

US Environmental Protection Agency Office of Pesticide Programs

Table 5: Requirements for RepackagingPesticide Products into RefillableContainers (40 CFR Part 165 Subpart D)

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Short Description	Reg Cite	Requirement		
SCOPE AND APPLICABILITY				
Who must comply?	165.60(b), 165.65(a), 165.67(a), 165.70(a)	Registrants who distribute or sell a pesticide product directly in refillable containers		
		 Registrants who distribute or sell a pesticide product to a refiller that is not part of its company 		
		• Refillers ¹ that are not registrants		
Which pesticides must comply?	165.63	Manufacturing use products, plant-incorporated protectants and certain antimicrobial products (see Table 2) are exempt.		
		All other products are subject to the refillable container requirements, although antimicrobial products used in swimming pools and closely related sites are subject to a reduced set of the requirements.		
Are there any other exceptions?	165.63(h)	The repackaging regulations do not apply to: (1) transport vehicles that hold pesticides in tanks that are integral parts of the vehicle; (2) refillable containers for gaseous pesticides; or (3) custom blending.		
COMPLIANCE DATE	E			
When is compliance required?	165.60(c)	Any pesticide product repackaged into a refillable container and released for shipment after August 16, 2011 must be in compliance with these requirements.		
CONDITIONS FOR R	REPACKAGING			
Conditions for repackaging by a refiller (that is not the registrant of the product)	165.67(b)&(c), 165.70(b)&(c)	A registrant may allow a refiller to repackage its pesticide into refillable containers and to sell or distribute that pesticide if all of these conditions are met:		
		• The repackaging results in no change in the pesticide formulation.		
		 One of the following conditions is met: (1) The pesticide is repackaged at a registered refilling establishment (per §167.20); or (2) The pesticide is repackaged by a registered refilling establishment (per §167.20) at the site of a user who intends to use or apply the product. 		
		• The registrant has entered into a written contract with the refiller to repackage the pesticide and to use the product's label.		
		• The pesticide is repackaged only into refillable containers that meet the standards in Subpart C.		
		• The pesticide is labeled and there are no changes to the label other than adding the appropriate net contents and the refiller's EPA establishment number.		

REGISTRANT RESPONSIBILITIES ²				
Pesticide integrity	165.65(b), 165.67(e)	Registrants are responsible for the integrity of pesticides repackaged into refillable containers. This applies when registrants conduct the refilling and when refillers operating under contract to the registrant conduct the refilling.		
Develop information: cleaning procedure	165.65(c)(1), 165.67(f)(1)	Registrants must develop a written residue removal procedure that describes how to clean refillable containers (portable and stationary) before they are refilled. The procedure must ensure the integrity of the pesticide sold or distributed in the refillable containers.		
Develop information: list of acceptable containers	165.65(c)(2), 165.67(f)(2)	• Registrants must develop a list of acceptable refillable containers (portable and stationary) that can be used to sell or distribute their pesticide.		
		• An acceptable container must meet the refillable container standards in Subpart C and must be compatible with the pesticide.		
		• Registrants must identify the containers by specifying the container materials of construction and information necessary to confirm compliance with the refillable container requirements.		
Recordkeeping	165.65(i)(1), 165.67(h)(2) &(3)	Registrants must keep the following records for the current operating year and for three years after that: (1) the residue removal procedure; and (2) the list of acceptable containers.		
Additional requirements for registrants who distribute or sell pesticides to refillers for repackaging	165.67(b), (d), (g) & (h)(1)	 The registrant must comply with the conditions for repackaging described above. 		
		• The registrant must provide the written contract to the refiller before selling or distributing pesticide to the refiller.		
		• The registrant must provide the residue removal procedure, list of acceptable containers and the pesticide's label before or at the time of distribution or sale of the pesticide to the refiller.		
		• The registrant must keep records of each written contract entered into with a refiller for the current operating year and for three years after that.		
REFILLER RESPO	NSIBILITIES ³			
Pesticide integrity	165.65(b), 165.70(d)	Refillers are responsible for the integrity of pesticides repackaged into refillable containers. This applies when registrants conduct the refilling and when refillers operating under contract to the registrant conduct the refilling.		
Registered establishment	165.65(d)(1), 165.70(e)(1)	The refiller's establishment must be registered with EPA as a producing establishment, as required by 40 CFR 167.20.		
No change to formulation	165.65(d)(2), 165.70(e)(2)	The refiller cannot change the pesticide formulation unless the refiller has a registration for the new formulation		
Acceptable containers	165.65(d)(3), 165.70(e)(3)	The pesticide must be repackaged into a refillable container that is identified on the list of acceptable containers.		

No quantity or size limits	165.65(d)(4), 165.70(e)(4)	• The refiller can repackage any quantity of pesticide into a refillable container, up to the rated capacity of the container.
		• There are no limits on the size of the refillable containers.
Items in possession	165.65(d)(5), 165.70(e)(5)	Before repackaging a pesticide, a refiller must have all of the following items for the pesticide: (1) the label and labeling; (2) the residue removal procedure; and (3) the list of acceptable containers.
Identify previous pesticide	165.65(d)(6), 165.70(e)(6)	A refiller must identify the pesticide previously contained in the container (by looking at the label) to determine if it is necessary to clean the container.
Inspection	165.65(d)(7)&(e), 165.70(e)(7)&(f)	A refiller must visually inspect the container before repackaging pesticide into it to determine whether the container meets the specified criteria ⁴ with respect to continued container integrity, required markings and openings.
Cleaning	165.65(d)(8), (f) & (g) 165.70(e)(8), (g) & (h)	A refiller must clean a refillable container according to the residue removal procedure unless each tamper-evident device and one-way valve (if required) is intact and either of these conditions is met:
		 The refillable container is being refilled with the same pesticide product; or
		• The container previously held a pesticide with a single active ingredient, the container is being used to repackage a pesticide with the same single active ingredient, and there is change that causes the repackaged pesticide to not meet the product integrity standard.
		If a tamper-evident device or one-way valve is not intact, the refiller must clean the container using the residue removal procedure of the product being repackaged. In addition, other procedures may be necessary to assure that the product's integrity is maintained.
		Note: Antimicrobial products used in swimming pools and closely related sites are not required to comply with the one-way valve/tamper-evident device requirements.
Labeling	165.65(d)(9)&(h), 165.70(e)(9)&(i)	A refiller must ensure that the pesticide's label is securely attached to the refillable container. The label and labeling must comply with 40 CFR Part 156 and, in particular, the refiller must ensure that the net contents and EPA establishment number appear on the label.
Recordkeeping - for each pesticide	165.65(d)(10) & (i)(1) 165.70(e)(10) & (j)(1)	A refiller must keep the following records for the current operating year and for three years after that: (1) the residue removal procedure; and (2) the list of acceptable containers.
Recordkeeping - refilling containers	165.65(d)(10) & (i)(2) 165.70(e)(10) & (j)(2)	• Each time a pesticide is repackaged, a refiller must generate the following records and keep them for three years after the date of repackaging: (1) the EPA registration number of the pesticide; (2) the date of repackaging; and (3) the serial number or other identifying code of the container.
		 Refillers of antimicrobial products used in swimming pools and closely related sites are not required to comply with this recordkeeping requirement.

Other requirements	165.65(d)(11) &(12)	• The refiller must maintain records as required by 40 CFR Part 169 (Books and Records of Pesticide Production and Distribution).
	165.70(e)(11) &(12)	 The refiller must report as required by 40 CFR Part 167 (Registration of Pesticide and Active Ingredient Producing Establishments; Submission of Pesticide Reports).
Additional requirements for refillers that are not registrants	165.70(b), (e)(5)(i), (e)(13), (e)(14) & (j)(1)(i)	 The refiller must comply with the conditions for repackaging described above.
		 Before repackaging a pesticide, a refiller must have the written contract from the pesticide's registrant.
		 The stationary pesticide containers at a refiller's establishment must meet the applicable requirements in the refillable container regulations (§165.45(f)).
		 Refillers may be required to comply with the containment standards in Subpart E.
		• The refiller must keep records of the written contract from the registrant for the current operating year and for three years after that.

Notes

1. Refiller is defined in the final regulations as a person who engages in the activity of repackaging pesticide product into refillable containers. This could include a registrant or a person operating under contract to a registrant.

2. The repackaging requirements in the regulations are split into three different sections, one for each of the three groups identified in the applicability section: (A) registrants who distribute or sell a pesticide product directly in refillable containers; (B) registrants who distribute or sell a pesticide product to a refiller that is not part of its company; and (C) refillers that are not registrants. The requirements listed in the registrant section of the table apply to registrants in both of the first two categories, unless otherwise specified.

3. The repackaging requirements in the regulations are split into three different sections, one for each of the three groups identified in the applicability section: (A) registrants who distribute or sell a pesticide product in refillable containers; (B) registrants who distribute or sell a pesticide product to a refiller that is not part of its company; and (C) refillers that are not registrants. The requirements listed in the refiller section of the table apply to all refillers – registrants who distribute or sell a pesticide product directly in refillable containers and refillers that are not registrants – unless otherwise specified.

4. The container fails the inspection and cannot be refilled unless it is repaired, reconditioned or remanufactured if the integrity of the container is compromised in at least one of the following ways:

- The container shows signs of rupture or other damage which reduces its structural integrity;
- The container has visible pitting, significant reduction in material thickness, metal fatigue, damaged threads or closures, or other significant defects;
- The container has cracks, warpage, corrosion or any other damage which might render it unsafe for transportation; or
- There is damage to the fittings, valves, tamper-evident devices or other appurtenances that may cause failure of the container.

The container fails the inspection and cannot be refilled until the container meets the refillable container standards in Subpart C if either or both of the following conditions exist:

- The container does not bear the required markings or the markings are not legible; or
- 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.

Note: Antimicrobial products used in swimming pools and closely related sites are not required to comply with the serial number marking or the one-way valve/tamper-evident device requirements. However, refillable containers holding these products must comply with any applicable DOT marking requirements.