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(2) EPA may waive or modify the requirements of paragraph (b) of this section regarding the DOT standards for pesticide products that are DOT hazardous materials if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves a level of safety that is at least equal to that specified in the requirements of paragraph (b) of this section. EPA will modify or waive the requirements of paragraph (b) of this section only after consulting with DOT to ensure consistency with DOT regulations and exemptions.

(h) *How do I obtain a waiver from or a modification to any of the refillable container standards?* To obtain a waiver from or a modification to any of the refillable container standards, you must submit a written request for a waiver or a modification to the EPA to the following address: Office of Pesticide Programs (7504P); U.S. Environmental Protection Agency; Ariel Rios Building; 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. You cannot distribute or sell the pesticide product in a refillable container that does not comply with all of the refillable container standards unless and until EPA approves the request for the waiver or modification in writing. You must include two copies of the following information (which may be part of an application for registration or amended registration) with your written request:

(1) The name and address of the registrant; the date; and the name, title, signature, and phone number of the company official making the request.

(2) The name and EPA registration number of the pesticide product for which the waiver or modification is requested.

(3) A statement specifying the requirement or requirements from which you are requesting a waiver or a modification.

(4) A description of the refillable container or containers for which the waiver or modification is requested.

(5) Documentation or justification to demonstrate that the applicable waiver or modification criteria in paragraph (g) of this section are satisfied.

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§ 165.47 What information must I report about my refillable containers?

You are not required to report to EPA with information about your refillable containers under the regulations in this subpart. You should refer to the reporting standards in part 159 of this chapter to determine if information on container failures or other incidents involving pesticide containers must be reported to EPA under FIFRA section 6(a)(2) (7 U.S.C. 136d(a)(2)).

§§ 165.48–165.59 [Reserved]

Subpart D—Standards for Repackaging Pesticide Products into Refillable Containers

§ 165.60 General provisions.

(a) *What is the purpose of the regulations in this subpart?* The regulations in this subpart establish requirements for repackaging some pesticide products into refillable containers for distribution or sale.

(b) *Do I have to comply with the regulations in this subpart?* You must comply with the regulations in this subpart if you are a registrant who distributes or sells a pesticide product in refillable containers, 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, or if you are a refiller of a pesticide product and you are not the registrant of the pesticide product. Each pesticide product that is subject to the regulations in this subpart as set out in § 165.63 and that is distributed or sold in a refillable container must be distributed or sold in compliance with the standards of these regulations.

(c) *When do I have to comply?* As of August 16, 2011, all pesticide products distributed or sold by you in refillable containers must be distributed or sold in compliance with these regulations.

§ 165.63 Scope of pesticide products included.

(a) *Are manufacturing use products subject to the regulations in this subpart?* No, the regulations in this subpart do not apply to manufacturing use products, as defined in § 158.153(h) of this chapter.

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(b) *Are plant-incorporated protectants subject to the regulations in this subpart?* No, the regulations in this subpart do not apply to plant-incorporated protectants, as defined in §174.3 of this chapter.

(c) *Which antimicrobial pesticide products are not subject to the regulations in this subpart?* The regulations in this subpart do not apply to a pesticide product if it satisfies all of the following conditions:

(1) The pesticide product meets one of the following two criteria:

(i) The pesticide product is an antimicrobial pesticide as defined in FIFRA section 2(mm); or

(ii) The pesticide product: (A) 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; and

(B) In the intended use is subject to a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act or a food additive regulation under section 409 of such Act.

(2) The labeling of the pesticide product includes directions for use on a site in at least one of the following antimicrobial product use categories: food handling/storage establishments premises and equipment; commercial, institutional, and industrial premises and equipment; residential and public access premises; medical premises and equipment; human drinking water systems; materials preservatives; industrial processes and water systems; antifouling coatings; wood preservatives; or swimming pools.

(3) The pesticide product is not a hazardous waste as set out in part 261 of this chapter when the pesticide product is intended to be disposed.

(4) EPA has not specifically determined that the pesticide product must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment according to the provisions of paragraph (e) of this section.

(d) *Which requirements must an antimicrobial swimming pool product comply*

with if it is not exempt from these regulations? (1) An antimicrobial swimming pool product that is not exempt by paragraph (a), (b), or (c) of this section must comply with all of the regulations in this subpart except for the following requirements:

Requirement	Requirement for registrants who distribute or sell directly in refillable containers	Requirement for refillers who are not registrants
Recordkeeping specific to each instance of repackaging	§ 165.65(i)(2)	§ 165.70(j)(2)
Container inspection: criteria regarding a serial number or other identifying code	§ 165.65(e)(3)	§ 165.70(f)(3)
Container inspection: criteria regarding one-way valve or tamper-evident device	§ 165.65(e)(4)	§ 165.70(f)(4)
Cleaning requirement: criteria regarding one-way valve or tamper-evident device	§ 165.65(f)(1)	§ 165.70(g)(1)
Cleaning if the one-way valve or tamper-evident device is not intact	§ 165.65(g)	§ 165.70(h)

(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 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. Alternatively, EPA may notify the applicant or registrant of its intent to make such a determination. 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