

(e) *Am I responsible for product integrity?* Yes, for a product that you distribute or sell to a refiller that is not part of your company for repackaging into refillable containers, you are responsible for the pesticide product not being adulterated or different from the composition described in its confidential statement of formula that is required under FIFRA section 3.

(f) *What information must I develop?* For each pesticide product distributed or sold in refillable containers, you must develop both of the following documents in writing.

(1) You must develop a refilling residue removal procedure that describes how to remove pesticide residue from a refillable container (portable or stationary pesticide container) before it is refilled.

(i) The refilling residue removal procedure must be adequate to ensure that the composition of the pesticide product does not differ at the time of its distribution or sale from the composition described in its confidential statement of formula that is required under FIFRA section 3.

(ii) If the refilling residue removal procedure requires the use of a solvent other than the diluent used for applying the pesticide as specified on the labeling under "Directions for Use," or if there is no diluent used for application, the refilling residue removal procedure must describe how to manage any rinsate resulting from the procedure in accordance with applicable Federal and State regulations.

(2) You must develop a description of acceptable refillable containers (portable or stationary pesticide containers) that can be used for distributing or selling that pesticide product.

(i) An acceptable container is one that you have determined meets the standards in subpart C of this part and is compatible with the pesticide formulation intended to be distributed and sold using the refillable container.

(ii) You must identify the containers by specifying the container materials of construction that are compatible with the pesticide formulation and specifying information necessary to confirm compliance with the refillable container requirements in subpart C of this part.

(g) *When must I provide the information to the refiller?* You must provide the refiller with all of the following information and documentation before or at the time of distribution or sale of your pesticide product to the refiller:

(1) Your written refilling residue removal procedure for the pesticide product.

(2) Your written description of acceptable containers for the pesticide product.

(3) The pesticide product's label and labeling.

(h) *What recordkeeping must I do?* You must maintain all of the records listed in this section for the current operating year and for 3 years after that. You must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe:

(1) Each written contract entered into with a refiller for repackaging your pesticide product into refillable containers.

(2) Your written refilling residue removal procedure for the pesticide product.

(3) Your written description of acceptable containers for the pesticide product.

§ 165.70 Refillers who are not registrants.

(a) *Must I comply with the standards in this section?* You must comply with the standards in this section if you are a refiller of a pesticide product and you are not the registrant of the pesticide product.

(b) *Under what conditions can I repack-age a registrant's pesticide product into refillable containers?* A registrant may allow you to repack the registrant's pesticide product into refillable containers and to distribute or sell such repackaged product under the registrant's existing registration if all of the following conditions are satisfied:

(1) The repackaging results in no change to the pesticide formulation.

(2) One of the following conditions regarding a registered refilling establishment is satisfied:

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(i) The pesticide product is repackaged at a refilling establishment registered with EPA as required by §167.20 of this chapter.

(ii) The pesticide product is repackaged at the site of a user who intends to use or apply the product by a refilling establishment registered with EPA as required by §167.20 of this chapter.

(3) The registrant has entered into a written contract with you to repack the pesticide product and to use the label of the registrant's pesticide product.

(4) The pesticide product is repackaged only into refillable containers that meet the standards of subpart C of this part.

(5) The pesticide product is labeled with the product's label with no changes except the addition of an appropriate net contents statement and the refillers EPA establishment number.

(c) *What violations are applicable to illegal repackaging?* Repackaging a pesticide product for distribution or sale without either obtaining a registration or meeting all of the conditions in paragraph (b) of this section is a violation of section 12 of the Act. Both you and the pesticide product's registrant may be liable for violations pertaining to the repackaged product.

(d) *Am I responsible for product integrity?* Yes, you are responsible for the pesticide product that you distribute or sell in refillable containers not being adulterated or different from the composition described in its confidential statement of formula that is required under FIFRA section 3.

(e) *What requirements must I follow regarding repackaging a pesticide product into refillable containers?* You must comply with all of the following provisions.

(1) Your establishment must be registered with EPA as a producing establishment as required by §167.20 of this chapter.

(2) You must not change the pesticide formulation unless you have a registration for the new formulation.

(3) You must repack a pesticide product only into a refillable container that is identified on the description of acceptable containers for that pesticide product provided by the registrant.

(4) You may repack any quantity of a pesticide product into a refillable container up to the rated capacity of the container. In addition, there are no general limits on the size of the refillable containers that you can use.

(5) You must have all of the following items at your establishment before repackaging a pesticide product into any refillable container for distribution or sale:

(i) The written contract from the pesticide product's registrant.

(ii) The pesticide product's label and labeling.

(iii) The registrant's written refilling residue removal procedure for the pesticide product.

(iv) The registrant's written description of acceptable containers for the pesticide product.

(6) Before repackaging a pesticide product into any refillable container for distribution or sale, you must identify the pesticide product previously contained in the refillable container to determine whether a residue removal procedure must be conducted in accordance with paragraph (g) of this section. You may identify the previous pesticide product by referring to the label or labeling.

(7) You must inspect each refillable container according to paragraph (f) of this section.

(8) You must clean each refillable container according to paragraph (g) or (h) of this section, if required by either paragraph.

(9) You must ensure that each refillable container is properly labeled according to paragraph (i) of this section.

(10) You must maintain records in accordance with paragraph (j) of this section.

(11) You must maintain records as required by part 169 of this chapter.

(12) You must report as required by part 167 of this chapter.

(13) The stationary pesticide containers at your establishment must meet the standards in §165.45(f).

(14) You may be required to comply with the containment standards in subpart E of this part.

(f) *How must I inspect refillable containers?* Before repackaging a pesticide product into any refillable container, you must visually inspect the exterior

and (if possible) the interior of the container and the exterior of appurtenances. The purpose of the inspection is to determine whether the container meets the necessary criteria with respect to continued container integrity, required markings, and openings. If the condition in paragraph (f)(1) of this section exists, the container fails the inspection and must not be refilled unless the container is repaired, reconditioned, or remanufactured in compliance with the relevant DOT requirement. If the condition in paragraph (f)(2) or (f)(3) of this section exists (or both), the container fails the inspection and must not be refilled until the container meets the standards specified in subpart C of this part. The conditions are:

(1) The integrity of the container is compromised in at least one of the following ways:

(i) The container shows signs of rupture or other damage which reduces its structural integrity.

(ii) The container has visible pitting, significant reduction in material thickness, metal fatigue, damaged threads or closures, or other significant defects.

(iii) The container has cracks, warpage, corrosion or any other damage which might render it unsafe for transportation.

(iv) There is damage to the fittings, valves, tamper-evident devices or other appurtenances that may cause failure of the container.

(2) The container does not bear the markings required by § 165.45(a), (b) and (d), or such markings are not legible.

(3) The container does not have an intact and functioning one-way valve or tamper-evident device on each opening other than a vent, if required.

(g) *How must I clean refillable containers?* You must clean each refillable container by conducting the pesticide product's refilling residue removal procedure before repackaging the pesticide product into the refillable container, unless the conditions in paragraph (g)(1) of this section and either paragraph (g)(2) or (g)(3) of this section are satisfied:

(1) If required, each tamper-evident device and one-way valve is intact.

(2) The refillable container is being refilled with the same pesticide product.

(3) Both of the following conditions are satisfied.

(i) The container previously held a pesticide product with a single active ingredient and is being used to repack a pesticide product with the same single active ingredient.

(ii) There is no change that would cause the composition of the product being repackaged to differ from the composition described in its confidential statement of formula that is required under FIFRA section 3. Examples of unallowable changes include the active ingredient concentration increasing or decreasing beyond the limits established by the confidential statement of formula or a reaction or interaction between the pesticide product being repackaged and the residue remaining in the container.

(h) *How must I clean a refillable container that has a broken (non-intact) tamper-evident device or one-way valve?* As required in paragraph (g) of this section, you must clean each refillable container that has a tamper-evident device or one-way valve that is not intact by conducting the pesticide product's refilling residue removal procedure before repackaging the pesticide product into the refillable container. In addition, other procedures may be necessary to assure that product integrity is maintained in such cases.

(i) *How must I label refillable containers?* Before distributing or selling a pesticide product in a refillable container, you must ensure that the label of the pesticide product is securely attached to the refillable container such that the label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. The label and labeling must comply in all respects with the requirements of part 156 of this chapter. In particular, you must ensure that the net contents statement and EPA establishment number appear on the label.

(j) *What recordkeeping must I do?* You must maintain all of the records listed in this section in addition to the applicable records identified in parts 167 and 169 of this chapter. You must furnish

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these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe.

(1) For each pesticide product distributed or sold in refillable containers, all of the following records must be maintained for the current operating year and for 3 years after that:

(i) The written contract from the pesticide product's registrant for the pesticide product.

(ii) The written refilling residue removal procedure for the pesticide product.

(iii) The written description of acceptable containers for the pesticide product.

(2) Each time you repackage a pesticide product into a refillable container and distribute or sell the product, the following records must be generated and maintained for at least 3 years after the date of repackaging:

(i) The EPA registration number of the pesticide product distributed or sold in the refillable container.

(ii) The date of the repackaging.

(iii) The serial number of the refillable container.

§§ 165.71–165.79 [Reserved]

Subpart E—Standards for Pesticide Containment Structures

§ 165.80 General provisions.

(a) *What is the purpose of the regulations in this subpart?* The purpose of the containment regulations in this subpart is to protect human health and the environment from exposure to agricultural pesticides which may spill or leak from stationary pesticide containers. This protection is achieved by the construction of secondary containment units or pads at certain facilities handling agricultural pesticides. These regulations will also reduce waste generation associated with:

(1) Storage and handling of large quantities of pesticide products.

(2) Pesticide dispensing and container-refilling operations.

(b) *Do I have to comply with the regulations in this subpart?* You must comply with the regulations in this subpart if you are an owner or operator of one of

the following businesses and if you also have a stationary pesticide container or a pesticide dispensing (including container refilling) area:

(1) Refilling establishments who repackage agricultural pesticides and whose principal business is retail sale (i.e., more than 50% of total annual revenue comes from retail operations).

(2) Custom blenders of agricultural pesticides.

(3) Businesses which apply an agricultural pesticide for compensation (other than trading of personal services between agricultural producers).

(c) *When do I have to comply?* You must comply with all applicable containment regulations for new and existing structures as of August 17, 2009.

§ 165.81 Scope of stationary pesticide containers included.

(a) *What is a stationary pesticide container?* A stationary pesticide container is a refillable container that is fixed at a single facility or establishment, or, if not fixed, remains at the facility or establishment for at least 30 consecutive days, and that holds pesticide during the entire time.

(b) *What stationary pesticide containers are subject to the regulations in this subpart?* Stationary pesticide containers designed to hold undivided quantities of agricultural pesticides equal to or greater than 500 gallons (1,890 liters) of liquid pesticide or equal to or greater than 4,000 pounds (1,818 kilograms) of dry pesticide are subject to the regulations in this subpart and must have a secondary containment unit that complies with the provisions of this subpart unless any of the following conditions exists:

(1) The container is empty, that is, all pesticide that can be removed by methods such as draining, pumping or aspirating has been removed (whether or not the container has been rinsed or washed).

(2) The container holds only pesticide rinsates or wash waters, and is labeled accordingly.

(3) The container holds only pesticides which would be gaseous when released at atmospheric temperature and pressure.