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 productspecific 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 <u>occupational use products</u> (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)).
- 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.

Route of	Toxicity Category by Route of Exposure of End-Use Product					
Exposure	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

CX-5

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

CX-5

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).

- <u>Glove Requirements for WPS Handlers for Products in Solvent Category A (Dry</u> <u>and Water-Based Formulations).</u> 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).
- <u>Glove Requirements for WPS Handlers for Products in Solvent Categories B H</u>
 (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).

• <u>NOTE: It is important that ONLY g</u>love 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).

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
В	high	high	slight	slight	none	slight	slight	slight
С	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
н	high	slight	slight	slight	none	none	none	High

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.)

*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.

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

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

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.

Pesticide Type	Vapor Pressure (mmHG)	Respirator Language		
	(1111113)	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 x 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 x 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 specifying the following RPD requirements and statement:	1 x 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	A NIOSH approved particulate respirator with any N, R or P filter with NIOSH approval number	

Table 5. Respirator Language

Liquid Products in Toxicity Category I: Products that are formulated or applied as liquids:	Lower than 1 x 10 ⁻⁰⁵	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 an R or P filter with NIOSH approval number prefix TC – 84A. ; or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C.	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, NIOSH approval number prefix TC-84A . ; or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C.
	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 powered air purifying respirator with organic vapor (OV) cartridge and combination HE filter with NIOSH approval number prefix TC-23C; 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 powered air purifying respirator with organic vapor (OV) cartridge and combination HE filter with NIOSH approval number prefix TC-23C; or a NIOSH approved gas mask with an organic vapor canister with NIOSH approval number prefix TC – 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. ; or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C.	A NIOSH approved particulate filter with any N, R, P filter with NIOSH approval number prefix TC-84A. ; or a NIOSH- approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C.
	Greater than 1×10^{-04}	A NIOSH approved respirator with an organic vapor (OV) cartridge with a combination R or P filter,	A NIOSH approved respirator with an organic vapor (OV) cartridge with a combination N, R or P filter with NIOSH approval

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	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
TC – 14G; or a NIOSH approved powered air purifying respirator with organic vapor (OV) cartridge and combination HE filter	respirator with organic
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).

Filter Efficiency	N-series particulate filters Not resistant to oil.	R-series particulate filters Oil-resistant.	P-series filters Oil-proof.
95%, 99%, and	N95/ N99/ N100 Not resistant to oil.	R95/ R99/ R100 Oil-resistant.	P95/ P99/ P100 Oil-proof
99.97%	May be used for solid & liquid particulate	May be used for solid & liquid particulate hazards.	May be used for solid & liquid particulate hazards.
	hazards. <u>Time limitations</u> : 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 <u>Use Limitation</u> section within PR Notice 98-9 for guidance on determining whether a respirator filter can still function after a particular exposure).	<u>Time limitations</u> : 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 <u>Use Limitation</u> section within PR Notice 98-9 for guidance on determining whether a respirator filter can still function after a particular exposure).	<u>Time limitations</u> : 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 <u>Use Limitation</u> section within PR Notice 98-9 for guidance on determining whether a respirator filter can still function after a particular exposure).

Table 6. Oil Resistance and Efficiency of Filters

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 vaporremoving 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, 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 chemicalresistant 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

 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 restrictedentry 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:
 - 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.

D. 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.

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.)	Ι	I ²

Table 8. Determining Acute Toxicity Category for REI Purposes

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:

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 <u>and</u> 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

Table 9. Determining the REI (See 156.208)

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.

CRITERIA	Subject to WPS?
Product is a manufacturing use product, or an unregistered pesticide used under an experimental use permit issued under <i>FIFRA section 5</i> , or under an exemption issued under <i>FIFRA section 18</i> .	NO
Product bears directions for use on an agricultural establishment or involving the production of an agricultural plant (defined at <i>40 CFR 170.3</i> 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 <u>not</u> 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.)	

APPENDIX A. Summary Table of the Scope of WPS

Revised December 2014 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 Disinfect:

To Control Mildew:

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

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

Table 1. Toxicity Categories

Pesticide Registration (PR) Notices are issued by the Office of Pesticide Programs to inform pesticide registrants and other interested persons about important policies,

CX-5

procedures and regulatory decisions. PR notices are important resources to help the label reviewer stay informed about current regulatory policies in OPP. These documents are available at: *Pesticide Registration (PR) Notices* | *Pesticides* | *US EPA*.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"To make spray solution, mix 1/2 to 2 pints of this product in 100 gals. of water. Apply 100 to 200 gals. of diluted spray solution per acre to trees depending on tree size and the coverage obtained with the spray equipment used".

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

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

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

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

CX-5

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 EPAapproved Experimental Use Permit program. This label must be in possession of the user at the time of pesticide application. For use in the following states only: (insert states listed on permit)".

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

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

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

E. Termiticides

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

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

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

F. Adult Mosquito Control Products

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

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

VI. Standard elements

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

- "Directions For Use Heading"
- ► Use Classification Statement

- Misuse and Related Statements
- ▶ Worker Protection Standard (WPS) Requirements (if applicable)
- I Instructions and Information Subheading (if applicable)
- Use Restrictions (if applicable)
- Chemigation Information (If applicable)
- Spray Drift Language (if applicable)
- Endangered Species Statement (if applicable)
- Storage and Disposal Statements

A. Directions for Use Heading

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

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

B. Use Classification Statement

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

C. Misuse Statement

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

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

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

"STOP! Read the label before using".

"Use only as directed on this label".

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

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

D. Worker Protection Standard (WPS)

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

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

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

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

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

E. Instructions and Information Subheading

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

F. Use Restrictions

Non-site- specific precautions, restrictions or limitations of the product comprise another important type of use restriction information in the Directions for Use section. Such a restriction may consist of an imperative sentence—practically any sentence that begins with

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

- ► User Restrictions;
- Rate Restrictions or Limitations;
- ▶ Site, Pest, Timing, Weather, Soil, Geographic Restrictions;
- Equipment, or Application Method Restrictions;
- Miscellaneous Precautions such as Staining, Phytotoxicity, Incompatibility with Other Products, etc.; and
- > PHIs or Rotational Crop Restrictions (unless site-specific).
- 1. Appropriateness of Precautions and Restrictions. The reviewer must carefully assess each restriction or limitation to make sure that it does not place on the product obligations that the user cannot reasonably carry out.

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

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

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

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

When used in reference to the response of crops and weeds to the proposed pesticide product (e.g., an herbicide label), registrants should use the word "tolerant" instead of

"resistant". For example, the label should refer to the use of the product on herbicide *tolerant* crops, not herbicide-resistant crops.

- 2. Use-Related Restrictions. Any other appropriate information (precautions or restrictions) should be presented in the restrictions subsection unless such statements apply only to some of the uses permitted by the label, in which case the statements belong with directions for specific site and pest groupings. Use related information can include restrictions regarding the timing of application, weather, soil conditions, geography, or other relevant considerations. This information should be appropriate for the intended user(s), site(s), and pest(s) listed on the label.
- **3.** Use Limitations for Specific Ingredients. The label reviewer needs to check the Confidential Statement of Formula to determine if peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, milk, Crustacean, or wheat commodities are listed. The reviewer should be aware that the presence of these common food allergens in pesticide products limits the acceptable use sites and application methods found in the directions for use. If the product contains these ingredients, evaluate label use directions for compliance with *40 CFR 180.1071*.

G. Resistance Management Labeling Considerations

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

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

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

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



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

Pesticide Registration Notice 2001-5 provides examples of standard resistance management labeling statements that focus on the following areas: (1) avoid repeated or sequential use of products in the same MOA class through rotation of MOA; (2) if tank mixes or premixes are legally allowed, makes sure each compound is from a different MOA class; (3) use an effective IPM program; (4) monitor for loss of product performance; (5) contact your extension specialist, certified crop consultant, or manufacturer for the latest resistance management information; and (6) contact the pesticide producer to report loss of efficacy. Alternatively, registrants may supply their own resistance management labeling statements that address these same areas. Registrants may also choose to have specific mandatory statements regarding resistance management, but these statements would not fall under "Resistance Management Recommendations".

H. Chemigation Information

Review of labels for agricultural uses, nursery uses, uses on golf courses, sod farms or in greenhouses should be conducted with reference to the guidance contained in *PR Notice 87-1* (chemigation), unless the product is solely for residential use, direct injection into plants,

post-harvest application, or is applied as a gas or solid (pellets, tablets, granules, or dusts). Subject labels (as specified above) must either include labeling statements regarding chemigation contained in PR Notice 87-1 or the statement:

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

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

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

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

I. Spray Drift Labeling

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

J. Endangered Species Label Statement

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

If EFED, AD or BPPD has determined that a product requires endangered species labeling, EPA will request that the registrant amend its labeling to place the following statement at the

beginning of the Directions for Use section under the heading "ENDANGERED SPECIES PROTECTION REQUIREMENTS:"

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

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

VII. Where the product is issued

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

A. Consistency of Listed Sites

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

B. Complete Site Information

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

C. Site Groupings

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

D. Site-Pest Considerations

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

E. Sites and the Intended User

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

VIII. The pests being claimed

The term pest is defined by 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 <u>http://www2.epa.gov/pesticide-registration/pesticide-registration-notices-year</u>

Check 40 CFR 156.10 for further guidance.

Label Review Manual Chapter 12: Labeling Claims



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 product if the name suggests some but not all the active ingredients in the product, 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.

The claim "new" may be used on the labeling of a product of new composition for a period of 6months following approval of the labeling; however, the word "new" may not be a part of the product name of record. 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 regulations take precedence.

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, such as an insecticide that claims control of Lyme disease.

- "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 or 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 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 not likely to contain 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.

CX-5

- 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 Eligible for USDA's National Organic Program

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*, and the clarification attached to it, http://www.epa.gov/PR_Notices/pr2003-1, and the clarification attached to it, http://www.epa.gov/PR_Notices/pr2003-1, and the clarification attached to it, http://www.epa.gov/PR_Notices/pr2003-1, and the clarification attached to it, http://www.epa.gov/PR_Notices/pr2003-1-clarification.html 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, regardless of whether BPPD is the registering division.

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 (TM 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

CX-5

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 multi-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-referenced 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 of efficacy 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 TM 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. Nevertheless, each registrant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration. EPA routinely 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 not supported by efficacy data that has been reviewed and accepted by the Agency are not allowed.
- 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. For example, 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. For example, formulation changes in an antimicrobial product can alter the efficacy of the product. Also, 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 to which the statements impact FIFRA label standards or the Agency's implementing regulations. An EPA guidance document on warranty statements was developed in 2006 and the examples it offers may be consulted at this site: *http://www.epa.gov/pesticides/regulating/labels/pdf/warranty.pdf* . Also see Chapter 3, Section IV. C. (page 8) for information on what is allowable for warranty statements on distributor product labels.

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, a warranty statement that the product may not work would undermine Directions 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 be reviewed 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)



Chapter 13: Storage and Disposal



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. However, registrants may submit to the appropriate EPA Product Manager team a request for a waiver or modification (with a justification) from EPA for any of the requirements in Subpart H. [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)

This chapter is organized so that general information is provided in section II followed by instructions for a general storage and disposal state in section III; pesticide storage in section IV; pesticide disposal in section V; and container handling (i.e., container cleaning instructions, reuse limitations, and container recycling or disposal) in section VI. Next, section VII describes how to present information on one label for multiple uses, container types and/or sizes. Attachments follow with information on (A) pesticide storage statements for products with certain active ingredients; (B) storage statements suggested by EPA; (C) container handling instructions by container type; and (D) sample storage and disposal statements for antimicrobial pesticides.

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."

Label Review Manual

B. Statement Location

Storage and Disposal instructions *(except for batch codes)* <u>must be</u> *grouped* together under the heading "Storage and Disposal" and <u>should be</u> *within* the "Directions for Use" section *at the end*, while clearly *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)) Alternatively, for refillable containers the Agency suggests (does not require) a subheading Subheadings commonly used are "Container Handling" or "Container Disposal". However, when making label revisions EPA recommends that registrants transition to using "Container Handling".

The example below shows the order and subheadings of a typical storage and disposal section of a label for a non-residential² use product.

DIRECTIONS FOR USE

Storage and Disposal

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

Storage³:

[Where and how to store the product.]

Pesticide Disposal⁴:

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

Container Handling⁵:

[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.]

² In this version of Chapter 13, EPA has simplified the phrase "residential/household use" from PR Notice 2007-1 for clarity, particularly when describing the opposite set of products. The phrase "non-residential use" is more clear than "non-residential/household use" or non-residential/non-household use". See footnote 10 for more details.

³ Registrants may use alternative subheadings such as "Pesticide Storage" or "Product Storage", with the approval of the EPA reviewer and/or EPA Product Manager.

⁴ Registrants may use alternative subheadings such as "Product Disposal" or "Disposal" with the approval of the EPA reviewer and/or EPA Product Manager.

⁵ Registrant may use alternative subheadings such as "Container Disposal" with the approval of the EPA Reviewer and/or EPA Product Manager. When making label revisions, EPA recommends that registrants transition to "Container Handling."

Label Review Manual

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 all products except for residential⁶ use products to bear the following statement for risk management purposes:

"Do not contaminate water, food, or feed by storage or disposal".⁷

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

Pesticide storage instructions are required by \$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). Registrants and EPA reviewers may use their discretion when choosing storage statements for any given product, unless certain instructions are specified in a PR Notice, RED, or a Registration Review Decision.

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). (Note that a complete set of sample storage and disposal statements for liquid sodium and calcium hypochlorites as well as solid calcium hypochlorite can be found in Attachment D.)

⁶ "Residential" was previously referred to as "residential/household" in PR Notice 2001-6.

⁷ EPA revised this statement to end "...by storage OR disposal" to correct an error in the 2008 version of Chapter 13 so it is consistent with PR Notice 83-3. When making label revisions, EPA recommends that registrants transition to the version of the statement that ends "...by store or disposal."
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), label reviewers and 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 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 or non-residential use) and whether it is a hazardous waste when discarded or "highly toxic".

Listed below are pesticide disposal statements for:

- A. Residential use **only** products (including non-antimicrobial residential use) that are <u>not</u> hazardous waste or highly toxic;
- B. Non-residential use products that are hazardous waste or are highly toxic; and
- C. Non-residential 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.

While Unit V focuses on pesticide disposal statements, some container handling statements are included here for clarity. First, section A shows the pesticide disposal and container handling instructions that are combined for residential use products. These combined pesticide disposal and container handling instructions should appear under the subheading "Pesticide Disposal and Container Handling."

- For non-antimicrobial residential use products, these combined statements were originally provided by *PR Notice 2001-6* (superseded by *PR Notice 2007-1*) and have been updated to reflect the container-containment regulations and *PR Notice 2007-4*.
- For antimicrobial residential use products, the pesticide disposal and container handling instructions that were provided in PR Notices 83-3 and 84-1 are still valid and have been updated to reflect the container-containment regulations. In addition, antimicrobial residential use products can voluntarily use the pesticide disposal and container handling instructions for non-antimicrobial residential use products.

Second, section B includes some adjustments to the container handling instructions that may be appropriate for pesticides that are acute hazardous wastes when discarded.

For non-antimicrobial residential 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 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 for residential uses can voluntarily use the pesticide disposal and container handling instructions for non-antimicrobial residential use products.

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

Description of Containers and Products	Pesticide Disposal and Container Handling Statements	Description of Residential Use Product
Pressurized container for any residential use product (PR Notices 94-2, 2007-1 & 2007-4; 40CFR 156.140(a))	"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	A pesticide product is considered to be a residential use product if it meets one or both of the following ⁹ :
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: 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." ⁸	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
Non-pressurized container for any residential use product PR Notices 2007-1 & 2007-4; 40 CFR 156.140(a))	"Nonrefillable container. Do not reuse or refill this container. ¹⁰ 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."	consumers for purchase, and of a size and type practicable for household use, regardless of

⁸ Although the sentence "At present, there are only a few such centers in the country." is consistent with PR Notice 94-2, the Agency recognizes this may no longer be the case. Therefore, it is acceptable for registrants to omit this sentence.

⁹ 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 of residential use applies to antimicrobial and non- antimicrobial products. Also, in this version of Chapter 13, EPA has simplified the phrase "residential/household use" from PR Notice 2007-1 for clarity, particularly when describing the opposite set of products. The phrase "non-residential use" is clearer than "non-residential/household use" or non-residential/non-household use". (See footnote 22 for an explanation of why residue removal instructions

residential/household use" or non-residential/non-household use". (See footnote 22 for an explanation of why residue removal inst are still required for most non-residential use products.)

¹⁰ 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 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."

Description of Containers and Products	Pesticide Disposal and Container Handling Statements	Description of Residential Use Product
Pressurized or non- pressurized container for antimicrobial residential/household use products (<i>PR Notices</i> 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."	whether it is also marketed for agricultural use. (PR Notice 2007-1)

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 solid waste agency or (insert toll free number or web site) for disposal instructions."; [Note: some toll free numbers and websites, such as 1-800-CLEANUP and www.earth911.org, may require a licensing agreement. For more information, registrants should contact the organization supporting the toll free number.]
- (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)

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

Description of pesticide products	Pesticide disposal statements	When a pesticide is a hazardous waste or highly toxic
For products that are not solely for residential 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, <u>are hazardous</u> waste under the Resource Conservation and Recovery
For products that are not solely for residential 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." ¹¹	 Act (RCRA), 40 CFR 261.33(e) and (f); 2) When discarded, meets the criteria in 40 CFR 261, Subpart C for <u>a</u> characteristic waste under RCRA; 3) Is in Toxicity Category I [DANGER] on the basis of oral or dermal toxicity, or skin or eye irritation
For products that are not solely for residential 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."	potential; or 4) Is in Toxicity Category I [DANGER] or II [WARNING] on the basis of acute inhalation toxicity.

¹¹ 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 for certain specific products, 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 C4 (*for nonrefillable paper & plastic bags*) and C8 (*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 C1 (*for nonrefillable metal containers, non-aerosol*), C3 (*for nonrefillable plastic containers*), C7 (*for other rigid nonrefillable containers*), C11 (*for refillable metal containers, non-aerosol*), C9 (*for refillable plastic containers*), and C13 (*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 <u>not solely</u> for residential use and are <u>not hazardous waste or highly toxic</u>

Description of pesticide products	Pesticide disposal statements
For products not specifically identified in a RED or a PR Notice, that are not solely residential use, are not hazardous wastes , and	"Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility."
are not highly toxic (as described above in section B) <i>Note: The second option may be</i> <i>preferred in some states.</i> <i>(PR Notice</i> 83-3)	"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 (1) "Nonrefillable container."; (2) container reuse/refill; and (3) container recycling/reconditioning. If placed on the label of a nonrefillable container, these three types of statements must be under an appropriate subheading. EPA recommends that registrants use "Container Handling" rather than "Container Disposal" or similar wording, and that they transition from using "Container Disposal" to "Container Handling". when making other label revisions,

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 \$3-3, \$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 " <i>refillable"</i> or " <i>nonrefillable"</i> 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 <u>for use only</u> .

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 <u>not intended to be filled again with a pesticide for sale or distribution.</u> (See §165.3)

Products registered solely for residential 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.

If it is a <i>nonrefillable</i> container, the label must have:	If it is a <i>refillable</i> 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 	 a. The refillable container statement b. Reuse limitations c. Who is responsible for cleaning & when d. How to clean The label <i>should have</i> container return or disposal instructions. EPA <i>recommends</i> 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; Closed, sonic-sealed dispensing systems used in industrial and institutional settings

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 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: This set of instructions is not in quotation marks because it is not verbatim from the regulations. It is up to the EPA reviewer and/or PM whether it can be accepted via notification or amendment. Also, in some situations EPA has waived the requirement to use the phrase "Nonrefillable container." when this set of reuse limitations is used.)

1c. and 1d. Cleaning instructionsCleaning instructions are required on the label if the nonrefillable container is rigid and the product is dilutable EXCEPT

if the product is a:

- Residential¹² 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: If a nonrefillable container is <u>not rigid</u> or the product is <u>not dilutable</u>, <u>or</u> <u>both</u>, cleaning instructions (both when and how) are not required. Preferred cleaning instructions for non-rigid container types such as bags can be found in PR Notice 83-3 (e.g., "Completely empty bag into application equipment.") and in the appropriate tables in Attachment C.

¹² More information on residue removal requirements for non-residential antimicrobial products can be found in footnote 22.

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 <u>before</u> they are used to formulate a product, although it depends on the specific directions for use on the label.

- **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 <u>liquid dilutable</u> pesticides in rigid, nonrefillable containers <u>small enough to shake (i.e., with</u> <u>capacities equal to or less than 5 gallons)</u>, "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 ¹/₄ 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 <u>antimicrobial products</u> with public health claims that are <u>dilutable pesticides</u> in rigid, nonrefillable containers EPA has approved the following alternative rinsing instructions that are generally added by amendment, not notification:

In containers <u>small enough to shake (i.e., with capacities equal to or less than 5 gallons or 50 pounds)</u>, "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."

In containers too large to shake (i.e. with capacities more than 5 gallons or 50 pounds), "Triple Rinse as follows: Fill the container ¹/₄ 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. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times."

v. For <u>seed treatment</u> products in rigid, nonrefillable containers, EPA has approved the following alternative rinsing instructions that are generally added by amendment, not notification:

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 ¼ 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: 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 ¼ 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.

The options for pressure rinse instructions for rigid, nonrefillable containers of dilutable pesticides are:

vi. For <u>liquid dilutable</u> 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."

vii. For <u>solid dilutable</u> 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 \$3-3)

The options for **container recycling/reconditioning** ($\S156.146(a)(3)$) 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)) In a situation where multiple containers are sold in one box, each container must have a batch code unless EPA approves a request (with a justification) to modify or waive the requirement.

2. REFILLABLE CONTAINERS

If the pesticide	e is distributed in a refillable container, the label,
MUST HAVE:	2a. The refillable container statement2b. Reuse limitations2c. Who is responsible for cleaning and when2d. How to clean
AND SHOULD HAVE:	2e. Return and/or disposal instructions

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. Reuse limitations

2a. The statement "Refillable container" and **2b.** Reuse limitations are required on the label of <u>all</u> 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.

CX-5

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 *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; or
- iv. Any other statement the registrant considers appropriate and EPA accepts.

CX-5

v. For seed treatment products in rigid, nonrefillable containers, EPA has approved the following alternative rinsing instructions that are generally added by amendment, not notification:
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.

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 C1 through C15 below for appropriate disposal instructions.

VII. Multiple container handling 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 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 non-residential use must have the statement: "Do not contaminate water, food, or feed by storage or disposal."
- Products distributed or sold in nonrefillable containers must have, and refillable containers are suggested to have, a subheading under the heading "STORAGE AND DISPOSAL". EPA recommends that when making label revisions registrant transition to using "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 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.

and errata sheet, 40 CFR 156.140 and	Active Ingredient	Pesticide Storage Statements ¹³	Source of Statement
	hypochlorite and Liquid sodium	Do not contaminate food or feed by storage, disposal, or cleaning of equipment. 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 must be diluted with water before disposal in a	PR Notice 84-1 & errata sheet, 40 CFR 156.140,

Table 2. Preferred Active-Ingredient Specific Pesticide Storage Statements

¹³ Not all instructions provided in this table are the complete storage and disposal instructions required for the active ingredient shown.

¹⁴ See Attachment D for a sample of complete container handling instructions for calcium hypochlorite (solid and liquid) and liquid sodium hypochlorite. Also, the last sentence was revised from "should be diluted" to "must be diluted". The Agency recommends making this change during label amendments or other actions submitted after Chapter 13 is posted on the web site.

Active Ingredient	Pesticide Storage Statements ¹³	Source of Statement
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. ¹⁵	PR Notice 84-1 & errata sheet, 40 CFR 156.140, and
		PR Notice 2007-4
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	PR Notice 84-1
	guidelines in the PR Notice for manufacturing use products only.) "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.	
Methyl bromide and	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.	DD Nation 94 5
Methyl bromide plus 2% or less chloropicrin	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.	PR Notice 84-5
	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."	

¹⁵ See Attachment D for a sample of complete Storage and Disposal instructions for calcium hypochlorite (solid and liquid) and liquid sodium hypochlorite.

Active Ingredient	Pesticide Storage Statements ¹³	Source of Statement
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."	<i>PR Notices 84-5</i> and <i>84-1</i>
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
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 ¹⁶	" Storage and Disposal	PR Notice 84-5	
	Do not contaminate water, food, or feed by storage or		
	disposal.		
	Pesticide Storage Store in dry, cool, well ventilated		
	area under lock and key. Post as a pesticide storage		
	area. If the storage area is in an occupied building, the		
	storage area must have either 1) a forced air ventilation system that meets required local ordinances for the		
	storage of hazardous materials and operates		
	continuously; or 2) be equipped with a permanently		
	mounted and properly maintained and functioning		
	sulfuryl fluoride monitoring device designed to alert		
	occupants of the building if sulfuryl fluoride in the air		
	of the storage area is greater than 1 ppm. Store		
	cylinders upright, secured to a rack or wall to prevent		
	tipping.		
	Pesticide Handling: Cylinders must not be subjected to		
	rough handling or mechanical shock such as dropping,		
	bumping, dragging, or sliding beyond that which would		
	normally occur when moving cylinders. Do not transport		
	any cylinders in closed vehicles where they occupy the		
	same common airspace as personnel. Transport securely only in an upright position.		
	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 supplier. Only the registrant is		
	authorized to refill cylinders. Do not use cylinder for		
	any other purpose. Follow registrant's instructions for		
	return of empty or partially empty cylinders.		
	Leak Procedures: Evacuate immediate area of leak.		
	Use a NIOSH or MSHA approved positive		
	pressure self-contained breathing apparatus (SCBA, not		
	SCUBA) or combination air-supplied/SCBA		
	respirator, such as manufactured by Ranger, Survivair, Scott, or MSA, for entry into affected areas to		
	correct problem. Move leaking or damaged cylinder		
	outdoors or to an isolated location, observing strict		
	safety precautions. Work upwind if possible. Do not		
	permit entry into leakage area by unprotected		
	persons until concentration of fumigant in the breathing		
	zone (areas within the structure where individuals		
	typically stand, sit or lie down) is determined to be 1 part		
	per million (ppm) or less, as determined by a		
	detection device with sufficient sensitivity such as an		
	INTERSCAN, MIRAN [SapphiRe] or Spectros		
	ExplorIR gas analyzers. For more detailed information on		
	the source and use of air monitoring devices or		
	respirators, consult the Vikane Gas Fumigant Structural Fumigation Manual.		
	Cylinder and Product Disposal: Refillable container.		
	Refill this container with pesticide only. Do not use this		
	container for any other purpose. Promptly return all		
	empty cylinders to your distributor of this product. Follow		
	proper cylinder handling directions above. Pesticide		
	wastes may be hazardous.		
	Improper disposal of excess pesticide is a violation of		

 $^{^{16}}$ The language for sulfuryl fluoride is suggested, rather than preferred, by EPA. Storage instructions in PR Notice 84-5 were updated by RD on 6/5/12 to bring it up to compliance with PR Notice 2007-4.

Federal law. If these wastes cannot be disposed of by use according to label instructions, consult your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.		
---	--	--

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	Container Type
C1	NONREFILLABLE METAL Containers (non-aerosol)
C2	NONREFILLABLE AEROSOL CANS
C3	NONREFILLABLE PLASTIC Containers
C4	NONREFILLABLE PAPER and PLASTIC BAGS
C5	NONREFILLABLE FIBER DRUMS with LINERS
C6	NONREFILLABLE FOIL OUTER POUCHES of WATER SOLUBLE PACKETS (WSP)
C7	OTHER <u>RIGID</u> NONREFILLABLE Containers
C8	OTHER NON-RIGID NONREFILLABLE Containers
С9	REFILLABLE METAL Containers (non-aerosol)
C10	REFILLABLE PLASTIC Containers
C11	REFILLABLE FIBER DRUMS WITH LINERS
C12	REFILLABLE COMPRESSED GAS CYLINDERS
C13	OTHER REFILLABLE CONTAINERS

Plant-incorporated prot pesticidal articles that a modification from EPA	Plant-incorporated protectants are only subject to the resticidal articles that are not already exempted by 40 modification from EPA for any of the requirements.	I able C1: Container Handling Statements for NONKEFILLABLE ME IAL Containers (non-aerosol) ed protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and s that are not already exempted by 40 CFR §152.25(a) are exempt from all requirements below. Registrants may request a waiver or n 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	b. Container type	[b] "Nonrefillable container. "
product and or container type are	and	[c1] "Do not reuse or refill this container."
exempt per $\S156.140(a)(5)$ $(See unit IV.C.1a or Table 1 of this chapter)$	c. Reuse limitations of 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."
Use [b] followed by one option from c1, c2, c3 or c4		[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	<i>d. When to clean</i>	[d1] "Clean container promptly after emptying."
rion- residential use only if product is dilutable		[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)
Use one option from d1, d2 or d3, followed		[d3] "Triple rinse container (or equivalent) promptly after emptying."

Chapter 13: Storage and Disposal

13-28

Are the Statements	Are the Statements Type of Statement	Specific Statements to Include on the Label
Required?		
by one option from	e. How to clean	[e1] For liquid dilutables in containers <u>small enough to shake</u> (5 gallons or less)
A "dilutable" product is mixed with a diluent by the end user before use or application		"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."
Registrants who wish to		[e2] For solid dilutables in containers small enough to shake (5 gallons or 50 pounds or less)
use a diluent other than water must contact EPA for approval		"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 <u>containers too large to shake</u> (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 <u>antimicrobial products</u> 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."

Chapter 13: Storage and Disposal

pesticidal articles that modification from EPA	pesticidal articles that are not already exempted by modification from EPA for any of the requirements.	pesticidal articles that are not arready exempted by 40 CFK 3132.23(a) are exempting in 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
e5 and e6 are		[e5] For liquid dilutable pesticides
used above, used above, otherwise,it is optional to add e5 or e6 after e1, e3 or e4		"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	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."
Use one opnon rom f1, f2 or f3		[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.

CX-5

Table C2: 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.

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	b. Container type	
lable 1 of this chapter)	and	
	c. Reuse limitations of container	
Not required because product is	d. When to clean	
(Also not required for residential uses or	e. How to clean	
products that are gases)		
Required	f. Recycle or dispose	[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."
Use f1 or f2	and pesticide disposal	[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. ¹⁷ 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.

¹⁷ Although the sentence "At present, there are only a few such centers in the country." is consistent with PR Notice 94-2, the Agency recognizes this may not longer be the case. Therefore, it is acceptable for registrants to omit this sentence.

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 <i>CFR §152.25(a)</i> are exempt from all requirements below. Regi may request a waiver or modification from EPA for any of the requirements.	Are the Statements Type of Specific Statements t Required? Statement	Required a. Subheading [a] "Container Handling" [or other appropriate subheading]	Required unlessb. Container[b] "Nonrefillable container."product and/ortype	container type are c. Reuse [c1] "Do not reuse or refill this container." exempt per	1	c1, c2, c3 or c4 [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 addited 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 d. When to clean [d1] "Clean container promptly after emptying."	non-residential /household use only if the <i>instructions for triple rinsing immediately followed by pressure rinsing</i> <i>instructions.</i>)	Use one option from d1, d2 or d3 followed [d3] "Triple rinse container (or equivalent) promptly after emptying. by one option from e1, e2, e3 or e4	Registrants who want e. How to clean [e1] For liquid dilutables in containers <u>small enough to shake</u> (5 gallons or less)
ject to the requirement for disposal instructions. Pesticides distributed only in transport already exempted by $40 \ CFR \ \delta 152.25(a)$ are exempt from all requirements below. Registrants EPA for any of the requirements.	Specific Statements to Include on the Label	subheading]			[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."	s the directions for use allow a different ntainer." (May use if product is ready-to-use and ir but concentrated] to be poured into container	s allowed by the directions for use." (May use if t to be refilled with same pesticide, and EPA	×.	or equivalent) promptly after emptying." ing immediately followed by pressure rinsing	mptly after emptying.	<u>iough to shake</u> (5 gallons or less)

 Table C3: Container Handling Statements for NONREFILLABLE PLASTIC Containers

 Plant-incorporated protectants are only subject to the requirement for disposal instructions.
 Pesticides distributed only in transport

Chapter 13: Storage and Disposal

13-32

intainer Handling Statement: ly subject to the requirement for e not already exempted by <i>40</i> from EPA for any of the require	ter Handling Statements for NONREFILLA oject to the requirement for disposal instructic already exempted by <i>40 CFR §152.25(a)</i> are EPA for any of the requirements.	BLE PLASTIC Containers ins. Pesticides distributed only in transport exempt from all requirements below. Registrants
Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
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		"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."
use or application		[e2] For solid dilutables in containers small <u>enough to shake</u> (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 <u>containers too large to shake</u> (larger than 5 gallons or 50 pounds)
		"Triple Rinse as follows: Empty remaining contents into application equipment or a mix tank.

Chapter 13: Storage and Disposal

Fill the container y_4 full with water. Replace and tighten closures. Tip container on its side and

container on its end and tip it back and forth several times. Turn the container over onto its roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the

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 <u>antimicrobial products</u> with public health claims for dilutable pesticide in rigid,

nonrefillable containers]:

Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for "Triple rinse as follows: Fill container 1/4 full with water and recap. Shake for 10 seconds.

rinsate disposal. Repeat procedure two more times."

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Not required, but if		[e5] For liquid dilutable pesticides
registrants maxa, e5 or e6 after e1, e2, e3 or e4		"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	f. Recycle + dispose	[f1] "Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration."
Use one option from f1, f2, f3 or f4		[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 reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration."
Not required, but registrants may add f5		[f5]"or if allowed by state and local authorities, by burning. If burned, stay out of smoke."
f6 or f7 after f1, f2, f3 or f4		[f6] "Do not burn, unless allowed by state and local ordinances."

Table C3: Container Handling Statements for NONREFILLABLE PLASTIC Containers

Chapter 13: Storage and Disposal

13-34

CX-5

vehicles and pesticidal may request a waiver	articles that are n or modification fro	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
		[f7]"In most states, burning is not allowed."
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 C4: Container Hand Plant-incorporated protectants are only subje exempted by <i>40 CFR §152.25(a)</i> are exempt any of the requirements.	C4: Container F tectants are only s §152.25(a) are exe ts.	Table C4: 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 <i>40 CFR §152.25(a)</i> 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 <i>unless</i> product and/or	b. Container type	[b] "Nonrefillable container. "
container type are exempt per	c. Reuse limitations	[c1] "Do not reuse or refill this container."
8156.140(a)(5) (See unit IV.C.1a or Table 1 of this chapter)	of 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.)
Use b followed by one option from c1 or c2		

CX-5

Table C4: 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.	ts.	•
Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Not required because the nonrefillable container is not rigid (Also not required for residential uses or products that are gases)	d. When to clean	
Required except for residential 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.

CX-5

Chapter 13: Storage and Disposal

[c2] "Do not reuse this container to hold materials other than pesticides or dilutable pesticides (rinsate). 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 concentrated) product to be diluted in the container." (May use If product is "ready-to-use" and directions (May use if product is ready-to-use, directions for use allow it to be refilled with same pesticide, and EPA approves use of 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 [f1] "then offer for recycling if available or dispose of in a sanitary landfill or by incineration"... [f2] ..."or if allowed by state and local authorities, by burning. If burned, stay out of smoke." [e] "Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. or use allow a different product [similar but concentrated] to be poured into container and diluted by end user [c3] "Do not reuse or refill this container unless the directions for use allow a different Table C5: Container Handling Statements for NONREFILLABLE FIBER DRUMS with LINERS [c4] "Do not reuse or refill this container unless allowed by the directions for use. Specific Statements to Include on the Label [f3] ..."Do not burn, unless allowed by state and local ordinances. [a] "Container Handling" [*or other appropriate subheading]* [f4] ..."In most states, burning is not allowed." Empty residue into application equipment." [c1] "Do not reuse or refill this container." [b] "Nonrefillable container." this language.) your state." Subheading e. How to clean of container Container limitations Statement f. Recycle + dispose Type of d. When to Reuse clean type a, Ь. ů any of the requirements. Are the Statements Use f1 followed by f5 registrant may add container is not rigid f2, f3 or f4 in between f1 and f5 Use [b] followed by Not required, but 'See unit IV.C.1a or container type are Required unless **Required?** one option from §156.140(a)(5) c1, c2, c3 or c4 product and/or Not required Table 1 of this nonrefillable because the exempt per Required Required Reguired chapter) Use [e]

Chapter 13: Storage and Disposal

13-37

anywhere g. Batch code on Table C6: Containel s may request a waiver or mod statements Type of uired? Statement a. Subheading er b. Container type this initations of container is not rigid e. How to clean	I.D. It drutte is contantinated 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.)
Table C6: Containely request a waiver or modnentsType ofnentsType ofs. Subheadinga. Subheadingb. Containerb. Containercontainerd. When tocontainerrigide. How to clean	A lot number, or other code used by the registrant or producer to identify the batch.
nentsType of Statementa. Subheadinga. Subheadinga. Subheadingb. Containerb. Containertypea orc. Reuselimitations of containerd. When to cleanrigide. How to clean	Table C6: Container Handling Statements for NONREFILLABLE FOIL OUTER POUCHES of WATER SOLUBLE PACKETS (WSP) equest a waiver or modification from EPA for any of the requirements.
a. Subheading b. Container type type limitations of container d. When to clean and e. How to clean	Specific Statements to Include on the Label
<i>b.</i> Container <i>type</i> <i>type</i> <i>and</i> <i>c.</i> Reuse <i>limitations of</i> <i>container</i> <i>d.</i> When to <i>container</i> <i>d.</i> When to <i>cean</i> <i>and</i> <i>e. How to clean</i>	
ired d. When to Te clean ole and is not rigid e. How to clean	
1	
Requiredt. Recycle +[t] "Offer foil pouch for disposeUse fWSP is unbroken."	[f] "Offer foil pouch for recycling if available or dispose of empty pouch in the trash as long as WSP is unbroken."
Required anywhere <i>g. Batch code</i> A lot number, or other coc on label or on container	A lot number, or other code used by the registrant or producer to identify the batch.

Chapter 13: Storage and Disposal

Plant-incorporated protectants are only subject to the pesticidal articles no already exempted by 40 CFR §1 modification from EPA for any of the requirements.	e only subject to the pted by 40 CFR §1 .	Plant-incorporated protectants are only subject to the requirement for disposal instructions. Pesticides distributed only in transport vehicles and pesticidal articles no 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 <i>unless</i> the product and/or container type are	b. Container type	[b] "Nonrefillable container."
exempt per <i>§156.140(a)(5)</i> 2000 unit 71/0/50 metric	c. Reuse limitations of	[c1] "Do not reuse or refill this container."
(see unit IV.C.1a or Table 1 of this chapter) Use [b] followed by	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."
one option from c1, c2, c3 or c4		[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."(<i>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.</i>)
Required for uses other than residential/house-hold use only	d. When to clean	[d1] "Clean container promptly after emptying."
<pre>if the product is dilutable Use one option from d1, d2 or d3</pre>		[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 C7 Container Handling Statements for OTHER RIGID NONREFILLABLE Containers
Are the Statements Type of Statement Specific Statements to Include on the Label Leadout from Leadout of the container's small enough to shake (5 gallons or less) Labor from "Triple Rines as follows: Empty the remaining contents into application equipment or a mix tank on option from Li, al. 2 or e4 [e1] For liquid dilutables in container's small enough to shake (5 gallons or less) "Triple Rines as follows: The proceedure two more times." "Triple Rines as follows: Point in for 10 seconds after the flow begins to drip. A "dilutable" product is mixed with a dilutent by the end user before use or application E1] For solid dilutables in container's fill with was and recept. Shake (7 gallons or 50 pounds or less the state that was mix tank or and store times." Registrants who want to use a dilutent other than water must first get EFA approval [e2] For solid dilutables in container's fill with water and recept. Shake for 10 seconds after the flow begins to drip. Registrants who want to use a dilutent other than water must first [e2] For solid dilutables in container's fill with water. Registrants who want to use a dilutent other than water must first [e2] For solid dilutables in container's fill with water and recept. Shake for 10 seconds. Pour rinsate in the state of returnes." Registrants who want to use a follows: Empty the remaining contents into application equipment or a mix fill the container '4 full with water. [e2] For and dilutables in container's fill with water.	pesticidal articles no already exempted by 40 CFR §15 modification from EPA for any of the requirements.	pted by 40 CFR §1 5 he requirements.	:2.25(a) are exempt from all requirements below. Registrants may request a waiver or
e. How to clean	Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
st th	Use one option from	e. How to clean	[e1] For liquid dilutables in containers <u>small enough to shake</u> (5 gallons or less)
st t	a1, a2 or a3 rollowea by one option from e1, e2, e3 or e4		"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
	A "dilutable" product is mixed with a diluent by the end user before use or application		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 <u>enough to shake</u> (5 gallons or 50 pound. "Triple Rinse as follows: Empty the remaining contents into application equipment o tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour ri application equipment or a mix tank or store rinsate for later use or disposal. Drain seconds after the flow begins to drip. Repeat this procedure two more times." [e3] For any dilutable pesticides in <u>containers too large to shake</u> (larger than 5 gallt pounds) "Triple Rinse as follows: Empty remaining contents into application equipment or a Fill the container ¼ full with water. Replace and tighten closures. Tip container on i roll it back and forth, ensuring at least one complete revolution, for 30 seconds. St container on its end and tip it back and forth several times. Turn the container over other end and tip it back and forth several times. This procedure two r 	Registrants who want to use a diluent other than water must first get EPA approval		
 "Triple Rinse as follows: Empty the remaining contents into application equipment o tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour ri application equipment or a mix tank or store rinsate for later use or disposal. Drain seconds after the flow begins to drip. Repeat this procedure two more times." [e3] For any dilutable pesticides in <u>containers too large to shake</u> (larger than 5 gallt pounds) "Triple Rinse as follows: Empty remaining contents into application equipment or a Fill the container ¼ full with water. Replace and tighten closures. Tip container on its roll it back and forth, ensuring at least one complete revolution, for 30 seconds. St container on its end and tip it back and forth several times. Turn the container over other end and tip it back and forth several times. Furn the container over other end and tip it back and forth several times. Furn the container over other end and tip it back and forth several times. Furn the container over other end and tip it back and forth several times. Furn the container over other end and tip it back and forth several times. Furn the container over other end and tip it back and forth several times. Furn the container over other end and tip it back and forth several times. Furn the container over other end and tip it back and forth several times. Furn the container over other end and tip it back and forth several times. Furn the container over other end and tip it back and forth several times. Furn the container over other end and tip it back and forth several times. Furn the container over other end and tip it back and forth several times. Furn the container over other end and tip it back and forth several times. I furn the container over other end and tip it back and forth several times. Furn the container over other end and tip it back and forth several times. 			[e2] For solid dilutables in containers small <u>enough to shake</u> (5 gallons or 50 pounds or less)
[e3] For any dilutable pesticides in <u>containers too large to shake</u> (larger than 5 galle pounds) "Triple Rinse as follows: Empty remaining contents into application equipment or a I Fill the container ¼ full with water. Replace and tighten closures. Tip container on i roll it back and forth, ensuring at least one complete revolution, for 30 seconds. St container on its end and tip it back and forth several times. Turn the container over other end and tip it back and forth several times. Turn the container over other end and tip it back and forth several times. Turn the container over other end and tip it back and forth several times. Turn the container over other end and tip it back and forth several times. Turn the route other other end and tip it back and forth several times. Turn the route over other end and tip it back and forth several times. Turn the route other other end and tip it back and forth several times. Turn the route other other end and tip it back and forth several times. Turn the route other other end and tip it back and forth several times. Turn the route other other end and tip it back and forth several times. Empty the rinsate into application other end and tip it back and forth several times. Empty the rinsate into application other end and tip it back and forth several times. Empty the rinsate into application other end and tip it back and forth several times. Empty the rinsate into application other end and tip it back and forth several times.			5
"Triple Rinse as follows: Empty remaining contents into application equipment or a I Fill the container ¼ full with water. Replace and tighten closures. Tip container on i roll it back and forth, ensuring at least one complete revolution, for 30 seconds. St container on its end and tip it back and forth several times. Turn the container over other end and tip it back and forth several times. Empty the rinsate into application or a mix tank or store rinsate for later use or disposal. Repeat this procedure two m			[e3] For any dilutable pesticides in <u>containers too large to shake</u> (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."

Chapter 13: Storage and Disposal

13-40

Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
		[e4] For <u>antimicrobial products</u> 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		[e5] For liquid dilutable pesticides
a1 or a2, registrants may add e5 or e6 after e1, e2, e3 or e4		"Pressure rinse as follows: Emptythe remaining contents into application equipment or a mix tank and continue to drain for 10seconds after the flow begins to drip. Hold container upside down over application equipments 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	f. Recycle, recondition or	[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."*
Use one option from T1, T2 of T3		[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.

13-41

Table C8 Container Handling Statements for OTHER <u>NON-RIGID</u> 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 <i>unless</i> the product and/or	b. Container type	[b] "Nonrefillable container."
container type are exempt per	c. Reuse limitations	[c1] "Do not reuse or refill this container."
§156.140(a)(5) [See unit IV.C.1a or Table 1 of this chapter]	for 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."
Use [b] followed by one option from c1, c2, c3 or c4		[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 <u>not rigid.</u> (Also not required for residential 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 dean" instructions for paper or plastic bags and fiber drums with liners for potentially applicable cleaning or emptying instructions from PR Notice 83-3.

Table C8 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	f. Recycle, recondition or	[f1] "Offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities."*
Use one option from f1, f2 or f3	aispose	[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.

CX-5

Table C9 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	gistrants may requ	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" <i>[or other appropriate subheading]</i>
Required except for plant-incorporated	b. Container tyne	[b] "Refillable container."
protectants	c. Reuse limitations	[c1] "Refill this container with pesticide only. Do not reuse this container for any other purpose."
Use [b] followed by c1 or c2	of container	[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	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"
Use d1 or d2 followed by one option from		[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, e2, e3 or e4, where the statements from [d1 and [e1 must be	e. How to clean	[e1] [The refilling residue removal procedure developed by the registrant for the pesticide product.*]
consistent		[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	[f1] "Return to point of sale."
	disposal	רובן נאווץ טנוופו ובנעווו אמנפווופות נווב ובטואנו מות נטואנעבוא מאו טאוומנבין

	1
	1
Ö	1
S	
0	
<u> </u>	
U	
σ	
Ĩ	
2	
ō	
ž	
. - .	
\sim	1
S	
<u> </u>	1
Ð	
Ē	
· 🗐	1
σ	
÷	
5	
0	1
Õ	
ILLABLE METAL C	
◀	
Ē.	
6.	
۳.	1
Σ	1
щ	
6	,
7	
N	
-1	
	1
Η.	1
ш.	
ш	
2	
F	
P	
for	
s for	
ts for	
nts for	
ents for	
nents for	
ments for	
ements for	
tements for	
atements for	
tatements for	
Statements for	
j Statements for	
ig Statements for	
ing Statements for	
ling Statements for	
dling Statements for	
ndling Statements for	
andling Statements for	
landling Statements for	
Handling Statements for	
r Handling Statements for	
er Handling Statements for	
ner Handling Statements for	
iner Handling Statements for	
ainer Handling Statements for	
tainer Handling Statements for	
ntainer Handling Statements for	
ontainer Handling Statements for	
Container Handling Statements for	
Container Handling Statements for	
9 Container Handling Statements for	
C9 Container Handling Statements for	
C9 Container Handling Statements for	
e C9 Container Handling Statements for	
ole C9 Container Handling Statements for	
q	
q	
q	
Table C9 Container Handling Statements for	
q	
q	

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
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."

Chapter 13: Storage and Disposal

from all requirements below	v. Registrants may	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	b. Container type	[b] "Refillable container."
protectants Use [b] followed by	c. Reuse limitations of container	[c1] "Refill this container with pesticide only. Do not reuse this container for any other purpose."
c1 or c2		[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	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,"
Use d1 or d2 followed by one option		[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, e2, e3 or e4, where the statements	e. How to clean	[e1] [The refilling residue removal procedure developed by the registrant for the pesticide product.*]
from [d] and [e] must be consistent		[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 numb for 2 minutes. Pour or pure reprint
		equipment or rinsate collection system. Repeat this rinsing procedure two more times."
		[e4] [Any other statement the registrant considers appropriate.*]

Table C10 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

	0
Table C10 Container Handling Statements for REFILLABLE PLASTIC Containers	
IC Cont	00101000
PLAST	00004
LLABLE	and not experied by 40 CED C1ED DE/allor discription distributed only in transcription you
or REFI	dintaile of
nents f	opinition of
g Statei	Pac/2/20
Handling	
tainer h	10 0V
C10 Con	1 0040000
Table (100 00
	ĉ

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.

	horse and a series of the	
Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
		* 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.]
Use f1 or f2 followed by f3 or f4, thon f5		[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."

Pesticidal articles that are not exempted by 40 CFR §152.25(a) are exempt from all requirements below. Registrants may request a waiver or Table C11 Container Handling Statements for REFILLABLE FIBER DRUMS WITH LINERS

[c2] "Refill this container with [common chemical name] only. Do not reuse this container for any other purpose." e1] [The refilling residue removal procedure developed by the registrant for the * The cleaning procedure must be appropriate for the characteristics and formulation of the [c1] "Refill this container with pesticide only. Do not reuse this container for any [d2] "Pressure rinsing the container before final disposal is the responsibility of [d1] "Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility pesticide product and must be adequate to protect human health and the environment. [e3] "Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment or a mix the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal"... e2] [Standard industry practices for cleaning refillable containers.*] e4] [Any other statement the registrant considers appropriate.*] Specific Statements to Include on the Label of the refiller. To clean the container before final disposal"... [a] "Container Handling" [or other appropriate subheading] [b] "Refillable container." pesticide product.*] other purpose." tank." cleaning and when c. Reuse limitations **Type of Statement** modification from EPA for any of the requirements. b. Container type responsible for e. How to clean a. Subheading of container d. Who is where the statements from Use d1 or d2 followed by Use [b] followed by c1 or household use products products that are gases Required except for Required except for Are the Statements and for residential/ [d] and [e] must be Not required but plant-incorporated one option from e1, e2, e3 or e4, recommended protectants **Required?** consistent З

Table C11 Container Handling Statements for REFILLABLE FIBER DRUMS WITH LINERSPesticidal articles that are not exempted by 40 CFR §152.25(a) are exempt from all requirements below. Registrants may request awaiver or modification from FDA for any of the requirements.

waiver or modification from EPA for any of the requirements.	n EPA for any of the requ	uirements.
Are the Statements Required?	Type of Statement	Specific Statements to Include on the Label
Not required but	f. Return, recycle or disposal	[f1] "Return to point of sale."
reconnicienced		[f2] [Any other return statement the registrant considers appropriate.]
f3 or f4, f3 or f4, followed by f5 or f6.		[f3] "or offer for recycling if available"
then f9		[f4] "or offer for recycling if available or reconditioning if appropriate"
May insert f5 or f6 in front of f9		[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	C12 Container H	Table C12 Container Handling Statements for REFILLABLE COMPRESSED GAS CYLINDERS	RESSED GAS CYLINDERS
Registrants may reques Are the Statements	st a waiver or modific Type of Statement	Registrants may request a waiver or modification from EPA for any of the requirements. Are the Type of Specific Statements for REFILLABLE COMPRESSED GAS CYLINDERS Statements Statement	SSED GAS CYLINDERS
Required?			
Not required but recommended	a. Subheading	[a] "Container Handling" [or other appropriate subheading]	subheading]
Required Use [b] followed by	b. Container type	[b] "Refillable container."	
c1 or c2	c. Reuse limitations	[c1] "Refill this container with pesticide only. Do not reuse this container for any other purpose."	t [c2] "Refill this container with [<i>common chemical name</i>] 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.]

Chapter 13: Storage and Disposal

13-50

Table C13 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	Registrants may requ	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-	b. Container type	[b] "Refillable container."
incorporated protectants	c. Reuse limitations	[c1] "Refill this container with pesticide only. Do not reuse this container for any other purpose."
Use [b] followed by c1 or c2		[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	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,"
products that are residential/ household use products		[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,"
Use d1 or d2 followed bv one	e. How to clean	[e1] [The refilling residue removal procedure developed by the registrant for the pesticide product.*]
option from		[e2] [Standard industry practices for cleaning refillable containers.*]
e1, e2, e3, or e4, where the statements from [d] and [e] must be consistent		[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.

E Containers	
R REFILLABLE C	
s for OTHER	
Statements	
itainer Handling	
Table C13 Con	

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.

(For dilutable²² products in containers 5 gallons or less) Clean container promptly after emptying. Triple Rinse as follows: Fill container ¼ 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.	(For dilutable products in containers larger than 5 gallons) Clean container promptly after emptying. Triple Rinse as follows: Fill the container 1/4 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. Turn the container over onto its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times.	Offer for recycling if available or reconditioning if appropriate or place in trash.	Refillable container. Refill this container with pesticide [or common chemical name] 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, fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Offer container for recycling if available or reconditioning if appropriate or place in trash."	Part II. Products with Solid Calcium Hypochlorite ²³	<i>For Residential use:</i> "STORAGE AND DISPOSAL Do not contaminate food or feed by storage, disposal, or cleaning of equipment. ²⁴ STORAGE: 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. PESTICIDE DISPOSAL: Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer. CONTAINER HANDLING ²⁵ : Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or place in trash.	²² There is confusion regarding "residential use" vs. "institutional use." PR Notice 84-1 only addresses container storage, pesticide product disposal, and in a couple of cases, pesticide container disposal. It does not address residue removal instructions for institutions that "For purposes of this PR Notice" when products are distributed or sold in a couple of cases, pesticide for institutional uses as they are for residue removal instructions. It explains that "For purposes of this PR Notice" when products are distributed or sold in a couple of cases, pesticide for institutional uses as they are for residue removal instructions provided in the notice. The requirements for residue removal instructions in §\$156.140 through 156.150 were put in place in 2006, well after PR Notice 84-1. Although §156.144 exempts products with residential uses (in §12.5.15, "use of a pesticide directly: (1) On humans or pets, (2) In, on, or around any structure, vehicle, article, surface, or area associated with the household, including but not limited to areas such as non-agricultural outbuildings, non-commercial greenhouses, pleasure boats and recreational verse as well as for rigid nonrefillable containers with dilutable products. (<i>Note: there are some exceptions that can be found in §156.144.</i>). The same footnotes provided above apply to these instructions as well as for rigid nonrefillable containers with dilutable products. (<i>Note: there are some exceptions that can be found in §156.144.</i>). The same footnotes provided above apply to these instructions as well as foor rigid nonrefillable containers with dilutable products. (<i>Note: there are some exceptions that can be found in §156.144.</i>). The same footnotes provided above apply to these instructions as well. as food, or feed by storage and disposal." for all products except residential use products. (<i>Note: there are some exceptions that can be found in §156.144.</i>). The same footnotes provided above apply to these instructions as well. as food, or feed by storage an	
(For dilutable² with water and i disposal. Repea	(For dilutable 1/4 full with wate seconds. Stand several times. F	Offer for recyclin	Refillable contai Cleaning the cor of the refiller. T with the pump f recycling if avail	Part II. Produc	For Residential use: "STORAGE AND DISPOSAL Do not contaminate food or STORAGE: Keep this produ In case of decomposition, i container. PESTICIDE DISPOSAL: Pro CONTAINER HANDLING ²⁵ :	 ²² There is confusion regarc container disposal. It does a for institutional uses as they in \$\$156.140 through 156.1 instructions, the size of the pesticide directly: (1) On h agricultural outbuildings, n (a.k.a. "cleaning instructions there are some exceptions there are some exceptions there are some exceptions to 23 The same footnotes prov 24 Although the Agency has sentence is required for sentence is required for sentence is required for S5 The language that follow CFR 156.140 – 156.159. 	



Label Review ManualChapter 14: Identification Numbers



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 Chapter 14 of the Registration Manual.

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	Α	т	I	ο	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.

14-1

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.

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.

SNURRONMEN AL PROTECTION

Revised August 2017

Label Review Manual

Chapter 15: Company Name and Address



Table of Contents

Wh	at's changed in this version?	1
	Introduction	
П.	Location and size	2
Ш.	Using qualifiers	2
A	. Non-producer	2
В	. Supplemental distributor	2
IV.	Using the correct name and address	2
V.	Non-emergency telephone number	3

What's changed in this version?

- > Added Table of Contents.
- > Added What's changed in this version? section.
- Updated hyperlinks.
- > Reformatted text to improve readability.
- > Removed *Foreign registrants* section containing non-label related address requirement.
- Added company address guidance for foreign registrants under new Using the correct name and address section.
- > Updated NPIC contact information including new hours of operation.
- Removed Company name and address changes section containing non-label related instructions to registrants for submitting change requests.

I. Introduction

Pesticide product labels must include the name and address of the producer, registrant, or person for whom the product was produced. <u>40 CFR 156.10(a)(1)(ii)</u>. For the purposes of this Chapter, this entity is presumed to be a "company" instead of an individual person.

II. Location and size

The name and address must be clearly legible in 6-point or larger type size and prominently displayed on the label. 40 CFR 156.10(a)(2). The name and address may be placed anywhere on the label; however, the front panel is preferred.

III. Using qualifiers

An unqualified name and address given on the label is considered to be the name and address of the producer.

A. Non-producer

If the name and address given is not the same as the producer's, then it must be qualified by appropriate wording such as "Manufactured for" or "Produced for." <u>40 CFR 156.10(c)</u>.

B. Supplemental distributor

Supplemental distribution allows a registrant to distribute or sell his/her registered product as a "distributor product" under a different name and address. The name and address of the distributor may be given on the distributor product's label instead of the registrant's, qualified by phrases such as "Packed for," "Distributed by," or "Sold by." <u>40 CFR 152.132(d)(2)</u>.

IV. Using the correct name and address

The name and address on the label provides a point of contact for the product. The name and address on the label should match the Agency's records as listed under the company (or distributor) number. For non-distributor products, this is the first set of numbers of the EPA Registration Number (ex. EPA Reg. No. **1234**-567). For distributor products, this is the last set of numbers of the EPA Registration Number (ex. EPA Reg. No. **1234**-567).

Note that:

- > If more than one company is given, appropriate qualifiers should be used.
- The company name cannot be abbreviated unless it is easily-recognizable as an abbreviation of its full name.
- If the company name is "a division of", "a subsidiary of", "c/o" (care of), or "dba" (d/b/a or doing business as) another company, the name(s) given on the label should match the Agency's records.
- The company address should include the street address and/or PO Box[™], plus ZIP Code[™] of the location where correspondence may be sent.
- An authorized, designated agent's name and address may be used instead of or in addition to the company's name and address.
- For foreign registrants, the United States address of record may be used instead of or in addition to the foreign address.

V. Non-emergency telephone number

The Agency strongly encourages that labels include a company telephone number or a toll-free hotline number that allows users to obtain additional product information. <u>PR Notice 97-4</u>. This is intended for non-emergency product information and is different from the emergency treatment information number (e.g. poison control) that is listed under the First Aid section.

As an option, the <u>National Pesticide Information Center (NPIC)</u> hotline number may be used, with the suggested 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, 8:00 AM to 12:00 PM Pacific Standard Time. In the event of a medical emergency, call your poison control center at 1-800-222-1222."

Note that the NPIC, formerly called the National Pesticide Telecommunications Network (NPTN), has decreased their hours of operation from 6:30 AM to 4:30 PM PST seven days a week to 8:00 AM to 12:00 PM PST Monday through Friday. However, NPIC staff will typically respond to all inquiries received through voice mail, email, or social media within one business day. Revised August 2017



Label Review Manual

Chapter 16: Graphics and Symbols



Table of Contents

Wha	at's changed in this version?	1
	Introduction	
	Acceptable graphics and symbols	
	Unacceptable graphics and symbols	
IV.	Organic pesticide logos	.5

Table of Contents

What's changed in this version?

- > Added Table of Contents.
- > Added What's changed in this version? section.
- > Updated hyperlinks and added new hyperlinks for symbol examples.
- > Reformatted text and style to improve readability.
- Shortened chapter title to *Graphics and Symbols*.
- Combined previous Other graphics and symbols which are acceptable section into Acceptable graphics and symbols section.
- > Combined all organic logo discussions under *Organic pesticide logos* section.

I. Introduction

Almost all graphics and symbols need Agency review, whether they are submitted as part of a label amendment or are made by notification (<u>PR Notice 98-10, Sections II.H</u>). There are only a limited number of graphics and symbols considered to be non-FIFRA elements that can be added by non-notification (<u>PRN 98-10, Section IV.C</u>).

Graphics and symbols are permitted on pesticide product labels, and cannot be false or misleading or otherwise cause the product to be misbranded. Graphics and symbols must be clear in their meaning to the reader and must not obscure or crowd required label language. Including explanatory text with the graphics and symbols, while not required, would help in preventing false and misleading labeling and misbranding. This Chapter provides guidance in determining the acceptability of graphics and symbols. (<u>PR Notice 98-10, Sections II.H</u>)

II. Acceptable graphics and symbols

Acceptable graphics and symbols on product labels can serve to enhance the understanding of the accompanying text. Examples of acceptable graphics and symbols include the following (<u>PR Notice 98-10, Sections II.H</u>):

- > Diagrams of how to open product containers.
- > Pictures illustrating proper pesticide use.
- > Graphics which display spray patterns of nozzles and/or application patterns.
- Pictograms located near the precautionary statements that illustrate the different exposure routes (oral, inhalation, or dermal) to pesticides.
- Pictures consistent with the label text showing examples of places where the pesticide may be used (e.g., a house or an office building).
- Child hazard drowning pictogram and labeling (a picture of a child turned upside down in a bucket within the universal negation symbol - 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"

CX-5

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.

- The "Mr. Yuk" symbol (a green frowning face with its tongue hanging out) on the label and/or outer container of the pesticide product. The "Mr. Yuk" symbol may be used with the skull & crossbones symbol for Toxicity Category I products used in or around the home or pool where children may be present.
- > Pictures illustrating appropriate protective gear.
- Certification symbols (i.e., <u>NSF</u> and Kosher symbols), which must provide proof of certification.
- Hazardous Materials Identification System/National Paint & Coatings Association/National Fire Protection Association (HMIS/NPCA and NFPA) ratings systems for hazard codes.
- Use of a logo to indicate absence of chlorofluorocarbons (CFCs) in a pesticide product. The logo must use the universal negation symbol (a red circle with a diagonal red slash through it) with the statement "Contains no CFCs or other ozone depleting substances. Federal regulations prohibit CFC propellants in aerosols." immediately next to the logo, and text set in at least 6-point font. <u>PR Notice 92-2.</u>
- Use of the <u>GHS</u> (Globally Harmonized System for Hazard Communication) explosives symbol and the GHS flammability symbol. These symbols can be added to the label in addition to any warning statements on the flammability or explosive characteristics of pesticide products required under <u>40 CFR 156.78</u>.
- The <u>Good Housekeeping Seal</u> 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.
- Department of Transportation symbols indicating the hazard and flammability of a particular pesticide product.

- The <u>USDA Certified Biobased Product label</u>, which must provide proof of certification. A disclaimer statement must also be placed directly under or beside the label indicating that it does not imply safety of the product.
- Barcodes and QR codes which allow for easier scanning of prices in retail stores. QR codes for the purpose of providing directions for use of the pesticide product are considered <u>web-distributed labeling</u>, which is discussed in Chapter 3.

III. Unacceptable graphics and symbols

Graphics and symbols are unacceptable if they violate <u>FIFRA 12(a)(1)(F)</u> or <u>FIFRA 2(q)(1)(A)</u> or the applicable regulations describing potential false and misleading statements in <u>40 CFR 156.10(a)(5)</u>. Examples of graphics and symbols that would generally be considered unacceptable include the following:

- 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 generally 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.
- 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.
- > Picture of a pest not claimed to be controlled by the product.
- Pictures that depict the fragrance of the product (except for antimicrobial products). Non-antimicrobial products are reviewed on a case-by-case basis.
- Pictures depicting food or food contact utensils, even in some cases where foodhandling area treatments are allowed on the label. Use directions generally require that food items and food contact utensils be covered or removed before the pesticide is applied.
- 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 such non-target organisms.

- Pictures of children, unless the product is registered for use on children or the product is registered for use in swimming pools. Reviewed on a case-by-case basis.
- > Pictures of candy. Similarly, containers that look like food or candy are prohibited.
- Symbols implying safety or non-toxicity, such as the caduceus or rod of Asclepius symbols for medicine.
- Pictures of residential use sites when the label limits use of the product to commercial or industrial sites.
- Recycling symbol or any other symbol implying that the product and/or its container can be recycled if in fact it cannot be.
- > EPA or any other agency logo which implies endorsement by a government agency.

IV. Organic pesticide logos

As discussed in Chapter 12, if the criteria described in <u>PR Notice 2003-1</u> are met, a pesticide product may bear the following phrases in logo format:

"For Organic Production" "For Organic Gardening" "For Organic Lawn Care" "For Use in Organic Production"

Logos from other groups that review materials proposed for organic agriculture may also be considered, e.g., Organic Materials Review Institute (OMRI). However, the following example would generally be considered unacceptable:

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.

Label reviewers should consult with the National Organic Program liaison in the Biopesticides and Pollution Prevention Division before approving any organic statements, logos, or claims.



Revised February 2018 Label Review Manual

Chapter 17: Net Contents/Net Weight



http://commons.wikimedia.org, photo by "Daderot"

Table of Contents

Wha	at's changed in this version?	. 1
I.	Introduction	. 2
П.	Location of the statement	. 2
Ш.	Expression of the statement	. 2
А	. Units of measure	. 2
В	Expression of net contents	. 3
C	Consistency with Directions for Use	. 3
IV.	Types of products/measurement	. 3
What's changed in this version?

- > Added Table of Contents.
- > Added What's changed in this version? section.
- Updated hyperlinks.
- > Editorial changes to text to improve readability.
- Switched order of Section III and IV.
- Updated Introduction section to include note on declaring net contents information on application form 8570-1, and leaving net contents information blank on draft label for refillable containers.
- > Updated NIST Handbook 130 reference for Bag on Valve unit measurements.

I. Introduction

The Net Contents/Net Weight statement indicates the quantity/volume of pesticide product that is in the container and must appear on the pesticide label pursuant to <u>FIFRA12(a)(1)(E)</u>) and <u>40 CFR 156.10(a)(1)(iii)</u>. 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. <u>40 CFR 156.10(d)</u> describes how the net contents must appear on the label, but does not require the term/heading "Net Weight" or "Net Contents" to be stated on the label. However, the Agency strongly recommends that labels include one of these qualifiers for clarity, as <u>40 CFR 156.10(d)(1)</u> 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; however, the applicant should declare the various net contents offered in Section III of the Application for Pesticide, Form 8570-1. Additionally, the net contents may be left blank for products distributed in refillable containers. <u>40 CFR 156.10(d)(7)</u>.

II. Location of the statement

There is no required location for the Net Contents/Net Weight statement. The preferred location is at 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 and shall be the average content unless explicitly stated as a minimum quantity. <u>40 CFR 156.10(d)(1)</u>.

III. Expression of the statement

Labels must meet the following requirements:

A. Units of measure

Conventional U.S. standard (also known as avoirdupois or imperial) units of measurement must be used on pesticide labels. Pesticide labels may also declare net contents in metric units (liters, kilograms, etc.), as long as U.S. units of measurement are declared (e.g., "Net Contents: 1 gallon (3.785 liters)"). It is not acceptable to declare net contents only in metric units. For consistency, EPA requests that applicants treat Directions for Use the same way. For example, in addition to expressing the application rate(s) in U.S. units of pound per acre, the registrant may also express the rates in equivalent metric units as kilograms per hectare.

B. Expression of net contents

The Net Contents must be stated in terms of the largest suitable units. For example, for a package containing 26 ounces of pesticide product, the label must state: "Net Contents: 1 pound (lb.) 10 ounces" rather than "Net Contents: 26 ounces." The label may indicate the net weight and quantity of individual units within the carton (e.g., "Net Weight 6.25 lbs. (20 - 5 oz. packets)"). <u>40 CFR 156.10(d)(4)</u>.

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 mislead consumers as to the net contents or net weight in the package or the proper application of the product. An example would be a granular product stating "Net Contents: 1 pound," that requires an application rate of 5 pounds per acre.

IV. Types of products/measurement

The Net Contents/Net Weight statement shall be expressed based on the product type as follows:

- Dry formulations (e.g., solids, dusts, granules, pelleted or tableted baits, wettable powder, microencapsulated, and impregnated materials)
 The net contents statement must be expressed as avoirdupois pounds and ounces.
 40 CFR 156.10(d)(3).
- > Liquid formulations (e.g., soluble and flowable concentrates, ready-to-use sprays)

The net contents must be expressed in terms of liquid measure at 68 °F (20 °C) in standard American units (gallons, quarts, pints, or fluid ounces). 40 CFR 156.10(d)(2).

Pressurized products (e.g., gases and aerosols)

The net contents must be expressed as avoirdupois pounds and ounces. <u>40 CFR 156.10(d)(3)</u>.

> Antimicrobial wipes, insect repellent wipes, and towelettes

The net contents per container for wipes and towelettes (wet or dry) must be expressed as avoirdupois pounds and ounces. <u>40 CFR 156.10(d)(3)</u>. This requirement is imposed for the total contents of the overall container and not on the basis of each individually-

packaged wipe or towelette within the container. 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, keeping in mind that the net content statement does not include the wrappers for individually-packaged wipes and towelettes. However, the net content declaration on the container may also include a statement such as *"Contains X count of x inch by y inch pre-moistened wipes."* in addition to the avoirdupois unit.

Bag on Valve (BOV)

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 2018 edition of NIST Handbook 130 requires that packages using BOV technology disclose the net quantity of the commodity in terms of weight that will be expelled from the container, enforceable after January 1, 2018. See <u>NIST Handbook 130 (2018)</u>, <u>Uniform Packaging and Labeling Regulation</u>, Section 10.3, including Note.

In the interest of consistency with the NIST 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).



Label Review Manual: Revised September 2013 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:

- 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)*.

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 ¹/₄ 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 refine the 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 countryspecific 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.