

EPA's Refillable Container and Repackaging Requirements

North Central C&T Workshop

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August 16, 2012

Outline

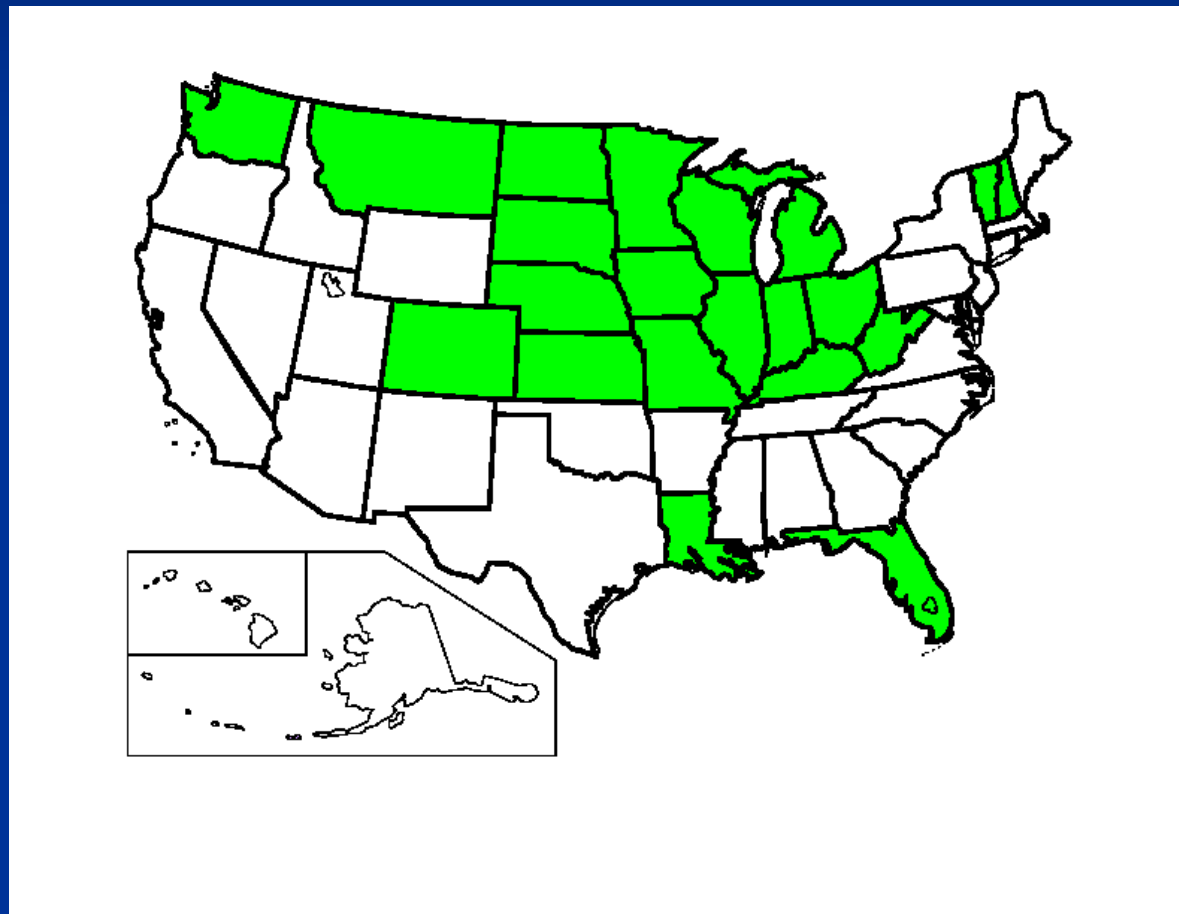
- Background on container-containment rule
- Portable refillable containers (minibulks/shuttles)
 - Which containers have to comply?
 - What are the container requirements?
 - What are the label requirements?
- Repackaging requirements
- Stationary bulk tanks
- Resources

Container-Containment Rule Overview

Category	Nonrefillable Containers	Refillable Containers	Repackaging Products	Container Labeling	Containment Structures
Who must comply?	Registrants	Registrants	Registrants Refillers	Registrants Users	Ag retailers Ag commercial applicators Ag custom blenders
Major Requirements	<ul style="list-style-type: none"> - DOT container design, construction & marking standards - Dispensing capability - Standard closures - Residue removal (99.99% removal) 	<ul style="list-style-type: none"> - DOT container design, construction & marking standards - One-way valves or tamper-evident devices - Vent, gauge & shutoff valve standards for large tanks 	<ul style="list-style-type: none"> - Registrants & refillers comply with specified conditions - Registrants develop & provide certain information - Refillers obtain & follow information; and clean, inspect & label containers before refilling them 	<ul style="list-style-type: none"> - Identify container as nonrefillable or refillable (<i>all</i>) - Statement to prohibit reuse and offer for recycling; batch code (<i>all nonrefillables</i>) - Cleaning instructions (<i>some nonrefillables</i>) - Cleaning instructions before disposal (<i>all refillables</i>) 	<ul style="list-style-type: none"> - Secondary containment structures (dikes) around large tanks - Containment pads for pesticide dispensing areas - Good operating procedures - Monthly inspections of tanks & structures
Compliance Date	Aug 17, 2009	Aug 17, 2011	Aug 17, 2011	Aug 17, 2011	Aug 17, 2009

States with Pesticide Containment Regs

CO MT
FL NE
IL NH
IN ND
IA OH
KS SD
KY VT
LA WA
MI WV
MN WI
MO



States with Pesticide Containment Regulations

- OPP determined that all 21 of these State programs are adequate to provided equivalent environmental protection to the federal containment regulations.
- EPA authorized these 21 States to continue implementing the state pesticide containment regulations in lieu of the federal containment regulations.
- Federal container regs apply in all States!

Portable Refillable Containers



Goals of the Refillable Container & Repackaging 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

Summary: Portable Refillable Containers

A portable refillable container must:

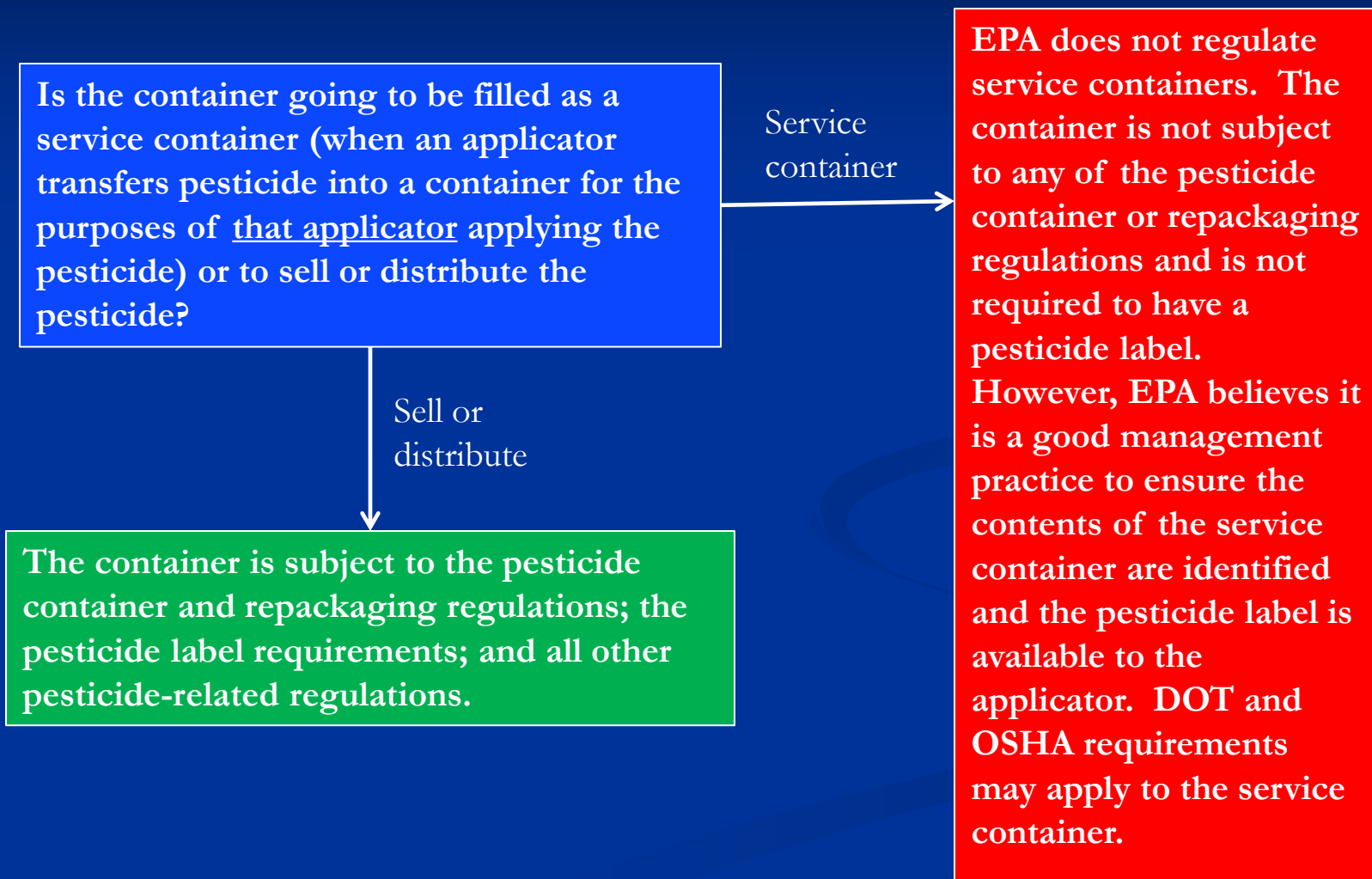
- Be on the registrant's description of acceptable containers;
- Comply with the DOT standards that EPA adopted (generally Packing Group III);
- Be durably marked with a serial number/identifying code;
- Have a tamper-evident device or a one-way valve or both on each opening other than a vent; and
- Be sound (in good condition).
- Be cleaned (if necessary) before it is refilled.
- Be properly labeled.

[§165.45(e); §165.70(f) & (i)]

Which containers have to comply?

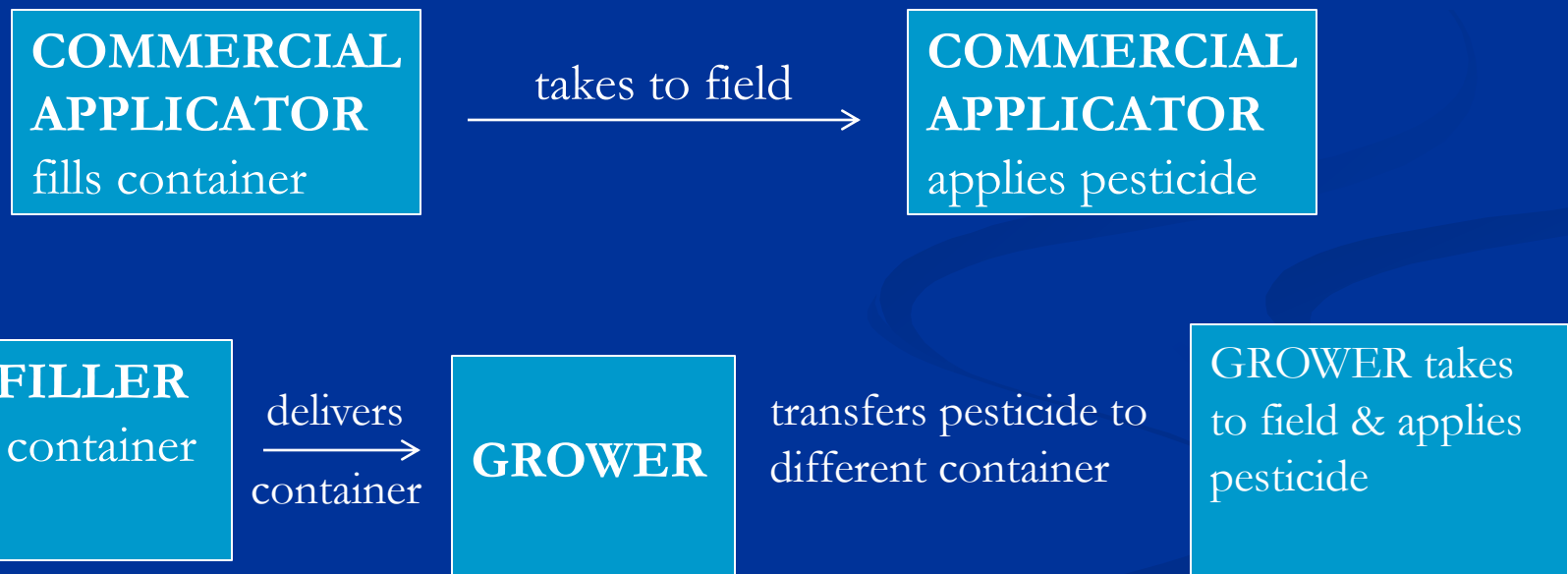
- Portable refillable containers used to **sell or distribute pesticides** have to comply with the regulations.
- **Service containers** do not have to comply.

Flow Chart 1: Is this container a service container or a portable refillable container?



Service Containers

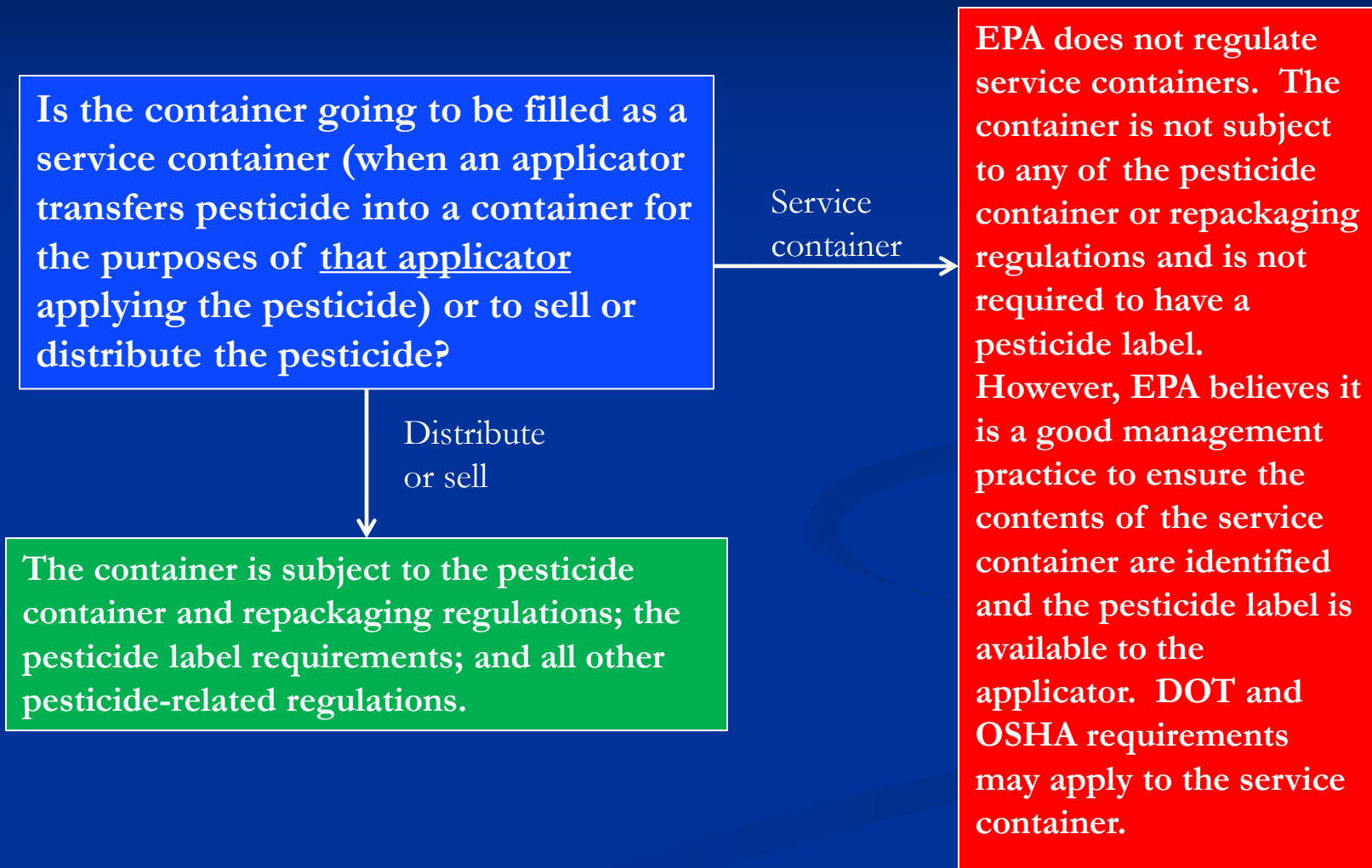
- Service container: when an applicator transfers pesticide into a container for purpose of that applicator applying the pesticide



| ---- sale/distribution ---- |

| ---- service container ---- |

Flow Chart 1: Is this container a service container or a portable refillable container?



Distribute or Sell

- Distribute or sell: distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and deliver or offer to deliver.



****Doesn't matter who owns the container or where the transfer takes place.****

Distribute or Sell



The refillable container & repackaging regs 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.



← Exempt

Distribute or Sell

- These are portable refillable containers used to sell or distribute pesticides (not exempt).



Not an integral part of the vehicle.



Not a vehicle.

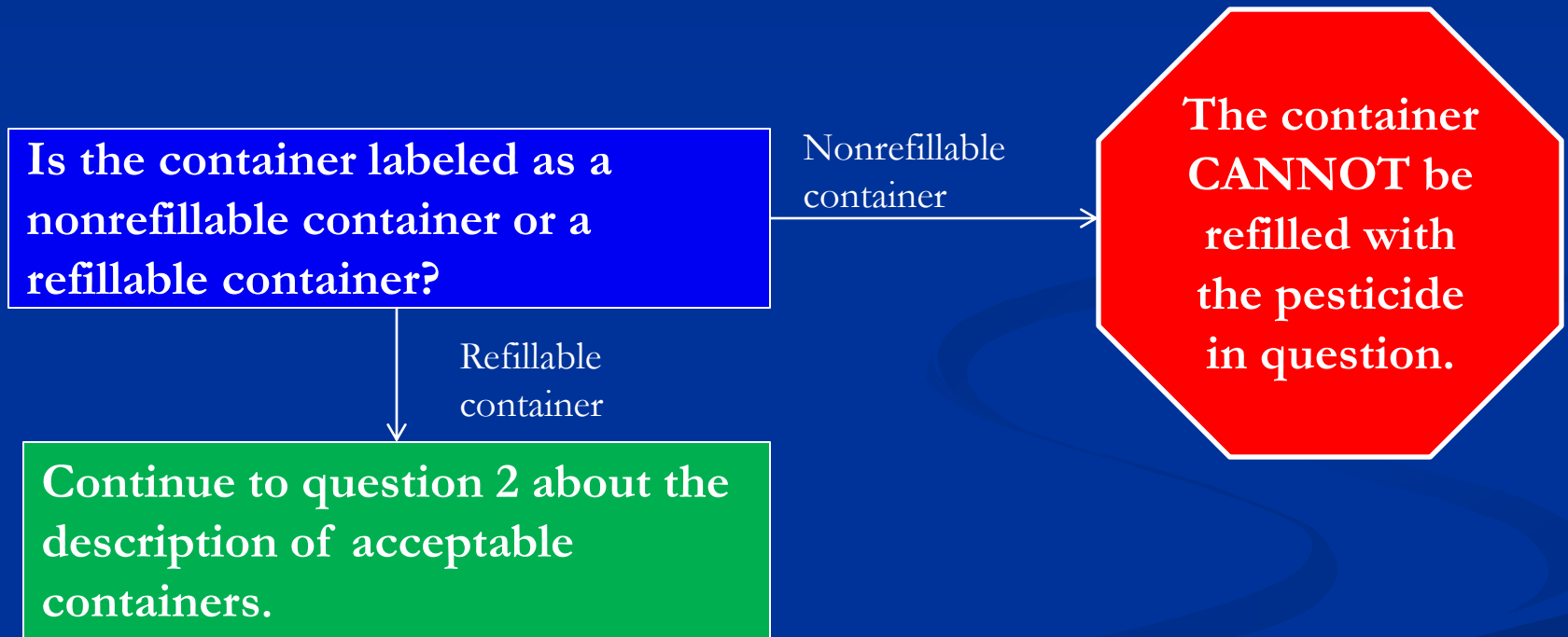


Flow Chart 2

- Can I fill this large portable refillable container?
(Large: greater than 119 gallons)



Question 1: Is the container labeled as a nonrefillable container or a refillable container?



Nonrefillable vs. Refillable Containers

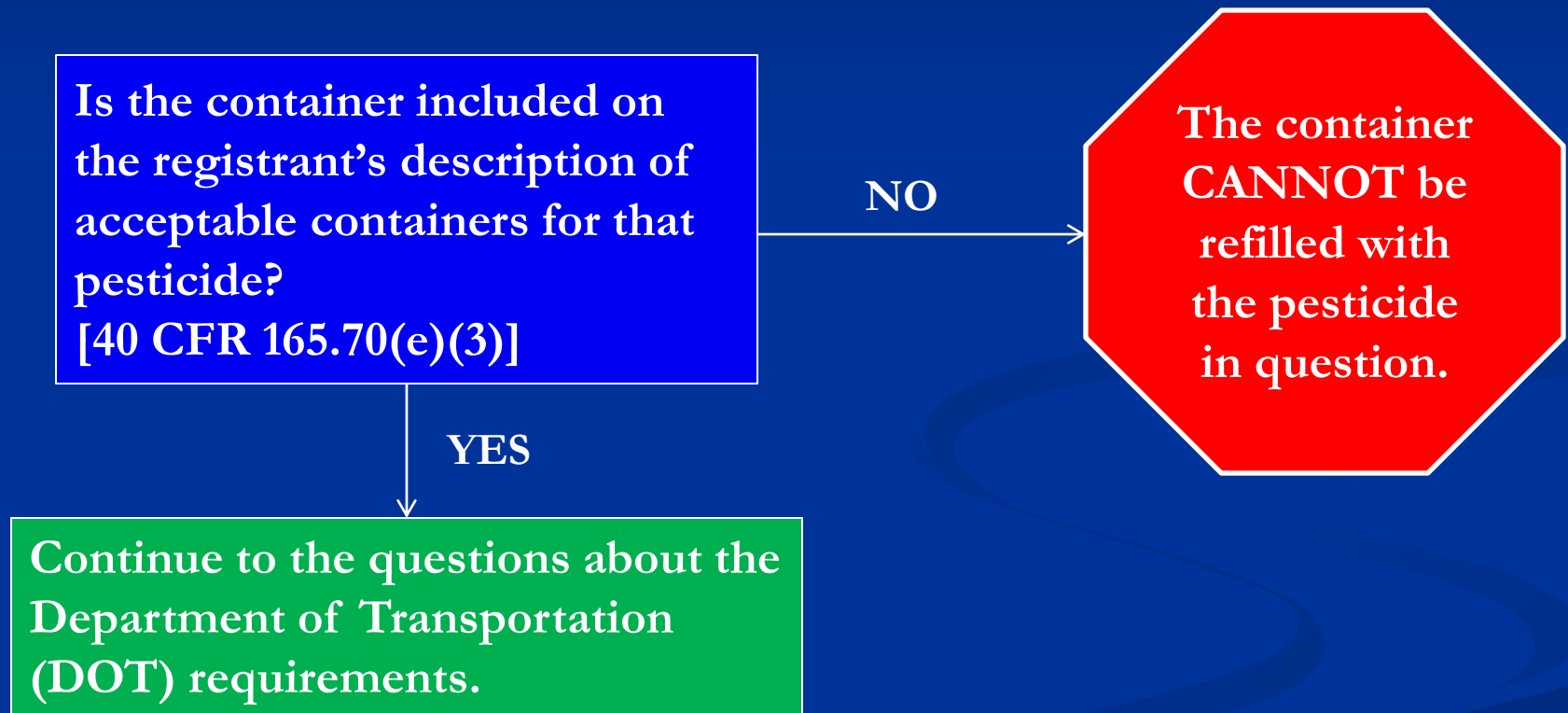
- **Nonrefillable container:** designed & constructed for one-time use and not intended to be filled again with a pesticide for sale or distribution.
- **Refillable container:** intended to be filled with pesticide more than once for sale or distribution.

[§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!**

Question 2: Is the container on the registrant's description of acceptable containers for that pesticide?



Description of Acceptable Containers

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

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

4. What DOT requirements apply?




- **Portable refillable containers must meet the DOT standards that EPA adopted at the packing group III level (at least).**
- §165.45(b): If the pesticide is a DOT hazardous material, the container must comply with applicable DOT requirements.

4. What DOT requirements apply?

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

DOT Requirements

The DOT marking, testing and inspection requirements vary based on the size of the container and how it is described on the description of acceptable containers.

Container size	Larger than 119 gallons	Larger than 119 gallons	119 gallons or less
Description of acceptable containers	The container is identified either by performance standards that include meeting the DOT Packing Group (PG) III standards (at least) or by a specific container design (e.g., using photos) that meets the DOT PG III standards (at least).	The container is identified by a specific container design (e.g., using photos) that is not marked with the UN symbol or DOT marking .	The container is identified either by performance standards that include meeting the DOT Packing Group (PG) III standards (at least) or by a specific container design (e.g., using photos) that meets the DOT PG III standards (at least).
Container classification under DOT	Intermediate bulk container (IBC) (Flow Chart 2, left side of page 1)	Non-DOT Specification portable tank (Flow Chart 2, right side of page 1)	Non-bulk container (Flow Chart 3)
Example containers			

DOT Pathway 1: IBCs

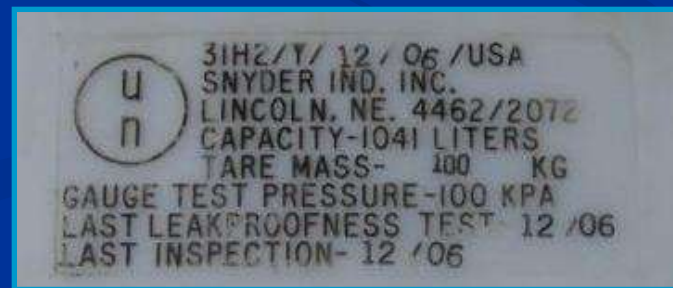
Question 4-1(a): For IBCs, what DOT marking is required?

- You can determine whether an IBC meets at least the Packing Group III requirements by looking at the DOT marking.
- 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



DOT Pathway 1: IBCs

- **Question 4-1(b & c) For IBCs, what DOT testing and DOT inspections are required?**
- 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
- Mark date (month & year) on container
- Keep records



DOT Pathway 2: Non-DOT Specification Portable Tanks

- 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.



DOT Pathway 2: Non-DOT Specification Portable Tanks

- **Question 4-2(a): 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.”

Question 4-2(a), continued

- 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**.

DOT Pathway 2: Non-DOT Specification Portable Tanks

- **Question 4-2(b & c): Do non-DOT Specification portable tanks such as Monsanto's Shuttle containers and 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, non-DOT Specification portable tanks such as Monsanto's Shuttle & CUBE containers 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.

Question 4-2(b & c), continued

- Monsanto's Shuttle & CUBE (>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).

Question 5: Is the container durably marked with a serial number or other identifying code?

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)]



Question 6: Does the container pass the EPA inspection each time before it is refilled?

- 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)]

Question 7: Are vents designed to minimize the amount of material that could be introduced into the container through it?



Question 8: Does each opening other than a vent have a one-way valve OR a tamper-evident device OR both?



Tamper-Evident Devices and One-Way Valves

- **One-way valve** means a valve that is designed and constructed to allow virtually unrestricted flow in one direction and no flow in the opposite direction, thus allowing the withdrawal of material from, but not the introduction of material into, a container.
- **Tamper-evident device** means a device which can be visually inspected to determine if a container has been opened.

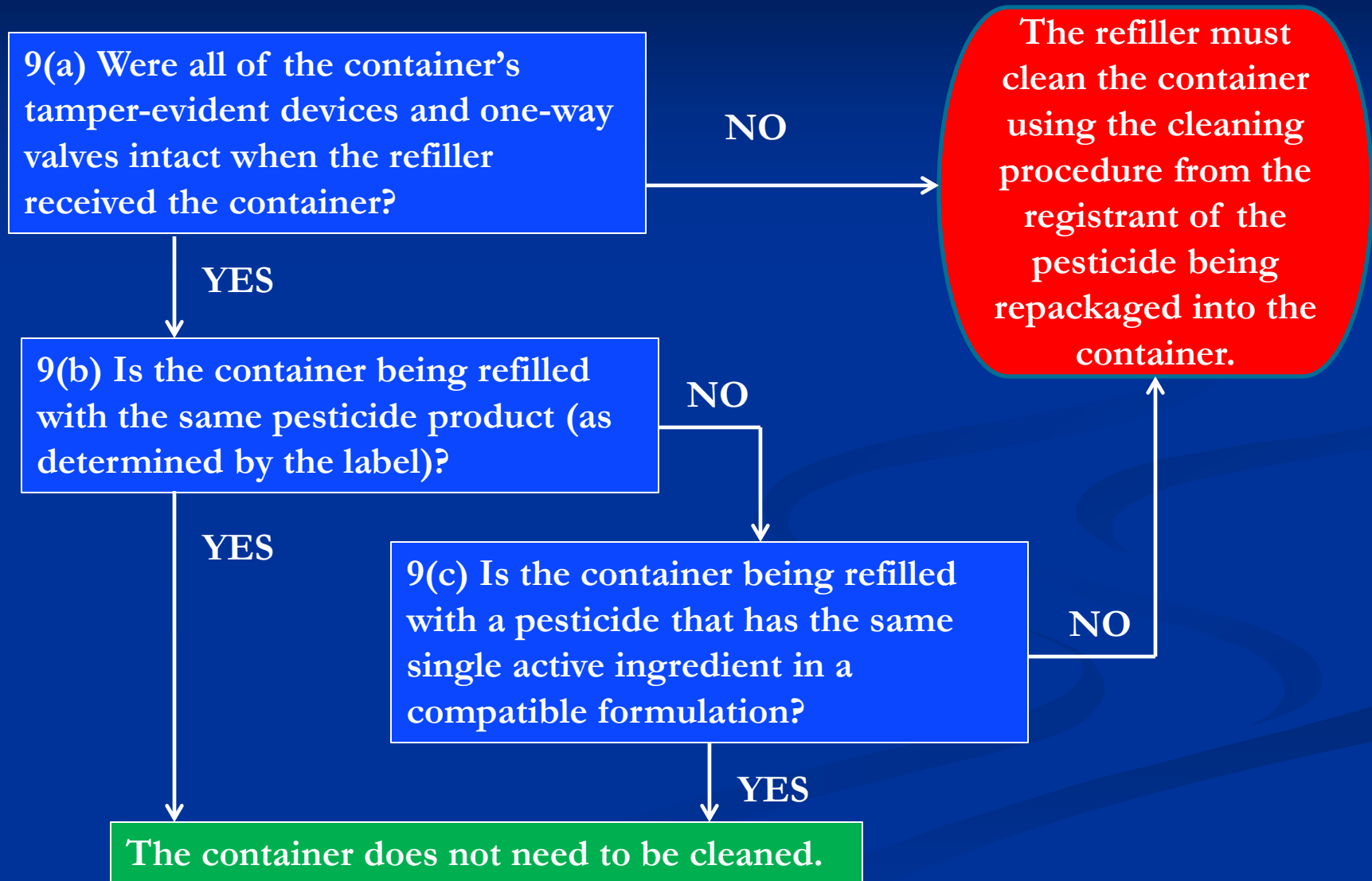
[\$165.3]

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).]



Question 9: Does the container need to be cleaned?



10. If it passes all of these steps, the container can be refilled with the registrant's pesticide.

After refilling the container, the refiller must:

- Close the fill port according to the container manufacturer's instructions and seal the fill port with a tamper-evident device, one-way valve or both;
- Record the date of repackaging, the container serial number/identifying code and the EPA Registration Number of the pesticide and keep that record for 3 years; and...

Refilling the container (continued)

After refilling the container, the 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)]

100.0% feeds, drugs or clothing.

Avoid Freezing — Store Above 40°F

EPA Reg. No. 52715-128 900-014875 / 00297782

*Trademark of Dow AgroSciences LLC
Dow AgroSciences LLC • Indianapolis, IN 46268 U.S.A.

STORAGE TANK
Check box - or -
Write in EPA Est. No. for producing facility.
 EPA Est. No.: 5955-9A-01 Des Moines, IA

EPA Est. No.:

REFILLABLE CONTAINER
Write in EPA Est. No. of repackaging or retailer facility.

EPA Est. No.: **EPA Est.# 546551-NH-001**

NET CONTENTS: 120 Gallons

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) are required for all pesticides, not just dilutable ones.

*** These are examples of allowable statements; variations allowed. ***

Repackaging Requirements

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)]**



Conditions for Repackaging

Under §165.67(b) & §165.70(b), a registrant may allow an independent refiller to repack a pesticide under the registrant's existing registration if:

1. There is no change to the pesticide formulation;
2. The refiller's establishment is registered with EPA;
 - And the pesticide is repackaged at the establishment or at the site of an end user who intends to use/apply the pesticide
3. The registrant & refiller have entered into a written contract to repack the pesticide and use the pesticide's label;
4. The pesticide is repackaged only into containers that comply with the refillable container requirements; and
5. The pesticide is labeled, with the only changes being the net contents and the refiller's EPA establishment number.

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 repackage any quantity; no container size limits.

(continued on next page)

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;
9. Ensure the container is properly labeled; and
10. Record the date, serial number/code of the container; & pesticide.

(continued on next page)

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
13. Maintain records required by Part 169 and report production as required by Part 167.

Stationary Pesticide Containers

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); and
- Properly labeled.

[§165.45(d), §165.70(f) & (i)]



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)

- <http://www.croplifeamerica.org> & www.croplifefoundation.org

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?

Nancy Fitz

703-305-7385

fitz.nancy@epa.gov

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

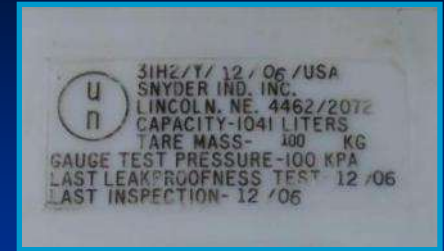
- **Question 4: Can a retailer fill a refillable container on a farm and, if so, what are the applicable regs?**
- **Answer:** Yes, a retailer can fill a refillable container on a farm as long as all of the conditions for repackaging (slide 33) are met and:
 - Containers must be properly labeled;
 - 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]



4. DOT Pathway 3 (for non-bulk)

Question 4-3(a): For non-bulk containers, what DOT marking is required?

- You can determine whether an IBC meets at least the Packing Group III requirements by looking at the DOT marking.
- 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

UN 1A1/Z1.4/150/05
USA/0000



4. DOT Pathway 3 (for non-bulk)

Question 4-3(b): For non-bulk containers, what DOT inspections are required?

- Before each reuse, the container must be inspected and may not be reused unless it is free from incompatible residue, rupture, or other damage which reduces its structural integrity. [49 CFR 173.28(a)]
 - No marking or recordkeeping of the inspection is required.
- A container that shows evidence of a reduction in integrity may not be reused unless it is reconditioned in accordance with §173.28(c). [49 CFR 173.28(b)(1)]
- No internal DOT inspection required.

4. DOT Pathway 3 (for non-bulk)

Question 4-3(c): For non-bulk containers, what other DOT requirements must be met for the container to be reused?

- The container must be in such condition that it is capable of passing all performance tests represented by the markings. [§173.28(a)]
- Metal and plastic drums and jerricans must meet the minimum thickness requirements. [§173.28(b)(4)]
- Metal and plastic drums and jerricans must be marked in a permanent manner (embossed) with the nominal thickness (for metal containers) or minimum thickness (for plastic containers) in mm. [§173.28(b)(4)]

4. DOT Pathway 3 (for non-bulk)

Question 4-3(d): For non-bulk containers, what DOT testing is required?

- Leakproofness test must be done before each reuse if the pesticide is a DOT hazardous material (173.28(b)(2)).
- If pesticide is not a DOT hazmat, EPA regulations (165.45(a)(2)) exempt refiller & container from the leakproofness test requirement if container complies with EPA's standards & refiller complies with repackaging requirements.