

Environmental Protection Agency

§ 165.63

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?* Any pesticide product repackaged into a refillable container and released for shipment by you after August 16, 2011 must be repackaged in compliance with the regulations of this subpart.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64227, Oct. 29, 2008]

§ 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.

(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(f)(2) | § 165.70(j)(2) |
| Container inspection: criteria regarding a serial number or other identifying code | § 165.65(e)(2) | § 165.70(f)(2) |
| Container inspection: criteria regarding one-way valve or tamper-evident device | § 165.65(e)(3) | § 165.70(f)(3) |
| 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 micro-biological 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 reason-

able 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.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64227, Oct. 29, 2008]

§ 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