

VI. Experimental Use Permit number

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. See *Section II.B* for information on the translation of file symbols to registration numbers (See *40 CFR 172.6 (a)(2)*)

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.

Revised November 2012

Label Review Manual

Chapter 15: Company Name and Address

http://life.nbii.gov, National Biological Information Infrastructure, Library of Images From the Environment, Randolph Femmer

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. *40 CFR 156.10(a)(1)(ii)*. For the purposes of this Chapter, the detail required for company name and address is, at a minimum, the company name or qualified company name and the address (including street address and /or P. O. Box plus ZIP code, or unique ZIP code) of the location at which a particular organization or person may be found or reached.

II. Company name

A. Location and Size

The name and address must be displayed prominently and within the range of type size that is required for all label text. *40 CFR 156.10(a)(2)*. The company name and address may be placed anywhere on the label, however; the preferred placement for the company name and address is on the front panel.

B. Qualifying a Company Name

When the registrant's name appears on the label and the registrant is not the producer of the product, the registrant's name must be qualified by phrases such as "Manufactured for…" or "Produced for…" to show that the registrant is not the producer of the product. *40 CFR 156.10(c)*.

The need to qualify the name of a non-producer company also applies to pesticide products distributed under a supplemental registration agreement under *40 CFR 152.132* (i.e., "distributor agreement"). If the distributor is not the producer and the distributor name appears on the label, 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..."

The company's name cannot be abbreviated on the 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 may be confusing and would not be allowed on distributor labels unless properly qualified. See *40 CFR 156.10(c)*. The company name that appears on the distributor label must be a correct reflection of the company name on the supplemental registration form. If multiple addresses appear on the label, the first address listed 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.

A company name appearing on the label without a qualifying phrase, such as those listed above, shall be considered as the name and address of the producer. *40 CFR 156.10(c)*.

III. Telephone numbers

The Agency encourages each registrant but does not require 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)* number for non-emergency information on the pesticide product label. The NPIC number, alone or along with a company phone number, should be placed on the front panel of the pesticide product label using the following statement:

"For information on this pesticide product (including general health concerns or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378, Monday through Friday, 7:30 AM to 3:30 PM Pacific time In the event of a medical emergency call your poison control center at 1-800-222-1222".*PR Notice 97-4* for more information.

Note: The National Pesticide Information Center (NPIC) was previously called the National Pesticide Telecommunications Network (NPTN).

IV. Foreign registrants

All applicants for pesticide registrations must provide a U.S. address for correspondence. *40 CFR 152.50(b)(2)*. All correspondence concerning the pesticide product or any subsequent registration actions will be mailed to the address of record in the U.S. for foreign registrants. Generally a registrant not located in the United States will designate an authorized agent who resides in the United States. See *40 CFR 152.50(b)(3)*. When a U.S. agent is designated, the agent's U.S. address is considered to be the U.S. address of record for the foreign registrant.

V. 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.

VI. Company name and address changes

Registrants are required to inform the Agency when there are changes to its company's name or address. *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. *40 CFR 152.130*. 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*.

Revised December 2014

Label Review Manual

Chapter 16: Graphics and Symbols on Labels

US Forest Service, Ann Keyser

I. Introduction

. 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, and are not false and misleading or otherwise cause the product to be misbranded. 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 may be 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.

In general, all symbols and graphics need Agency approval, whether they are submitted as part of a label amendment, or are made by notification as provided for some graphics and symbols in PR Notice 98-10, section II .H and M. There are a limited number of graphics/symbols considered to be non-FIFRA elements that can be added by non-notification, as described in PRN 98-10, section IV. C.

II. Acceptable graphics and symbols

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 if they are not false or misleading (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 ensure they qualify for notification review.

1. Diagrams of how to open product containers.
2. Pictures illustrating proper pesticide use.
3. Graphics which display spray patterns of nozzles and/or application patterns.
4. Pictograms located near the precautionary labeling statements that illustrate the different exposure routes (oral, inhalation, and/or dermal) to pesticides.
5. 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.
6. 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). Historically, the Agency has stated that the pictogram cannot 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 generally recommends that registrants use the word "precaution" or "notice". However, the Agency understands that often pesticide producers purchase

buckets that already have the drowning hazard pictogram and the word "WARNING" embossed or labeled on the container. If this is the case, then when labeling the bucket with FIFRA information, registrants should make every effort to separate the FIFRA information from the pictogram and associated word "WARNING" in order to avoid confusion with the human hazard signal word for the pesticide product.

7. The "Mr. Yuk" symbol on the label and/or outer container of the pesticide product. The "Mr. Yuk" symbol consists 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.

8. Pictures illustrating appropriate protective gear.

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 on labels by *40 CFR 156.10(a)(2)*).

III. Unacceptable graphics and symbols

If the draft label under review contains graphics or symbols that violate *FIFRA 12(a)(1)(F)* and *2(q)(1)(A)* or the applicable regulations describing potential false and misleading statements in *156.10(a)(5)*, then the label reviewer must advise the registrant to remove these from the label. Examples have included the following (note: these examples are based on case-by-case determinations and may not apply to every similar situation):

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, except for antimicrobial products.

5. Pictures depicting food or food contact utensils even in some cases where food-handling-area treatments are allowed on the label. Directions for use generally require that food items and food contact utensils be covered or removed before the pesticide is applied.

6. Pictures of persons applying pesticides in areas *accessible* to children, pets, and other non-target 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 have been prohibited.

9. Symbols implying safety or non-toxicity, such as 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

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. USDA BioBased Product Certification Mark.

A registrant may apply for a label amendment to add a USDA approved Biobased Certification Mark. The link below explains the procedure that a company needs to follow to get the mark added to a pesticide label. Basically, first they will need to seek and receive certification of their product from USDA, and once they have that documentation, they can submit the USDA certification letter along with a draft label which includes the mark, accompanied by a disclaimer statement direct under or beside the mark indicating that the mark does not imply safety of the product.
http://www.epa.gov/oppfead1/cb/csb_page/updates/2013/labelstatement.html

4. Bar codes which allow for easier scanning of prices in retail stores.

V. Logos for organic pesticides

As discussed in *Chapter 12* of this manual, if the criteria described in *Pesticide Registration (PR) Notice 2003-1* are met, a pesticide product may bear the following phrases in logo format:

"For Organic Production",

"For Organic Gardening",

"For Organic Lawn Care", and

"For Use in Organic Production".

Logos from other groups that review materials proposed for organic agriculture may also be considered (E.g. OMRI). The reviewer needs to determine if this information is false or misleading. Label reviewers should consult with the National Organic Program Liaison in the Biopesticides and Pollution Prevention Division for an evaluation of the product's proposed labeling before approving any organic labeling or logos.

Revised August 2015

Label Review Manual

Chapter 17: Net Contents/Net Weight Statement

http://commons.wikimedia.org, photo by "Daderot"

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)(2)(C)(iii)* and *40 CFR 156.10(a)(1)(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 that describes how the net contents must appear on the label 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 *40 CFR 156.10(d)(1)* requires that the quantity listed describe the amount of pesticide product in the container as opposed to the total weight of the pesticide product plus the weight of the container. The amount of product may be left blank on the master label in instances where more than one size of packaging is offered or where the product is distributed in refillable containers.

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 may request that the statement be placed at the bottom of the front panel. The Net Contents/Net Weight quantity must be exclusive of any wrappers or other materials. *40 CFR 156.10(d)(1)*.

III. Types of products/measurement

Check the draft label to determine if the Net Contents/Net Weight statement is expressed correctly.

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. *40 CFR 156.10(d)(3)*.

2. **Liquid Formulations.** The net contents must be expressed in terms of liquid measure at 68º F(20º C): gallons, quarts, pints or fluid ounces. *40 CFR 156.10(d)(2)*.

3. **Pressurized Products** (includes gases and aerosols). The net contents must be expressed as pounds and ounces. *40 CFR 156.10(d)(3)*.

4. **Antimicrobial Wipes, Insect Repellent Wipes, and Towelettes.** The net contents per container for antimicrobial products, including wipes (wet or dry) must conform to the requirements stated in *40 CFR 156.10(d)(3)*, namely, the net content must be expressed as avoirdupois pounds and ounces. The requirements are imposed for the overall container and not on the basis of each individually packaged wipe when sold in multiple units. The net content statement is to be expressed taking into account the weight of the wipe material plus the weight of the pesticide added to the wipe. However, the net content declaration on the container may also include such a statement as "contains X count of x inch by y inch pre-moistened wipes" in addition to the avoirdupois pounds and ounces statement.

5. **Bag on Valve (BOV) Technology.** Where a pesticide product container uses "Bag on Valve" (BOV) technology, the pesticide is contained within a bag, which is contained within a canister. In order to dispense the pesticide, pressurized gas is released within the canister, but outside of the bag. This squeezes the bag containing the pesticide, causing the pesticide to be expelled. The gas remains entirely within the canister, and the pesticide never comes into contact with the gas.

   The U.S. Department of Commerce's National Institute of Standards and Technology (NIST) publishes "Uniform Laws and Regulations in the Areas of Legal Metrology and Engine Fuel Quality," otherwise known as "NIST Handbook 130." The 2015 edition of NIST Handbook 130 articulates a model regulation that would require packages using BOV technology to disclose the net quantity of the commodity in terms of weight that will be expelled from the container. That model regulation also suggests that it not be enforceable until after January 1, 2018. See NIST Handbook 130 (2015), Uniform Packaging and Labeling Regulation, section 10.3, including Note.

   In the interest of consistency with the NIST model regulations, the net content statement for pesticide products using BOV technology should be in terms of weight expressed as avoirdupois pounds and ounces, per *40 CFR 156.10(d)(3)*.

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

EPA interpretation of the statutory and regulatory requirements is that the label must state the total weight for the entire contents as sold and distributed. 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”. *40 CFR 156.10(d)(4)*. In addition, the label may indicate the net weight and quantity of individual units within the carton. For example, "Net Weight 6.25 lbs. (20 - 5oz. packets)."

C. Consistency with Directions for Use

The Directions for Use on the label should not require a quantity of pesticide product that exceeds the Net Contents/Net Weight of the package as this may be construed as misleading. 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.

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Label Review Manual

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. Foreign language labeling

Foreign language text, in addition to the full English text, is permitted in part or in 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.

. For products falling under the scope of the Worker Protection Standard, labels for products in toxicity categories I or II must include Spanish signal words and the statement below. (40 CFR 156.206 (e)). 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. Use of the statement and "Aviso" is optional for products in toxicity categories III and IV:

> *"**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.)**"*

III. Soluble packets

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.

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.

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.)

IV. Multi-packs/co-packs

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.

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 label 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.

The regulation at *40 CFR 152.3* states that the "pesticide product" includes the package intended to be distributed or sold. EPA has jurisdiction over the packaging and labeling

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. The user may be instructed on the label to tank mix the products that were packaged together just before application. (*FIFRA 2(u)*)

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)*)

Approaches regarding the labeling for multi-packs and co-packs are dependent on the specific issues of each case. Registrants should contact the appropriate division for additional information before submitting registrations or amendments that feature multi- packs or co-packs or before deciding whether such packaging requires registration.

V. Small containers

Some containers are too small to contain all required label text. In such cases, it is permissible to have text located on accompanying pamphlets or other collateral material, all of which are considered product labeling. The Agency historically has 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
- EPA Establishment Number
- the phrase "RESTRICTED USE PESTICIDE" (if so classified)

- 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.

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.

VI. Child-attracting packaging ("Attractive Nuisance")

From time to time, registrants package pesticides in containers attractive to children. For example, 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. The Agency can require child-resistant packaging when the toxicity criteria and use criteria are met. To ensure that packaging is acceptable the reviewer may require the applicant to submit the intended packaging before the product is registered. See *40 CFR 157.20*, et al.

VII. Child-resistant packaging

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 toxic or 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)*.

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*). 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. Voluntary use of CRP requires the registrant meet the same standards as mandatory CRP.

Any changes in CRP will require an amendment of the pesticide registration (*40 CFR 152.44*) and a new CRP certification. This amendment must include its designation using the

American Society for Testing Materials (ASTM) standard D3475-06 "Standard Classification of Child-Resistant Packages". Agency approval is required before any packaging change can occur. CRP changes are not notifications.

A pesticide product may be exempt from the CRP requirements if it is 1) classified for restricted use, 2) if the package is of a large size (as defined in *40 CFR 157.24 (a)(2)*), 3) if the pesticide is not toxic, or 4) 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.

Outside of the listed exemptions above, the Agency has partially exempted products from some CRP requirements in two instances. For the following types of packaging, review the cited Federal Register notices to determine whether CRP requirements have been met:

1. 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
(*67 FR 35910, May 22, 2002*).

2. Prefilled, nonrefillable termite insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact (*67 FR 35909, May 22, 2002*).

VIII . Pesticides used to treat seeds

A. Dye Requirements for Seed Treatment Pesticide Products

Under *40 CFR 153.155(a)*, any pesticide product intended for use in treating seeds must contain an EPA-approved dye. The purpose of such dye is to impart an unnatural color to the seed to signify that it has been so treated.

B. Exemptions to Dye Requirements (and related label statements)

However, the dye requirement does not apply if appropriate tolerances or other clearances have been established under the FFDCA for residues of the pesticide. In addition there are some exemptions from the requirement to use a dye that relate to how the product is labeled.

These exemptions are: (1) products intended and labeled for use solely by commercial seed treaters (provided a label condition is met, discussed further below); (2) products intended and labeled for use solely as at-planting or hopper box treatments; and (3) products that are gaseous in form or are used as fumigants. *40 CFR 153.155(b)(1)-(3)*.

1. **Commercial Seed Treaters.** Pesticide products intended and labeled for use solely by commercial seed treaters that do not have a tolerance or tolerance exemption need not contain a dye, "*provided* that the (pesticide product) label bears a statement requiring the user to add an EPA-approved dye with the pesticide during the seed treatment process." *40 CFR 153.155(b)(1)*. An appropriate label statement would be, for example:

   "Note: This product does not contain dye and is not covered by an appropriate tolerance, tolerance exemption, or other clearance under the Federal Food, Drug and Cosmetic Act. To comply with 40 CFR 153.155, therefore, all seed treated commercially with this product must be colored with an EPA-approved dye or colorant of a suitable color to prevent accidental use as food for man or feed for animals".

   Any seed treated by a commercial seed treater using a pesticide product labeled in this manner cannot be used for or mixed with food or animal feed, or processed for oil.

   If the directions for use indicate a specific dye to use, verify that it is EPA-approved by reviewing the lists offered in *40 CFR 153.155(c)*. EPA-approved dyes for seed treatment are listed in various sections of EPA's FIFRA regulations. For instance, 40 CFR sections *180.910, 180.920*, and *180.950* contain those dyes approved for seed treatment use where a tolerance exemption has been established for the dye. In the future, *40 CFR 180.2010* will contain those dyes approved for seed treatment use where EPA has determined that residues of the dye only will be present, if at all, at levels that are below the threshold of regulation. Finally, *40 CFR 180.2020* contains those dyes approved for seed-treatment use where EPA has determined that no tolerance or tolerance exemption is needed for the dye because the use is not likely to result in residues in or on food or feed.

   To the extent that the pesticide product is covered by an appropriate tolerance, tolerance exemption or other clearance under the FFDCA, no such label statement is necessary on the pesticide product, the commercial seed treater is not required to add a dye to the pesticide product before treating seed, and the treated seed can be used for or mixed with food or animal feed, or processed for oil, in accordance with the applicable tolerance, tolerance exemption, or other clearance under the FFDCA. See
   40 CFR 153.155(a).

Note: If a commercial seed treatment product contains no dye and no instructions to dye seeds are mentioned on the label, the label reviewer needs to ensure that the tolerance or tolerance exemptions are adequate for all ingredients in the pesticide as one would do for a pesticide with food- or feed-site uses.

2. **At-planting or Hopper Box Treatments.** If the product is intended for direct use on seed at planting time, and the pesticide is not cleared by EPA for food and feed use, the following statement is recommended on the pesticide product label:

   "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".

   A statement may be required to ensure no unreasonable adverse effects depending upon the characteristics of the ingredients of the product, such as:

   "Do not store excess treated seeds beyond planting time".

C. Label Statements Based on the Worker Protection Standard (WPS)

Seed treatment products may fall under the scope of the WPS depending on the type of treatment. Seed treatment on agricultural establishments in hopper-box, planter box, or other seed-treatment applications at or immediately before planting is within the scope of the
WPS. Commercial treatment of seeds is not within the scope of the WPS.

An exclusionary statement may be added to a seed-treatment pesticide's label to clearly distinguish between products with uses subject to WPS and those without. The following statement may be appropriate for the labels of seed-treatment pesticide products solely used at commercial seed treatment facilities.

"Not for use on agricultural establishments in hopper-box, planter-box, slurry-box or other seed treatment applications at or immediately before planting".

Non-commercial seed treatment products must contain all required WPS labeling as appropriate. See *40 CFR 156.200*, et al. For seed treatment products, there may be a WPS exception statement that specifically applies to the Restricted Entry Interval (REI). If the treated seeds are soil injected or soil incorporated, the registrant may add the following statement directly after the REI statement in the Agricultural Use Requirements box.
PR Notice 93-7, page 39.

"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".

D. Label Statements Based on Risk Assessments

The label reviewer needs to consult the risk assessment. Necessary mitigation measures may require that commercial seed treaters add information to the labeling for the seeds.

Such additional language would be found in the Directions for Use instructing the seed treater to appropriately label the seeds he or she treats. To help promote proper use of the product through its life cycle, including after it has been incorporated in the seed, any restriction on the pesticide product that relates to use of the crop or seed should be included on the seed label. Without these restrictions being transferred to the seed label, the person who buys the seed may be unaware of these restrictions. The seed label should include statements such as grazing restrictions, and replanting dates need to cover treated seed to prevent harm to birds, etc., as specified in the risk assessment.

Examples of additional label statements that may be required on seed-treatment product labels on a case-by-case basis in the risk assessment include:

"The U.S. Environmental Protection Agency requires the following statements (or a subset of the following statements as appropriate) on containers containing seed treated with (insert name of product)":

- *"Store treated seed away from food and feedstuffs".*
- *"Do not allow children, pets or livestock to have access to treated seeds".*
- *"Wear long pants, long-sleeved shirt and protective gloves when handling treated seed".*
- *"Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting (such as in row ends)".*
- *"Dispose of all excess treated seed by burying seed away from bodies of water".*
- *"Dispose of seed packaging or containers in accordance with local requirements".*

In addition, other label statements may be required according to the risk assessment on a case-by-case basis to address identified environmental or toxicity hazards from the treated seed. Consult *Chapter 8* for detailed guidance concerning environmental hazard statements.

E. Labeling Statements Associated with Federal Seed Act

Commercial seed labels for treated seeds, as distinct from seed treatment pesticide product labels, are required to comply with both the Federal Seed Act (FSA) and USDA's regulations concerning the labeling of treated seed (as found in the *Federal Seed Act* and *7 CFR Part 201*). In addition, EPA recommends that the labeling of a pesticide product intended for use as a seed treatment also identify all the language that will be required for the seed label (under the FSA and the USDA regulations).

Although the statements below are not required under FIFRA for pesticide labeling, it is considered a prudent measure to include these statements on seed-treatment pesticides so the user is aware of his or her obligations under the FSA when labeling seed.

1. **Toxicity Category I Pesticide Label Statements.** For commercial seed treatment products assigned Toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the following labeling statements are recommended to be placed in the direction for use section of the pesticide labeling to address the *Federal Seed Act* requirements for treated seed (consult: *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRD3317429* for a detailed explanation):

   "The Federal Seed Act requires that bags containing seed treated with this product shall be labeled with the following information:

   (a) a statement such as "*Poison*", "*Poison treated*", or "*Treated with Poison"*, (b) the skull and crossbones symbol,

   (c) "*This seed has been treated with (insert name of active ingredient of pesticide)*". and,

   (d) *"Do not use for food, feed or oil purposes".*

2. **Other Commercial Seed Treatment Statements.** The following labeling statement is recommended to be placed in the directions for use section of the labeling for commercial seed treatment pesticide products that do not have appropriate tolerances or tolerance exemptions:

   "The Federal Seed Act requires that bags containing seed treated with this product shall be labeled with the following information: "This seed has been treated with (insert name of active ingredient of pesticide). Do not use for food, feed or oil purposes".

F. Rinsing Instructions

General labeling requirements for residue removal or rinsing instructions are contained in 40 CFR 156.144 – 156. Part 156.144 (e) states that EPA may, at its own discretion or based on data submitted by any person, modify or waive the requirements of those sections or permit or require alternative labeling statements. The language below has been approved by EPA as modifications to rinsing instructions that are appropriate for labeling of seed treatment products.

1. Nonrefillable container

Plastic containers: Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Then offer container for recycling if available, reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Triple rinse as follows: *For containers with capacity equal to or less than 5 gallons*: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Add water - at least 2% of the container volume, and up to 1/3 of the volume of water needed to make the proper slurry composition with a maximum of 1/4 of the container volume - and recap. Shake for 30 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water.

For containers with capacities greater than 5 gallons: Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Add water - at least 2% of the container volume, and up to 1/3 of the volume of water needed to make the proper slurry composition with a maximum of 1/4 of the container volume. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 60 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water.

2. Refillable container

Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container before final disposal, empty the remaining contents into application equipment or mix tank. Add water – at least 2% of the container volume, and up to 1/3 of the volume of water needed to make the proper slurry composition with a maximum of ¼ of the container volume. Replace and tighten closure. Agitate vigorously or recirculate the rinsate with a pump for at least 2 minutes, ensuring that the rinsate rinses the walls of the container. Empty the rinsate into application equipment or rinsate collection system, for later use or disposal. Repeat this procedure two more times. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water.

Recycling: Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer, or contact the Ag Container Recycling Council (ACRC) at 1-877-952-2272 (toll free) or *www.acrecycle.org*.

IX. North American Free Trade Agreement (NAFTA) labeling

Registrants may volunteer products for NAFTA label development at any time.

A. Applying for Registration

The registrant should review the information provided in the "*Guidance on How to Develop a NAFTA Label*". Ultimately, a joint submission of the proposed label and the U.S. and Canadian product specifications must be made to EPA and Canada's Pest Management

Regulatory Agency (PMRA). In the United States, the submission should be as a label amendment. However, because EPA and PMRA continue to develop this process and refinethe guidance for NAFTA label development, the first step should be to contact either EPA or PMRA to obtain the most current information and to discuss the submission. Currently, Mexico has not been involved in the NAFTA labeling process, but may be in the future.

B. Registration of NAFTA Labels

For existing registrations, the U.S. and Canadian label review will run essentially independently, with each regulatory authority having independent responsibility for the booklets for use in the appropriate country and shared responsibility for the container label. Specifically, the container label would be reviewed by both regulatory authorities, while review of the booklets that contain the directions for use would be independent of each other.

For a new registration, the regulatory processes would run concurrently. The regulatory agencies would commit to the current accelerated timeframes for joint reviews. In the event of one country lagging behind in the registration process, and hence delaying approval of its label, the registrant could proceed with essentially the same label, absent the NAFTA language, and using only the Directions for Use for the country that is ready to proceed with registration.

C. Amendments to NAFTA Labels

The process required for registration or amendment of a NAFTA label is dependent on the format chosen for the labels. The preferred label format consists of separate U.S. and Canadian booklets with the respective directions for use. This format has the advantage of resulting in essentially independent regulatory processes for many types of label amendments. This approach is advantageous for registrants because it allows many types of label amendments to move ahead at the pace they normally would,

without necessitating delay, repackaging, or other issues that are inherent in a single label approach.

There are several types of potential registration amendments. For the purpose of the NAFTA label, they are divided as follows:

1. **Registration amendments limited to changes that are exclusive to the country- specific booklets that contain directions for use,** (e.g., addition of a pest, change to pre-harvest interval, application timing, etc.) and that do not affect the container label. The U.S. and Canadian processes would run essentially independently of each other, with each regulatory authority taking responsibility for the content exclusive to the appropriate country-specific booklet. The container label would be reviewed as part of the amendment (since it forms part of the NAFTA label for each country). If no changes to the container label are made, the label amendment may be approved by the country involved with the booklet change. If a change to the booklet would require changes to the container label, these changes to the container label would be provided immediately to both Agencies for their simultaneous review.

2. **Registration amendments affecting the container label** (e.g., product name change, change to precautionary statements, etc.) **that may or may not affect the booklet(s).** This type of amendment would require review by both countries. If the registrant desires to have the regulatory processes run concurrently, the regulatory agencies would be bound by their respective timeframes for the amendment, but commit to trying to achieve the shorter timeframe (between the two agencies) where possible.

3. **Amendment to change the product formulation.** This may or may not directly affect the NAFTA label but could have implications for the determination that the products are substantially similar.

   The registration of a NAFTA label for a product is based on the product formulation being substantially similar in both countries and manufactured by the same registrant. Any application to amend the formulation would be required to be made to both agencies simultaneously to ensure that substantial similarity is maintained. The regulatory processes would run concurrently and would require review by both countries (the review may or may not include a review of the product label). The agencies would be bound by their respective timeframes for the action, but commit to trying to achieve the shorter timeframe (between the two agencies) where possible.

X. Other types of labeling

Manuals

If the master label makes reference to a manual, then the registrant is required to submit it to the Agency for our review. The manual should describe in detail any special procedures and/ or technical apparatus involved in the application of the product if the manual is inconsistent with the EPA approved label, the Agency will consider the product misbranded.