§ 165.65 Registrants who distribute or sell pesticide products in refillable containers.

(a) Must I comply with the standards in this section? You must comply with the standards in this section if you are a

(2) For the purposes of this subpart, an antimicrobial swimming pool product is a pesticide product that satisfies both of the following conditions:

(i) The pesticide product is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.

(ii) The labeling of the pesticide product includes directions for use on only a site or sites in the antimicrobial product use category of swimming pools.

(e) How will EPA determine if an antimicrobial pesticide product otherwise exempted must be subject to the repackaging regulations in this subpart to prevent an unreasonable adverse effect on the environment?

(1) EPA may determine that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the repackaging regulations in this subpart to prevent an unreasonable adverse effect on the environment if all of the following conditions exist:

(i) EPA obtains information, data or other evidence of a problem with the containers of a certain pesticide product or related group of products.

(ii) The information, data or other evidence is reliable and factual.

(iii) The problem causes or could reasonably be expected to cause an unreasonable adverse effect on the environment.

(iv) Complying with the container regulations could reasonably be expected to eliminate the problem.

(2) If EPA determines that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the repackaging regulations in this subpart to prevent an unreasonable adverse effect on the environment, EPA may require, by rule, that the product be repackaged in compliance with all or some of the requirements in this subpart. After allowing the applicant or registrant a reasonable amount of time to reply, EPA may require, by notification and as a condition of registration, that the product be repackaged in compliance with all or some of the requirements in this subpart. For the purpose of the previous sentence, 60 days would be a reasonable amount of time to reply, although EPA may, in its discretion, provide more time. EPA may deny registration or initiate cancellation proceedings if the registrant fails to comply with the repackaging regulations within the time frames established by EPA in the rule or in its notification.

(f) What other pesticide products are subject to the regulations in this subpart? The regulations in this subpart apply to all pesticide products other than manufacturing use products, plant-incorporated protectants, and antimicrobial products that are exempt paragraph (c) of this section. Antimicrobial products covered under paragraph (d) of this section are subject to the regulations indicated in that section.

(g) What does “pesticide product” or “pesticide” mean in the rest of this subpart? In §§ 165.63(h) through 165.70, the term “pesticide product” or “pesticide” refers only to a pesticide product or a pesticide that is subject to the regulations in this subpart as described in paragraphs (a) through (f) of this section.

(h) Are there any other exceptions? (1) The regulations in this subpart do not apply to transport vehicles that contain pesticide in pesticide-holding tanks that are an integral part of the transport vehicle and that are the primary containment for the pesticide.

(2) Custom blending is not subject to the regulations in this subpart.

(3) The regulations in this subpart do not apply to containers that hold pesticides that are gaseous at atmospheric temperature and pressure.

§ 165.65 Registrants who distribute or sell pesticide products in refillable containers.

(a) Must I comply with the standards in this section? You must comply with the standards in this section if you are a
registrant who distributes or sells pesticide products in refillable containers. This means that you conduct all of the repackaging for a pesticide product and that you do not distribute or sell the pesticide product to a refiller that is not part of your company for repackaging into refillable containers. If you are a registrant that repackages a product directly into refillable containers for sale or distribution and you also sell or distribute other quantities of that product to an independent refiller for repackaging, then you must meet the requirements in this section for those quantities you distribute or sell directly and the requirements in §165.67 for those quantities that you distribute or sell to an independent refiller.

(b) 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.

c) 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.

d) What requirements must my individual establishments follow regarding repackaging a pesticide product into refillable containers? A refiller at your individual establishment that repackages a pesticide product into refillable containers for distribution or sale must comply with all of the following provisions.

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

(2) The refiller must not change the pesticide formulation unless the refiller has a registration for the new formulation.

(3) The refiller must repackage a pesticide product only into a refillable container that is identified on your description of acceptable containers for that pesticide product.

(4) The refiller may repackage 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 the refiller can use.

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

(i) The pesticide product’s label and labeling.

(ii) The written refilling residue removal procedure for the pesticide product.
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(iii) The written description of acceptable containers for the pesticide product.

(6) Before repackaging a pesticide product into any refillable container for distribution or sale, the refiller 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 (f) of this section. The refiller may identify the previous pesticide product by referring to the label or labeling.

(7) The refiller must inspect each refillable container according to paragraph (e) of this section.

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

(9) The refiller must ensure that each refillable container is properly labeled according to paragraph (h) of this section.

(10) The establishment must maintain records in accordance with paragraph (i) of this section.

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

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

(e) How must my individual establishments inspect refillable containers? Before repackaging a pesticide product into any refillable container, a refiller at your establishment 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 (e)(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 (e)(2) or (e)(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.

(f) How must my individual establishments clean refillable containers? A refiller at your establishment 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 (f)(1) of this section and either paragraph (f)(2) or (f)(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-age 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.

(g) How must my individual establishments clean a refillable container that has a broken (non-intact) tamper-evident device or one-way valve? As required in paragraph (f) of this section, a refiller at your establishment 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.

(h) How must my individual establishments label refillable containers? Before distributing or selling a pesticide product in a refillable container, a refiller at your establishment 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, the refiller at your establishment must ensure that the net contents statement and EPA establishment number appear on the label.

(i) What recordkeeping must my individual establishments do? Each of your individual establishments that repackages a pesticide product into refillable containers for distribution or sale 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. The establishment 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. For each pesticide product distributed or sold in refillable containers, both of the following records must be maintained for the current operating year and for 3 years after that:

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

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

2. Each time a refiller at your establishment repackages a pesticide product into a refillable container and distributes or sells 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 or other identifying code of the refillable container.

§ 165.67 Registrants who distribute or sell pesticide products to refiners for repackaging.

(a) Must I comply with the standards in this section? You must comply with the standards in this section if you are a registrant who distributes or sells pesticide products to a refiller that is not part of your company for repackaging into refillable containers.

(b) Under what conditions can I allow a refiller to repack my pesticide product into refillable containers? You may allow a refiller to repack your pesticide product into refillable containers and to distribute or sell such repackaged product under your 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:

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

3. You have entered into a written contract with the refiller to repack the pesticide product and to use the label of your pesticide product.

4. The pesticide product is repackaged only into refillable containers.