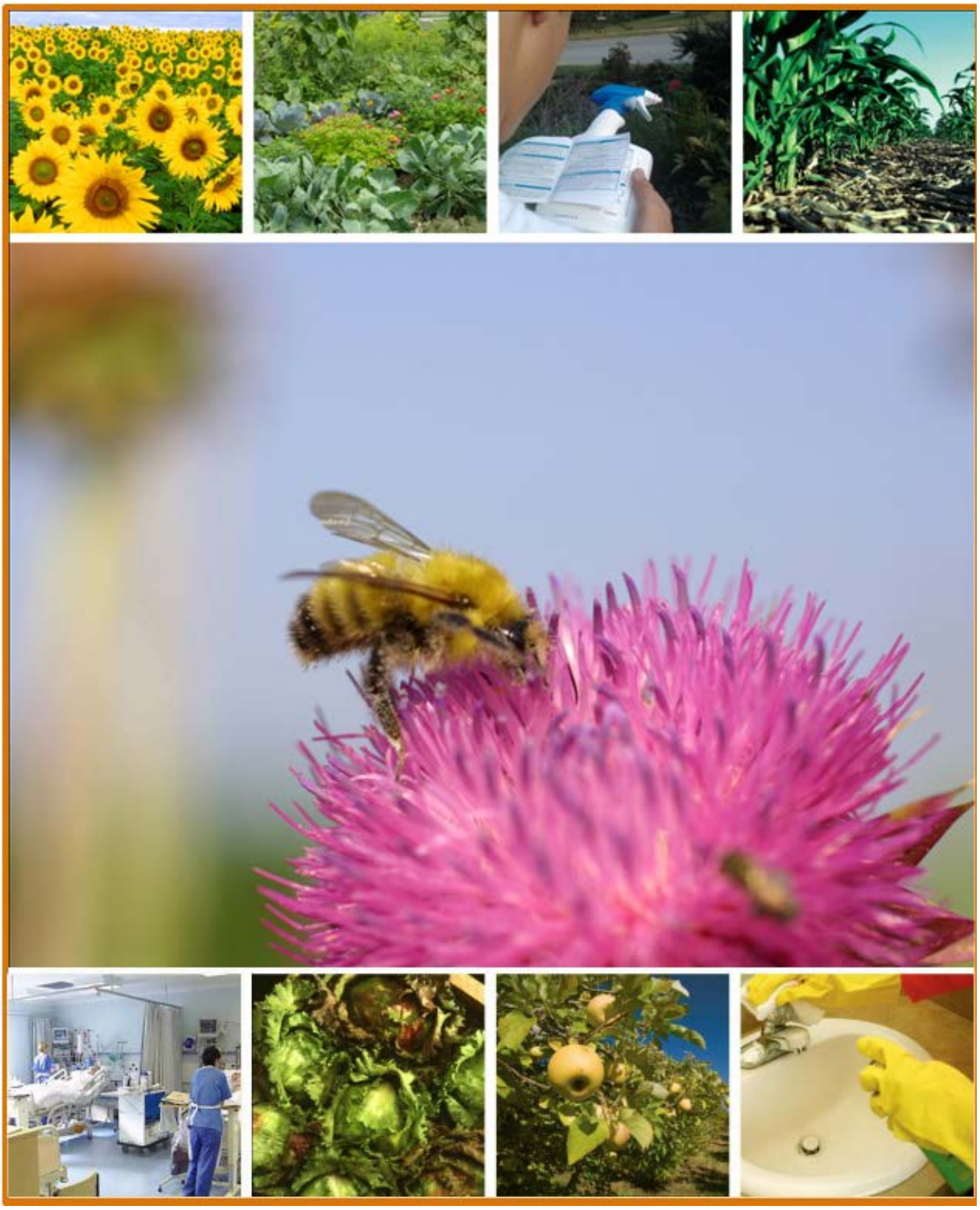
Label Review Manual: Revised September 2013

Chapter 18: Unique Product Labeling



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

I. Introduction

Certain specialty products pose a challenge to meeting the regulatory labeling requirements. Package size, shape, and composition often dictate unorthodox approaches to attaching the necessary information. While many labeling provisions of *40 CFR 156.10* are mandatory, other provisions provide the flexibility necessary to address challenging specialty products. The following examples have been accepted by the Agency and may be used as models for new and novel products that may be developed in the future. Label reviewers must address each product on a case-by-case basis, and determine whether the labeling meets applicable legal requirements.

II. Foreign language labeling

Foreign language text, in addition to the full English text, is permitted in part or in its entirety on the product so long as it is a true and accurate translation of the English text. (See *PR Notice 98-10*) A registrant may provide bilingual labeling on any product without notification. However, if it is submitted, the Office of Pesticide Programs (OPP) currently does not review the translation for accuracy or stamp/approve it. If the foreign text is inaccurate or goes beyond the reviewed and accepted English labeling, the Office of Enforcement and Compliance Assurance may take enforcement action. Products marketed in Puerto Rico can be labeled in English only or in English and Spanish.

. For products falling under the scope of the Worker Protection Standard, labels for products in toxicity categories I or II must include Spanish signal words and the statement below. (40 CFR 156.206 (e)). The Spanish signal word for toxicity category I products is "***PELIGRO***" and for toxicity category II products is "***AVISO***". The statement that appears on toxicity category I and II WPS products is as follows. Use of the statement and "Aviso" is optional for products in toxicity categories III and IV:

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

III. Soluble packets

An increasingly popular means of packaging dry pesticides is the water-soluble packet. For some chemicals, EPA has required water-soluble packaging to reduce exposure of mixer-loaders to dust, vapor, or liquid pesticides. This method of packaging, however, presents problems in labeling. Since the immediate container is the film, a strict application of the regulations would require front panel text to be printed on the film itself. Although recent technological advances have made such printing possible, most standard printing techniques and inks are not compatible

with the polyvinyl alcohol films. In order to accommodate this desirable method of packaging, the Agency has accepted other labeling approaches. See *PR Notice 94-8* for complete information.

The most widely used packaging is a tear-open foil envelope containing each soluble packet; the foil envelope bears the required labeling. This foil envelope method has the added benefit of protecting the soluble packet from moisture which could cause shelf-life problems. Another acceptable method is a muffin-pan type of package where each packet is enclosed in a depression with a tear-off top that seals each chamber. The tear-off top bears the required labeling.

A vital consideration in dealing with soluble packets is how to reduce the likelihood of the user removing unlabeled packets from labeled containers long before use and then forgetting what they are. Because laundry detergents and dry bleaches are also manufactured in soluble packets, there is the possibility that pesticides could be mistaken as these products. The Agency believes that simply packaging a quantity of unlabeled soluble packets in an outer container where they could be easily separated from the accompanying labeling does not meet the FIFRA registration standard. Each packet must either bear identifying labeling on the film itself (where feasible) or on packaging immediately enclosing that packet. *PR Notice 94-8* describes in more detail the concerns the Agency has with pesticide products containing water-soluble packaging (See *Chapter 10* for reduced Personal Protective Equipment for water-soluble packaging products subject to the Worker Protection Standard.)

IV. Multi-packs/co-packs

A. Registered Pesticide Packaged with a Non-Pesticide

A registered pesticide product, in one container, may be packaged with a non-pesticide component, such as an adjuvant, in a separate container (which is to be added to the pesticide during mixing). These two containers, combined in one package, may be sold as a single unit only if the adjuvant is referred to in the Directions for Use on the label.

The two containers are distributed and sold as a single retail unit, and together comprise the pesticide product. (See *40 CFR 152.3* and *FIFRA 2(u)* defining pesticide to include a "mixture of substances"). If the two components are bound together with a shrink-wrap sleeve or in a box, the full label of the pesticidal component must be visible through the wrapping, or the label must be duplicated and attached to, or printed on, the outermost container.

The regulation at *40 CFR 152.3* states that the "pesticide product" includes the package intended to be distributed or sold. EPA has jurisdiction over the packaging and labeling of any "non-pesticide" which is part of the package. This means that the Agency reviews and accepts or disapproves of the non-pesticide that is packaged with the pesticide. The reviewer

examines the non-pesticide labeling to determine whether it contains any language that conflicts with the pesticide label, but the reviewer does not actually stamp the non-pesticide label. An example of such a non-pesticide would be an activator (such as potassium permanganate) which accompanies a pesticide (sodium bromide). EPA reviews the labels for both products, but stamps only the accepted pesticide label, noting any problems or changes needed for the non-pesticide label.

B. Two or More Pesticides Packaged Together

Two or more pesticide products may be packaged in separate containers but sold together as a single unit. The user may be instructed on the label to tank mix the products that were packaged together just before application. (*FIFRA 2(u)*)

Each container must bear, or be accompanied by, full labeling, and the full labels of both containers must be visible. If the outermost packaging obscures any part of the labeling of the pesticides, the full labels must be duplicated and attached to the outermost container. (*40 CFR 156.10(a)(4)(i)*)

Approaches regarding the labeling for multi-packs and co-packs are dependent on the specific issues of each case. Registrants should contact the appropriate division for additional information before submitting registrations or amendments that feature multi-packs or co-packs or before deciding whether such packaging requires registration.

V. Small containers

Some containers are too small to contain all required label text. In such cases, it is permissible to have text located on accompanying pamphlets or other collateral material, all of which are considered product labeling. The Agency historically has required certain information to appear on the label of small containers:

- ingredient statement
- signal word
- skull and crossbones (when required)
- child hazard warning
- EPA Registration Number
- EPA Establishment Number
- the phrase “RESTRICTED USE PESTICIDE” (if so classified)
- a reference statement to any accompanying pamphlets.

Outer boxes, bubble packs, accordion-pleated attached labels, and plastic self-sealing envelopes containing additional labeling have been accepted.

Whatever the approach, it is important to stress that all labeling must accompany the product at point of sale, and that the immediate container must bear a statement referring the user to the location of any additional labeling which is securely affixed to the container. All of this labeling must be reviewed and accepted. Registrants are encouraged to consult with the Agency about special labeling needs.

VI. Child-attracting packaging ("Attractive Nuisance")

From time to time, registrants package pesticides in containers attractive to children. For example, bait-type pesticides for rodents and roaches have been marketed in little doll houses, fire trucks, and other toy-like dispensers or containers that look like food containers, e.g., a milk-carton shape. The Agency has not found these types of packages to be acceptable. It may be difficult for the reviewer to determine the package style when the final printed label is only a printer's proof and is not usually given a final review. The Agency can require child-resistant packaging when the toxicity criteria and use criteria are met. To ensure that packaging is acceptable the reviewer may require the applicant to submit the intended packaging before the product is registered. See *40 CFR 157.20*, et al.

VII. Child-resistant packaging

Child-Resistant Packaging (CRP) is defined as packaging that is designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein in a reasonable time and that it not be difficult for normal adults to use properly. See *40 CFR 157.21(b)*.

If the pesticide is subject to CRP regulations the registrant must certify (*40 CFR 157.34*) to the Agency that the pesticide as packaged meets the standards set forth in the regulations (*40 CFR 157.32*). An example of the proper CRP certification language is found in *PR Notice 96-2*. Additionally, a registrant must maintain adequate records to substantiate the CRP certification for the life of the pesticide registration. Voluntary use of CRP requires the registrant meet the same standards as mandatory CRP.

Any changes in CRP will require an amendment of the pesticide registration (*40 CFR 152.44*) and a new CRP certification. This amendment must include its designation using the *American Society for Testing Materials (ASTM) standard D3475-06 "Standard Classification of Child-Resistant Packages"*. Agency approval is required before any packaging change can occur. CRP changes are not notifications.

A pesticide product may be exempt from the CRP requirements if it is 1) classified for restricted use, 2) if the package is of a large size (as defined in *40 CFR 157.24 (a)(2)*), 3) if the pesticide is not toxic, or 4) if an exemption is based on technical factors that preclude using the product. In the last two cases, the exemption must be approved by the Agency before the exemption can occur.

Outside of the listed exemptions above, the Agency has partially exempted products from some CRP requirements in two instances. For the following types of packaging, review the cited Federal Register notices to determine whether CRP requirements have been met:

1. Prefilled, nonrefillable ant and roach insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact (*67 FR 35910, May 22, 2002*).

2. Prefilled, nonrefillable termite insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact (*67 FR 35909, May 22, 2002*).

VIII. Pesticides used to treat seeds

A. Dye Requirements for Seed Treatment Pesticide Products

Under *40 CFR 153.155(a)*, any pesticide product intended for use in treating seeds must contain an EPA-approved dye. The purpose of such dye is to impart an unnatural color to the seed to signify that it has been so treated.

B. Exemptions to Dye Requirements (and related label statements)

However, the dye requirement does not apply if appropriate tolerances or other clearances have been established under the FFDCA for residues of the pesticide. In addition there are some exemptions from the requirement to use a dye that relate to how the product is labeled.

These exemptions are: (1) products intended and labeled for use solely by commercial seed treaters (provided a label condition is met, discussed further below); (2) products intended and labeled for use solely as at-planting or hopper box treatments; and (3) products that are gaseous in form or are used as fumigants. *40 CFR 153.155(b)(1)-(3)*.

1. **Commercial Seed Treaters.** Pesticide products intended and labeled for use solely by commercial seed treaters that do not have a tolerance or tolerance exemption need not contain a dye, "*provided* that the (pesticide product) label bears a statement requiring the user to add an EPA-approved dye with the pesticide during the seed treatment process." *40 CFR 153.155(b)(1)*. An appropriate label statement would be, for example:

   "Note: This product does not contain dye and is not covered by an appropriate tolerance, tolerance exemption, or other clearance under the Federal Food, Drug and Cosmetic Act. To comply with 40 CFR 153.155, therefore, all seed treated commercially with this product must be colored with an EPA-approved dye or colorant of a suitable color to prevent accidental use as food for man or feed for animals".

   Any seed treated by a commercial seed treater using a pesticide product labeled in this manner cannot be used for or mixed with food or animal feed, or processed for oil.

   If the directions for use indicate a specific dye to use, verify that it is EPA-approved by reviewing the lists offered in *40 CFR 153.155(c)*. EPA-approved dyes for seed treatment are listed in various sections of EPA's FIFRA regulations. For instance, 40 CFR sections *180.910*, *180.920*, and *180.950* contain those dyes approved for seed treatment use where a tolerance exemption has been established for the dye. In the future, *40 CFR 180.2010* will contain those dyes approved for seed treatment use where EPA has determined that residues of the dye only will be present, if at all, at levels that are below the threshold of regulation. Finally, *40 CFR 180.2020* contains those dyes approved for seed-treatment use where EPA has determined that no tolerance or tolerance exemption is needed for the dye because the use is not likely to result in residues in or on food or feed.

   To the extent that the pesticide product is covered by an appropriate tolerance, tolerance exemption or other clearance under the FFDCA, no such label statement is necessary on the pesticide product, the commercial seed treater is not required to add a dye to the pesticide product before treating seed, and the treated seed can be used for or mixed with food or animal feed, or processed for oil, in accordance with the applicable tolerance, tolerance exemption, or other clearance under the FFDCA. See *40 CFR 153.155(a)*.

Note: If a commercial seed treatment product contains no dye and no instructions to dye seeds are mentioned on the label, the label reviewer needs to ensure that the tolerance or tolerance exemptions are adequate for all ingredients in the pesticide as one would do for a pesticide with food- or feed-site uses.

2. **At-planting or Hopper Box Treatments.** If the product is intended for direct use on seed at planting time, and the pesticide is not cleared by EPA for food and feed use, the following statement is recommended on the pesticide product label:

   "Do not use treated seed for food or feed purposes or process for oil. Treat only those seeds needed for immediate use, minimizing the interval between treatment and planting".

   A statement may be required to ensure no unreasonable adverse effects depending upon the characteristics of the ingredients of the product, such as:

   "Do not store excess treated seeds beyond planting time".

C. Label Statements Based on the Worker Protection Standard (WPS)

Seed treatment products may fall under the scope of the WPS depending on the type of treatment. Seed treatment on agricultural establishments in hopper-box, planter box, or other seed-treatment applications at or immediately before planting is within the scope of the WPS. Commercial treatment of seeds is not within the scope of the WPS.

An exclusionary statement may be added to a seed-treatment pesticide's label to clearly distinguish between products with uses subject to WPS and those without. The following statement may be appropriate for the labels of seed-treatment pesticide products solely used at commercial seed treatment facilities.

"Not for use on agricultural establishments in hopper-box, planter-box, slurry-box or other seed treatment applications at or immediately before planting".

Non-commercial seed treatment products must contain all required WPS labeling as appropriate. See *40 CFR 156.200*, et al. For seed treatment products, there may be a WPS exception statement that specifically applies to the Restricted Entry Interval (REI). If the treated seeds are soil injected or soil incorporated, the registrant may add the following statement directly after the REI statement in the Agricultural Use Requirements box. *PR Notice 93-7*, page 39.

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

D. Label Statements Based on Risk Assessments

The label reviewer needs to consult the risk assessment. Necessary mitigation measures may require that commercial seed treaters add information to the labeling for the seeds. Such additional language would be found in the Directions for Use instructing the seed treater to appropriately label the seeds he or she treats. To help promote proper use of the product

through its life cycle, including after it has been incorporated in the seed, any restriction on the pesticide product that relates to use of the crop or seed should be included on the seed label. Without these restrictions being transferred to the seed label, the person who buys the seed may be unaware of these restrictions. The seed label should include statements such as grazing restrictions, and replanting dates need to cover treated seed to prevent harm to birds, etc., as specified in the risk assessment.

Examples of additional label statements that may be required on seed-treatment product labels on a case-by-case basis in the risk assessment include:

"The U.S. Environmental Protection Agency requires the following statements (or a subset of the following statements as appropriate) on containers containing seed treated with (insert name of product)":

- *"Store treated seed away from food and feedstuffs".*
- *"Do not allow children, pets or livestock to have access to treated seeds".*
- *"Wear long pants, long-sleeved shirt and protective gloves when handling treated seed".*
- *"Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting (such as in row ends)".*
- *"Dispose of all excess treated seed by burying seed away from bodies of water".*
- *"Dispose of seed packaging or containers in accordance with local requirements".*

In addition, other label statements may be required according to the risk assessment on a case-by-case basis to address identified environmental or toxicity hazards from the treated seed. Consult *Chapter 8* for detailed guidance concerning environmental hazard statements.

E. Labeling Statements Associated with Federal Seed Act

Commercial seed labels for treated seeds, as distinct from seed treatment pesticide product labels, are required to comply with both the Federal Seed Act (FSA) and USDA's regulations concerning the labeling of treated seed (as found in the *Federal Seed Act* and *7 CFR Part 201*). In addition, EPA recommends that the labeling of a pesticide product intended for use as a seed treatment also identify all the language that will be required for the seed label (under the FSA and the USDA regulations). Although the statements below are not required under FIFRA for pesticide labeling, it is considered a prudent measure to include these statements on seed-treatment pesticides so the user is aware of his or her obligations under the FSA when labeling seed.

1. **Toxicity Category I Pesticide Label Statements.** For commercial seed treatment products assigned Toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the following labeling statements are recommended to be placed in the direction for use section of the pesticide labeling to address the *Federal Seed Act* requirements for treated seed (consult: *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRD3317429* for a detailed explanation):

   "The Federal Seed Act requires that bags containing seed treated with this product shall be labeled with the following information:

   (a) a statement such as "*Poison*", "*Poison treated*", or "*Treated with Poison"*,

   (b) the skull and crossbones symbol,

   (c) "*This seed has been treated with (insert name of active ingredient of pesticide)*". and,

   (d) *"Do not use for food, feed or oil purposes"*.

2. **Other Commercial Seed Treatment Statements.** The following labeling statement is recommended to be placed in the directions for use section of the labeling for commercial seed treatment pesticide products that do not have appropriate tolerances or tolerance exemptions:

   "The Federal Seed Act requires that bags containing seed treated with this product shall be labeled with the following information: "This seed has been treated with (insert name of active ingredient of pesticide). Do not use for food, feed or oil purposes".

F. Rinsing Instructions

General labeling requirements for residue removal or rinsing instructions are contained in 40 CFR 156.144 – 156. Part 156.144 (e) states that EPA may, at its own discretion or based on data submitted by any person, modify or waive the requirements of those sections or permit or require alternative labeling statements. The language below has been approved by EPA as modifications to rinsing instructions that are appropriate for labeling of seed treatment products.

1. Nonrefillable container

Plastic containers: Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Then offer container for recycling if available, reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Triple rinse as follows: *For containers with capacity equal to or less than 5 gallons*: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after

the flow begins to drip. Add water - at least 2% of the container volume, and up to 1/3 of the volume of water needed to make the proper slurry composition with a maximum of 1/4 of the container volume - and recap. Shake for 30 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water.

For containers with capacities greater than 5 gallons: Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Add water - at least 2% of the container volume, and up to 1/3 of the volume of water needed to make the proper slurry composition with a maximum of 1/4 of the container volume. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 60 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water.

2. Refillable container

Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container before final disposal, empty the remaining contents into application equipment or mix tank. Add water – at least 2% of the container volume, and up to 1/3 of the volume of water needed to make the proper slurry composition with a maximum of ¼ of the container volume. Replace and tighten closure. Agitate vigorously or recirculate the rinsate with a pump for at least 2 minutes, ensuring that the rinsate rinses the walls of the container. Empty the rinsate into application equipment or rinsate collection system, for later use or disposal. Repeat this procedure two more times. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water.

Recycling: Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer, or contact the Ag Container Recycling Council (ACRC) at 1-877-952-2272 (toll free) or *www.acrecycle.org*.

IX. North American Free Trade Agreement (NAFTA) labeling

Registrants may volunteer products for NAFTA label development at any time.

A. Applying for Registration

The registrant should review the information provided in the "*Guidance on How to Develop a NAFTA Label*". Ultimately, a joint submission of the proposed label and the U.S. and Canadian product specifications must be made to EPA and Canada's Pest Management

Regulatory Agency (PMRA). In the United States, the submission should be as a label amendment. However, because EPA and PMRA continue to develop this process and refinethe guidance for NAFTA label development, the first step should be to contact either EPA or PMRA to obtain the most current information and to discuss the submission. Currently, Mexico has not been involved in the NAFTA labeling process, but may be in the future.

B. Registration of NAFTA Labels

For existing registrations, the U.S. and Canadian label review will run essentially independently, with each regulatory authority having independent responsibility for the booklets for use in the appropriate country and shared responsibility for the container label. Specifically, the container label would be reviewed by both regulatory authorities, while review of the booklets that contain the directions for use would be independent of each other.

For a new registration, the regulatory processes would run concurrently. The regulatory agencies would commit to the current accelerated timeframes for joint reviews. In the event of one country lagging behind in the registration process, and hence delaying approval of its label, the registrant could proceed with essentially the same label, absent the NAFTA language, and using only the Directions for Use for the country that is ready to proceed with registration.

C. Amendments to NAFTA Labels

The process required for registration or amendment of a NAFTA label is dependent on the format chosen for the labels. The preferred label format consists of separate U.S. and Canadian booklets with the respective directions for use. This format has the advantage of resulting in essentially independent regulatory processes for many types of label amendments. This approach is advantageous for registrants because it allows many types of label amendments to move ahead at the pace they normally would, without necessitating delay, repackaging, or other issues that are inherent in a single label approach.

There are several types of potential registration amendments. For the purpose of the NAFTA label, they are divided as follows:

1. **Registration amendments limited to changes that are exclusive to the country-specific booklets that contain directions for use,** (e.g., addition of a pest, change to pre-harvest interval, application timing, etc.) and that do not affect the container label. The U.S. and Canadian processes would run essentially independently of each other, with each regulatory authority taking responsibility for the content exclusive to the appropriate country-specific booklet. The container label would be reviewed as part of the amendment (since it forms part of the NAFTA label for each country). If no changes to the container label are made, the label amendment may be approved by the country involved with the booklet change. If a change to the booklet would require changes to

the container label, these changes to the container label would be provided immediately to both Agencies for their simultaneous review.

2. **Registration amendments affecting the container label** (e.g., product name change, change to precautionary statements, etc.) **that may or may not affect the booklet(s).** This type of amendment would require review by both countries. If the registrant desires to have the regulatory processes run concurrently, the regulatory agencies would be bound by their respective timeframes for the amendment, but commit to trying to achieve the shorter timeframe (between the two agencies) where possible.

3. **Amendment to change the product formulation.** This may or may not directly affect the NAFTA label but could have implications for the determination that the products are substantially similar.

   The registration of a NAFTA label for a product is based on the product formulation being substantially similar in both countries and manufactured by the same registrant. Any application to amend the formulation would be required to be made to both agencies simultaneously to ensure that substantial similarity is maintained. The regulatory processes would run concurrently and would require review by both countries (the review may or may not include a review of the product label). The agencies would be bound by their respective timeframes for the action, but commit to trying to achieve the shorter timeframe (between the two agencies) where possible.

X. Other types of labeling

Manuals

If the master label makes reference to a manual, then the registrant is required to submit it to the Agency for our review. The manual should describe in detail any special procedures and/ or technical apparatus involved in the application of the product.If the manual is inconsistent with the EPA approved label, the Agency will consider the product misbranded.