EPA’s Refillable Container Requirements

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Outline

- Background on container-containment rule
- Which containers have to comply?
- New requirements in 2011 - standards for:
  - Portable refillable containers (minibulks/shuttles)
  - Labels
  - Repackaging
  - Stationary Bulk Tanks
- Review/Resources
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# Container-Containment Rule Overview

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Goals of the New Regulations

- Ensure the **integrity/strength** of refillable containers
- Minimize the potential for **cross contamination**
- Ensure that containers and repackaging **comply** with federal pesticide law (**FIFRA**)
- **Encourage** the use of refillable containers
What is the difference between nonrefillable & refillable containers?

- **Nonrefillable container:** designed & constructed for one-time use and not intended to be filled again with a pesticide for sale or distribution.

- **Refillable container:** intended to be filled with pesticide more than once for sale or distribution.

§165.3. A nonrefillable container will have a label that says: “Nonrefillable container. Do not reuse or refill this container.” **These containers cannot legally be reused or refilled!**
1. Which Containers Must Comply?

- Pesticide containers & facilities must comply with these regulations if the containers are used to **SELL or DISTRIBUTION** a pesticide. Ex:

  - **REFILLER** fills container
  - delivers container
  - **GROWER**, who applies pesticide

  - **GROWER**, who brings container
  - **REFILLER** fills container
  - **GROWER**, who takes to farm & applies pesticide

**Doesn’t matter who owns the container.**
1. Which Containers?

- A container does not have to comply with these regs if it is a **service container**.

  - If an applicator transfers a pesticide into a container for the purposes of **that applicator applying** the pesticide, the container is considered to be a service container. (71 FR 47383, August 16, 2006)

- EPA does not currently regulate service containers; good management practice to identify contents & label is available to the applicator.

  - **SERVICE CONTAINER**, product name, EPA Registration Number, active ingredient, signal word
1. Which Containers?

Service container examples:

- COMMERCIAL APPLICATOR fills container
- takes to field
- COMMERCIAL APPLICATOR applies pesticide

- REFILLER fills container
- delivers container
- GROWER transfers pesticide to different container
- GROWER takes to field & applies pesticide

| ---- sale/distribution ---- | | ---- service container ---- |
2. New Requirements in 2011

If you repackage pesticides under contract/agreement with a registrant, you must comply with the following requirements when you repackage a pesticide (& release it for shipment) after **August 16, 2011**:

1. Standards for portable refillable containers;
2. Use a compliant label;
3. Operational and recordkeeping requirements regarding repackaging; and
4. Standards for stationary bulk tanks.
3. Portable Refillable Containers

You must repackage into portable refillable containers that meet these six standards:

- Are on the registrant’s description of acceptable containers;
- Comply with at least DOT Packing Group III standards that EPA adopted;
- Are durably marked with a serial number/identifying code;

[§165.45(a)-(e); §165.70(e)(3)]
3. Portable Refillable Containers

You must repackage into portable refillable containers that meet these six standards:

- Have a tamper-evident device or a one-way valve or both on each opening other than a vent; and
- Are sound (good condition).
- Are properly labeled.

[§165.45(e); §165.70(f) & (i)]
3.A. Description of Acceptable Containers

- Registrant must provide refiller with a description of acceptable containers for each pesticide and refiller must have this.

- Acceptable container: meets the EPA standards and is compatible with the pesticide.

- Registrant must specify:
  - Compatible materials
  - Info necessary to confirm compliance.
3.A. Description of Acceptable Containers Examples

- **Specific container types:**
  - 150 gallon capacity.
  - Company-identified tamper evident 3” one-way dip-tube valve, either a 5” tamper evident closure or 3” tamper evident fill valve, and tamper evident vent.

- **Performance standards:**
  - Meet at least DOT Packaging Group III specifications;
  - Equipped with tamper evident seal, one-way valve or both;
  - Have a capacity of one gallon or greater;
  - Have a serial number;
  - Constructed of approved materials of construction specified for the pesticide in the repackaging contract.
3.B. DOT Requirements

- Portable refillable containers must meet the DOT standards that EPA adopted at the packing group III level (at least).

- §165.45(a): A pesticide product that does not meet the definition of a hazardous material in 49 CFR 171.8 must be packaged in a refillable container that, if portable, is designed, constructed, and marked to comply with the requirements of 49 CFR 173.4, 173.5, 173.6, 173.24, 173.24a, 173.24b, 173.28, 173.155, 173.203, 173.213, 173.240(c), 173.24(d), 173.241(c), 173.241(d), Part 178 and Part 180 that are applicable to a Packing Group III material...

- §165.45(b): If it is a DOT hazardous material, must comply with applicable DOT requirements.
3.B. DOT Requirements

- Portable refillable containers must meet DOT standards that EPA adopted at the packing group III level (at least). [§165.45(a) & (b)]

- Generally, can determine this by the UN/DOT marking, such as: un 31HA2/Y/12/06/USA/...

- Important: look for UN symbol and X, Y or Z
  - X = meets packing group (PG) I & II & III stds (most stringent)
  - Y = meets PG II & III stds
  - Z = meets PG III stds
3.B. DOT Requirements
3.B. DOT Requirements

- The DOT standards that are incorporated in §165.45(a) authorize use of “non-DOT Specification portable tanks suitable for transport of liquids” that do not require the UN marking.
Question 1

Why can Monsanto’s 120-, 150- and 250-gallon Shuttle containers and 265-gallon CUBE containers be used under EPA’s pesticide container regulations even though they do not have the UN/DOT marking?

Answer:

- Because they are “non-DOT Specification portable tanks suitable for the transport of liquids” and
- The DOT regulations in 49 CFR 173.241(c), which are incorporated into EPA’s pesticide container regulations, authorize the use of “non-DOT Specification portable tanks suitable for the transport of liquids.”
Monsanto has **not** received a specific exemption or waiver from EPA for its Shuttles & CUBEs (> 119 gallons).

Monsanto’s Shuttles & CUBEs (> 119 gallons) must comply with the other *regulations for portable refillable containers*:
- Included on registrant’s description of acceptable containers
- Durably marked with a serial number/identifier, be sound, be properly labeled
- One-way valve or tamper-evident device on openings.

Retailers & distributors that refill Shuttles & CUBEs (> 119 gallons) with Monsanto pesticides must follow all of the requirements in the *repackaging regulations*. 
3.B. DOT Requirements

- The DOT standards that are incorporated also include **ongoing maintenance and testing** (e.g., leakproofness test).

- **For containers > 119 gallons & have UN/DOT marking** (called intermediate bulk containers or IBCs by DOT):
  - Leakproofness test every 2.5 years after date of manufacture
  - External DOT inspection: every 2.5 years after date of manufacture
  - Internal DOT inspection: at least every 5 years
3.B. DOT Requirements

Ongoing maintenance and testing

- **For containers \(\leq 119\) gallons** (must have UN/DOT marking – called nonbulk packagings by DOT):
  - External DOT inspection: before each reuse by 49 CFR 173.28(b).
  - Leakproofness test *before each reuse* if pesticide is DOT hazardous material (173.28(b)(2)).
    - If pesticide is not a DOT hazmat, EPA regulations (165.45(a)(2)) exempt refiller & container from leakproofness test requirement if container complies with EPA’s standards & refiller complies with repackaging requirements.
  - No internal DOT inspection required
Question 2

Do Monsanto’s 120-, 150- and 250-gallon Shuttle containers and 265-gallon CUBE containers need to be leakproofness tested every 2.5 years? Do they need to pass the DOT external inspection every 2.5 years or the DOT internal inspection every 5 years?

Answer:

No, Monsanto’s Shuttle & CUBE containers (> 119 gallons) do not need to be leakproofness tested or DOT inspected according to the requirements in 49 CFR 180.352, which are incorporated into EPA’s refillable container regulations.
Monsanto’s Shuttle & CUBEs (>119 gallons) are “non DOT-Specification tanks” rather than intermediate bulk containers (IBCs).

The requirements for retest & inspection of IBCs in 49 CFR 180.352 only apply to IBCs “constructed in accordance with a UN standard.”

There are no EPA-specific requirements for leakproofness testing. However, EPA’s repackaging regulations require all refillable pesticide containers to be inspected each time before they are refilled. (40 CFR 165.65(e) & 165.70(f))

Monsanto is considering a revision to their repackaging contracts to require refillers to conduct a periodic performance test of some type on the Shuttles & CUBEs (> 119 gallons).
3.C. Serial Number/Identifying Mark

Each refillable container must be durably marked with a serial number or other identifying code. [§165.45(d)]

Durable marking includes an adhesive label if it’s securely attached = can reasonably be expected to remain affixed during the foreseeable conditions and period of use. [§156.10(a)(4)]
3.D. Tamper-Evident Device/One-Way Valve

- For portable refillable containers holding liquid pesticides, each opening other than a vent must have a one-way valve OR a tamper-evident device OR both.

- A vent must be designed to minimize the amount of material that could be introduced into the container through it. 
  
  [§165.45(d)]
3.D. Tamper-Evident Device/One-Way Valve

- The valve at the bottom of this minibulk is **not** a one-way valve. The end user has to break the tamper-evident device to remove pesticide from the minibulk through this valve.

- This minibulk **complies with the refillable container regs**; it has a tamper-evident device.

- However, when the minibulk is returned, **the refiller must clean the minibulk**, even if he is refilling it with the same pesticide product. [See §165.70(g) & (h).]
3.E. Container must be sound.

- The container must **pass a visual inspection before each refill.** Look for:
  - Are there signs of rupture, cracks, damage, etc. that might render it unsafe for transportation?
  - Are the markings (container identifier & any DOT marking) there and legible?
  - Is there an intact & functioning one-way valve or tamper-evident device on each opening other than a vent?

[§165.70(f)]
3.F. Properly Labeled

- Refiller must ensure that the label of the pesticide is securely attached (reasonably be expected to remain affixed during the foreseeable conditions & period of use) and comply with all label requirements, including:
  - Net contents
  - Refiller’s EPA Est. No.
  - New label statements.

[§165.70(i)]
3.F. EPA Requirements: New Label
Instructions for Refillable Containers

- “Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose.”

- “Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.”

- Cleaning instructions (for final disposal) – required for all pesticides, not just dilutable ones.

*** These are examples of allowable statements; variations allowed. ***
3.F. Pesticide Labels (General)

- Pesticide labels and enforcement
  - “Label is the law” principle
  - If the label is incorrect, the pesticide is misbranded.
  - If the user does not follow the label, it is a misuse violation.

- EPA pesticide label policies & regulations
  - Label Review Manual (LRM)
  - http://www.epa.gov/oppfead1/labeling/lrm/
3.F. Other Info on Containers

- Some labels submitted to EPA have info devoted to non-FIFRA issues, e.g., DOT shipping requirements, New York City fire code symbols, National Fire Protection Association or other hazard codes & rating systems, bar codes, etc.

- A registrant may choose to place such text on the label but may not replace, obscure, conflict with or supersede the FIFRA required text. (LRM Chapter 3.V)
3.F. Other Info on Containers

- A registrant may choose to place such text on the label but **may not** conflict with the FIFRA required text. (LRM Chapter 3.V)

- **EPA Signal Words:** DANGER, WARNING, CAUTION (§156.64)
  - Other stickers cannot conflict with these words.
3.F. Other Info on Containers

- **Label**: the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers. (FIFRA §2(p))

- Acceptable & not part of EPA’s label review (LRM Chapter 16):
  - “Good Housekeeping Seal of Approval”
  - DOT symbols
  - Bar codes.

- Current policy: everything else is part of EPA’s label review.
New Requirements in 2011

1. Standards for portable refillable containers;
2. Use a compliant label;
3. **Operational and recordkeeping requirements regarding repackaging**; and
4. Standards for stationary bulk tanks;
4. Repackaging Requirements

- Conditions for repackaging under a registrant’s existing registration [§165.70(b)]
- Registrants develop and provide certain information to each refiller: [§165.67(d), (f) & (g)]
  - Written contract
  - Refilling residue removal procedure
  - Description of acceptable containers
- Requirements for independent (non-registrant) refillers [§165.70(e)]
4. Refiller Requirements

An independent refiller must comply with all of the requirements in §165.70(e):

1. Register the establishment per §167.20;
2. Not change the formulation; and
3. Have the following items at the facility before repackaging:
   - Contract + label/labeling
   - Registrant’s cleaning procedure and description of acceptable containers.

4. Can repack any quantity; no container size limits.
   - Stationary containers must meet certain standards.
   - You may be required to comply with the federal containment standards.

(continued on next page)
4. Refiller Requirements

These requirements apply each time a container is refilled. The refiller must:

5. Repackage only into a refillable container on registrant’s description of acceptable containers;

6. Identify the pesticide previously in the container;

7. Visually inspect the container;

8. Clean the container if necessary
   - Must be cleaned between uses unless all tamper-evident devices and one-way valves are intact and filled with the same or a very similar product;

9. Ensure the container is properly labeled; and

10. Record the date, serial number/code of the container; & pesticide.

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4. Refiller Requirements

The following recordkeeping and reporting requirements apply. The refiller must:

11. Maintain records of the information from the registrant for the current operating year and for 3 years after:
   - Contract
   - Cleaning procedure
   - Description of acceptable containers.

12. Maintain records of repackaging (date, container identifier & pesticide) for 3 years; and

New Requirements in 2011

1. Operational and recordkeeping requirements regarding repackaging
2. Standards for portable refillable containers;
3. Use a compliant label; and
4. Standards for stationary bulk tanks.
5. Standards for Stationary Tanks

Stationary tanks (used to sell or distribute pesticide, e.g., at a refiller’s or end user’s site) must be:

- Included on description of acceptable containers;
- Durably marked with a serial number/identifying code;
- Sound (pass visual inspection);
- Properly labeled;…

[§165.45(d), §165.70(f) & (i)]
5. Standards for Stationary Tanks

Stationary tanks (capacity of 500 gallons or more & at the facility of a refiller operating under contract with a registrant) must:

- Meet integrity/strength standards;
- Have a vent;
- Have a shut-off valve on any connection below the normal liquid level; and
- Not have an external sight gauge.

[§165.45(d) & (f)]
Review/Resources
Key New Requirements for Refillers

- Repackage only into compliant refillable containers. For **portable** containers, this means the container:
  - Is on the registrant’s description of acceptable containers;
  - Is DOT compliant;
  - Is marked with a serial number/identifying code;
  - Has tamper-evident devices and/or one-way valves;
  - Is sound and properly labeled.

- Clean container between uses unless all tamper-evident devices & one-way valves are intact and you are refilling with the same or a very similar product.

- Get the cleaning procedure & description of acceptable containers from the registrant for each product.

- For each refill, record the date, serial number/code of container; and pesticide.
For More Information

Environmental Protection Agency (EPA)
- http://www.epa.gov/pesticides/regulating/containers.htm
- Nancy Fitz, 703-305-7385; fitz.nancy@epa.gov

American Agronomic Stewardship Alliance (AASA)
- http://www.aginspect.org/USEPA.html

CropLife America (CLA)

Mid America CropLife Association (MACA)
- http://www.maca.org/edu

Pesticide Stewardship: See Container Handling for inspection video
- http://pesticidestewardship.org/Pages/default.aspx

State Inspector Training
- http://pirt.pested.psu.edu/resources
Questions?

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Appendix
Frequently Asked Questions
FAQs: August 16, 2011 Deadline

■ **Question 1:** If a retailer filled a minibulk container on August 1, 2011, does it have to comply with the regulations?

■ **Answer:** It depends. The regs apply to pesticides that are **released for shipment** after 8/16/11. “Released for shipment” basically means the producer has **packaged & labeled** the pesticide in the manner in which it will be distributed or sold.

■ On 8/1/11, the retailer filled a minibulk, labeled it, closed it and it is in the condition that it will be shipped. The container & label do not have to comply with the new regs. (Good to document the date.)

■ On 8/17/11, a retailer filled, labeled and closed a minibulk. This must be done in compliance with the refillable container & repackaging regs and the label must have the new statements.
FAQs: August 16, 2011 Deadline

- **Question 2**: Is it a problem if a retailer has old, non-compliant minibulk containers in a storage area after 8/16/11?

- **Answer**: They are a temptation, not a violation!
  - It is not illegal to have old, non-compliant containers sitting in a storage area.
  - It is only a violation if the retailer fills those containers and uses them to sell or distribute a pesticide after 8/16/11.
FAQs: Which containers?

- **Question 3:** If a farmer owns a minibulk, does it have to comply?

- **Answer:** Yes. It doesn’t matter who owns the tank. If the minibulk is being used to sell or distribute a pesticide, it must comply with all relevant requirements.
FAQs: Other

Question 4: Can a retailer fill a refillable container on a farm and, if so, what are the applicable regs?

Answer: Yes, a retailer can fill a refillable container on a farm as long as all of the conditions for repackaging (slide 33) are met and:

- Containers must be properly labeled;
- Portable refillable containers must meet all six standards (slides 10 & 11); and
- Stationary refillable containers must be: on description of acceptable containers; durably marked with a serial number; sound and properly labeled (slide 38).

Federal regs do not require containment at farms; state regulations might.
FAQs: Which containers?

**Question 5:** Do minibulks that retailers use for their own application purposes have to comply?

**Answer:** No, service containers are not subject to the container regulations.

- If an applicator transfers a pesticide into a container for the purposes of that applicator applying the pesticide, the container is considered to be a service container. (71 FR 47383, August 16, 2006)
- EPA does not currently regulate service containers; good management practice to identify contents.
6. Can I use a tank that doesn’t have the DOT marking?

- **Answer**: It depends on the registrant’s description of acceptable containers.

- The DOT standards that are incorporated in §165.45(a) authorize the use of some “non-specification portable tanks” that do not require the UN marking.

- Registrant’s responsibility: ensure that containers on the description of acceptable containers meets the refillable container requirements.
6. Can I use this tank that doesn’t have the DOT marking?

- Yes, if description of acceptable containers includes:
  - 150 gallon capacity.
  - Company-identified tamper evident 3” one-way dip-tube valve, either a 5” tamper evident closure or 3” tamper evident fill valve, and tamper evident vent.

- No, if description of acceptable containers includes:
  - Meet at least DOT Packaging Group III specifications;
  - Equipped with tamper evident seal, one-way valve or both;
  - Contain a capacity of one gallon or greater;
  - Contain a serial number;
  - Constructed of approved materials of construction specified for the pesticide in the repackaging contract.
FAQs: DOT

**Question 7:** Can a retailer conduct the leakproofness test on a minibulk container?

- **Answer:** Yes, a retailer (or anyone) can conduct the leakproofness test & DOT inspections if he/she:
  - Follows the procedures in DOT regs;
  - Marks the container;
  - Keeps records; and
  - Is DOT-haz mat trained. [49 CFR 172.704 & 173.1]