

New Container/Containment Regulations: Issues & Concerns From the Regulated Community

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Nonrefillable Containers

- **A test has been requested from EPA to establish that a nonrefillable container for a liquid pesticide meets EPA's design/construction standard for glugging (i.e., that the liquid contents pour from the container in a continuous, coherent stream).**
 - **Per the preamble for the 1994 proposed regulation, "EPA is not proposing specific numerical standards or test methods to verify ... [the glugging standard]. The [Pesticide Containers]: Report to Congress contains a method to demonstrate glugging based on a variation in internal pressure of the container and this method could be adapted for use by registrants. The registrant could use the data from this method or use photographic evidence to demonstrate dispensing capability..."**
 - **Interested registrants & EPA should cooperate on this issue (could build on the preliminary test procedure for glugging and/or use the suggestion of maximum time to empty a jug in a continuous pour or develop photographic evidence).**
 - **Report to Congress also concluded that "certain container design features can result in ... glugging during normal use activities". Thus, EPA expects registrants to examine container design criteria that minimize glugging.**
 - **User education to minimize glugging should also be promoted.**
 - **If necessary, registrants can request a waiver or modification to this standard per 40 CFR 165.25(f).**

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Nonrefillable Containers

- **The refillable container compliance date is: “As of Aug. 17, 2009, all pesticide products distributed or sold by you [the registrant] in nonrefillable containers must be distributed or sold in compliance with these regulations”. This could imply that as of this date, any unsold product (e.g. in a manufacturer’s distribution warehouse or returned to manufacturer) in a noncompliant nonrefillable container would need to be repackaged.**
 - **However, per the preamble, “EPA is not finalizing the 5-year channels of trade provision in the final rule to minimize the disruption and burden of implementing the rule. EPA does not believe that current products and containers pose a large enough hazard (compared to the containers that would be used to comply with the requirements) to justify the cost of recalling them from retailers and distributors to either repackage or dispose of them. EPA believes that setting a date for which products distributed or sold by registrants must comply is sufficient. Products that are distributed and sold before this date can adequately work their way through the distribution system. ”**
 - **The above suggests should be able to interpret “distributed and sold” to include product that has been fully released for distribution or sale by manufacturer prior to Aug. 17, 2009.**

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Refillable Containers

- How do the container/containment requirements for **portable** and **stationary**¹ refillable containers differ?²

Portable Refillable Container	Stationary Refillable Container
Referenced DOT regulations apply (various sections of 49 CFR Part 173 + Parts 178 & 180 as applicable PG III unless DOT hazardous material - then 49 CFR Parts 171 - 180 apply). ³	Referenced DOT regulations apply (various sections in 40 CFR Part 173 + Parts 178 & 180 as applicable PG III unless DOT hazardous material - then 49 CFR Parts 171 - 180 apply). ³
Durable marking (serial # or other identifier) visible on outside container required. ³	Durable marking (serial # or other identifier) visible on outside container required. ³
1-Way valve &/or tamper-evident device on all openings except vent if holds liquid pesticide (x DOT cylinder). Vent design must minimize amount material can introduce through it. ³	
	Container integrity / vent/ shutoff valve / gauge standards at 40 CFR §165.45(f) apply if <u>≥500 gal (liquid)/≥4000 lb (dry) & at establishment of refiller who is not the registrant.</u> ⁴
New containment pad requirements apply to pesticide dispensing areas where portable refillable containers are emptied, cleaned, rinsed, or refilled <u>at a refiller with >50% annual revenue from retail operations.</u> ⁵	New secondary containment requirements apply to large stationary containers (≥500 gal/≥4000 lb) <u>at a refiller with >50% annual revenue from retail operations or at a custom blender or a for hire applicator.</u> ⁵

- Stationary refillable container: Fixed at single facility or, if not fixed, remains at facility for at least 30 consecutive days & holds pesticide during entire time.
- MUPs, PIPs, & certain antimicrobials are exempt all requirements. Antimicrobials used in swimming pools & closely related sites not exempt antimicrobials but are exempt from durable marking/opening requirements.
- All portable or stationary refillable containers used to sell a pesticide product must comply with this standard. **Did EPA inadvertently stipulate that referenced DOT regulations also apply to stationary refillables?**
- Only integrity standard applicable if dry pesticide.
- Applies to all agricultural pesticides.

Refillable Containers

- How do the container/containment requirements for stationary refillable containers ¹ designed to hold **<500 gal** vs. **≥500 gal** of a liquid pesticide differ? ²

Stationary Refillable Container, <500 gal	Stationary Refillable Container, ≥500 gal
Referenced DOT regulations apply (various sections in 40 CFR Part 173 + Parts 178 & 180 as applicable PG III unless DOT hazardous material - then 49 CFR Parts 171 - 180 apply). ³	Referenced DOT regulations apply (various sections in 40 CFR Part 173 + Parts 178 & 180 as applicable PG III unless DOT hazardous material - then 49 CFR Parts 171 - 180 apply). ³
Durable marking (serial # or other identifier) visible on outside container required. ³	Durable marking (serial # or other identifier) visible on outside container required. ³
	Container integrity / vent/ shutoff valve / gauge standards at 40 CFR §165.45(f) apply if ≥500 gal (liquid)/≥4000 lb (dry) & <u>at establishment of refiller who is not the registrant.</u> ⁴
	New secondary containment requirements apply to large stationary containers (≥500 gal/≥4000 lb) <u>at a refiller with >50% annual revenue from retails sales or at a custom blender or a for hire applicator.</u> ⁵

- Stationary refillable container: Fixed at single facility or, if not fixed, remains at facility for at least 30 consecutive days & holds pesticide during entire time.
- MUPs, PIPs, & certain antimicrobials are exempt all requirements. Antimicrobials used in swimming pools & closely related sites not exempt antimicrobials but are exempt from durable marking/opening requirements.
- All portable or stationary refillable containers used to sell a pesticide product must comply with this standard. **Did EPA inadvertently stipulate that referenced DOT regulations also apply to stationary refillables?**
- Only integrity standard applicable if dry pesticide.
- Applies to all agricultural pesticides.

Refillable Containers

- **What is the meaning of the exemption from the refillable container design standards at 40 CFR §165.43(h) for “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 pesticide”.**
 - **Per the initial draft of the new regulations, EPA does not intend to address the design of transport vehicles: “... EPA would like to exclude tank cars and tank trucks used in the distribution of bulk pesticides from the container design standards of this subpart.”**
 - **Should note that transport vehicles as defined above are also similarly exempt from the repackaging regulations (see 40 CFR 165.63(h)).**

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Refillable Containers

- **The refillable container compliance date is: “As of Aug. 16, 2011, all pesticide products distributed or sold by you [the registrant] in refillable containers must be distributed or sold in compliance with these regulations”.**
 - **Channels of trade is not discussed by EPA in the preamble to the final refillable containers regulations.**
 - **However, EPA extended the compliance period for refillable containers to 5 years and writes that “Companies that have already made significant investments in refillable containers will be able to use their existing containers for 5 years, which covers the average expected lifetime of a plastic minibulk container. Also, the changes to the refillable containers will allow existing refillable containers that meet the DOT Packaging Group III standards to be retrofitted relatively easily (by durable marking ... and having a one-way valve and/or tamper-evident device on each opening ...) so they can continue being used. EPA believes that the longer compliance period in the final regulations is reasonable and should apply equally to all products and all refillable containers.”**
 - **The above suggests EPA expects the transition to compliant refillables, which see more strenuous and longer service than nonrefillable containers, should be completed by the 2011 compliance date.**

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Refillable Containers

- **The durable marking requirement is: “Each refillable container [portable and stationary] must be marked in a durable and clearly visible manner with a serial number or other identifying code that will distinguish the individual container from all other containers... includes but is not limited to etching, embossing, ink jetting, stamping, ... mechanically attaching a plate... and marking with durable ink. ...must be located on the outside part of the container except on a closure ”.**
 - **Standard would seem to support the use of bar coding but probably not a chip, which some registrants might prefer.**
 - **Both methods would be consistent with EPA’s intent to use serial number or other identifying code to help identify the source of a faulty container and goal to let registrant/refiller use their own system to insure can differentiate any container from another.**
 - **That the serial number or other identifying code must distinguish any individual container from all others suggests companies may need to include a company reference in the code.**
 - **EPA should confirm bar coding allowable and rule on chip.**

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Nonrefillable/Refillable Containers

- **If a pesticide product has a DOT exemption, how does this work with the DOT-related provisions in the new nonrefillable and refillable container regulations?**
 - **The intent of EPA is that if a pesticide product is packaged in compliance with all relevant DOT requirements, it would be acceptable under EPA's new container regulations. However, the new container regulations as currently written may not accomplish this because they only refer to the DOT regulations at 49 CFR Parts 171-180 and the DOT exemptions are at 49 CFR Part 107 Subpart B.**
 - **Given how the regulations are currently written, registrants probably have to request a waiver from EPA for any pesticide with a DOT exemption (see 40 CFR 165.25 (g)&(h) and 165.45 (g)&(h) for procedure).**
 - **EPA should add the DOT exemption to the new container regulations (or the equivalent) to make a request for waiver unnecessary.**

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Repackaging

- Define the registrant's requirements for the description of acceptable refillable containers (portable & stationary) that must be developed for each pesticide product repackaged by a refiller. **For each repackaged pesticide product, the registrant must specify the acceptable containers according to Option 1 or 2:**

Option 1	Option 2
Compatible materials of construction for portable & stationary refillable containers	Specific portable and stationary containers by model # and manufacturer
Referenced DOT regulation requirements (can specify acceptable portable & stationary ⁽¹⁾ refillable containers by their level of DOT testing which is usually Packaging Group III)	
Durable marking visible on outside of portable & stationary refillable containers requirement	
Opening requirements (1-way valve or tamper-evident device on all openings except vent which must minimize product introduction) <u>if a portable refillable for a liquid pesticide</u>	
Integrity / vent/shutoff valve / gauge requirements <u>if a large stationary refillable (≥500 gal/≥4000 lb) at the refilling establishment of a non-registrant</u>	

1. Did EPA inadvertently stipulate that referenced DOT regulations also apply to stationary refillables?

Repackaging

- **What are the recordkeeping requirements for refillers?
A refiller must maintain the following records for each pesticide product repackaged for the current + 3 years:**
 - **Written contract from the product's registrant**
 - **Written refilling residue removal procedure from registrant**
 - **Written description of acceptable refillable containers (portable & stationary) from registrant**
 - **Each time a pesticide product is repackaged into a refillable container - the EPA Reg. No. of product, date of the repackaging, & serial number [or other identifier] of the refillable container**
 - **Construction, inspection, & maintenance records for all containment structures as required by 40 CFR §165.95**
 - **The pesticide production, inventory, distribution, disposal etc. records as required by 40 CFR Parts 167 & 169 ¹**
- **Do these requirements need to be hard copy or are electronic copies acceptable?**
 - **Regulated community prefers option to keep electronic records whenever possible**

1. Most of these records only need to be maintained for 2 years.

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Repackaging

- **Per the new regulations, a registrant must enter into a written contract with each refiller, i.e., option of written authorization was not finalized since EPA believes (1) two mechanisms are not necessary (2) “written contract” is more familiar terminology and more defined in law than “written authorization”, (3) two virtually indistinguishable in format, length & detail and (4) dropping written authorization would have no impact on current repackaging operations.**
 - **If EPA intends that each refiller must sign and return an original of the written contract to the registrant, it would be very burdensome on the registrant and not achievable when a registrant has a very large number of refillers.**
 - **Regulated community did not have chance to comment on this change since it was not “proposed”, i.e., it only appeared in the final regulations.**

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Repackaging

- **Standard for when must clean a refillable: Must clean a refillable container with the registrant's residue removal procedure unless each tamper-evident device and 1-way valve is intact and refilling with the same product or one with the same single ai and refilling will not cause the composition of the product being repackaged to differ from the composition on its CSF.**
 - Some registrants think the stipulation of “same single active ingredient” should be expanded to “same multiple active ingredients”.
 - BASF only allows refilling with the same product
- **Standard for the residue removal procedure: Must meet the performance standard of being adequate to ensure that the composition of the pesticide product being repackaged does not differ at the time of its distribution or sale from the composition on its CSF. Must also comply with the PR Notice on cross contamination. ¹**
 - This suggests registrant needs to validate the cleaning procedure especially if cross contaminant level is low.

1. PR Notice 96-8: “Toxicologically Significant Levels of Pesticide Active Ingredients”.

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Repackaging

- **A clarification that custom blending is exempt from the repackaging requirements has been requested.**
 - **In the preamble to the new regulations (FR, p. 47382), EPA states “EPA decided to exempt custom blending from.. the repackaging requirements. ...EPA determined that there is an inherent difference between custom blending and repackaging pesticide products for sale or distribution. When a product is repackaged ..., it must meet the ingredient contents identified on the label...a custom blend intentionally mixes a pesticide with another substance. ... the material in the custom blend is no longer just the pesticide product identified on the label.”**
 - **Should note, however, that custom blenders of agricultural pesticides are not exempt from the new containment regulations in 40 CFR 165 subpart E.**

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Repackaging

- **Per the preamble to the new regulations, the Bulk Pesticide Enforcement Policy will remain in effect until the date specified for compliance with the refillable container and repackaging regulations (Aug. 16, 2011) after which it will be rescinded. Clarification of what this means has been requested.**

- **Means that registrants & independent refillers will have until Aug. 16, 2011 to comply with the new refillable container and repackaging regulations but up to that time, the Bulk Pesticide Enforcement Policy will remain in effect.**
- **EPA also believes it is acceptable for registrants and independent refillers to repackage pesticide products under the new regulations which includes repackaging into smaller containers (<55 gal) before the 5 year compliance date as long as they are in full compliance with the refillable container and repackaging regulations.¹**

1. That is, (1) Containers comply with refillable container regulations (meet specified DOT standards, have durable serial # /other identifying code, have 1-way valve and/or tamper-evident device on each opening other than vent, & vent that minimizes possibility of product introduction); (2) Registrant meets repackaging conditions & develops / provides necessary information, including description of acceptable containers & cleaning procedure; (3) Refillers meet repackaging conditions & comply with operational procedures, including inspecting/cleaning/labeling the containers; & (4) All other requirements in refillable container and repackaging regulations are met.¹⁵

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Repackaging

- **Service containers ¹ are used to move pesticide products from bulk storage to end-use applicators in the field, e.g., tanks that are integral part of application or nurse vehicles. EPA has been requested to clarify the boundaries for the regulation of the service container concept, i.e., size, distance, elapsed time, etc. Also, is it only for concentrated pesticide or may it be a diluted solution or both?**
 - **EPA currently does not regulate service containers and this includes the new container and repackaging regulations.**
 - **The new regulations only regulate the containers and repackaging of products for sale or distribution.**
 - **Thus, size, distance, elapsed time etc. are not relevant although EPA has assumed once pesticides are diluted that the elapsed time prior to use should not be excessively long.**
 - **Per EPA's definition of a service container, it may hold concentrated pesticide or the pesticide use dilution.**

1. EPA defines a service container as “any container used to hold, store, or transport a pesticide concentrate or a pesticide use-dilution mixture, other than the original labeled container in which the product was distributed or sold...”

Repackaging

- **The new regulations do not specifically mention (1) the practice of “topping off” a partially filled refillable container or (2) that a refillable container must be empty at the time of refilling.**
 - **Provided each 1-way valve and tamper-evident device is intact and the requirements for inspection prior to repackaging a refillable have been met, “topping off” a partially filled refillable container with the same pesticide product without cleaning (per the registrant’s refilling residue removal procedure for the product) would be compliant since there be no change in composition per the Confidential Statement of Formula. “Topping off” with another pesticide product would not meet the CSF requirement.**
 - **However, registrants must always do/require of their independent refillers what is necessary to ensure the integrity of their product. For example, if there is any chemical or physical stability issue, the registrant would have to address this.**

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Repackaging

- The wording in 40 CFR §165.67 and §165.70 is unclear: “The pesticide product is repackaged **at the site of a user who intends to use or apply the product by a refilling establishment registered with EPA ...**”. What does this mean?
 - EPA is allowing a refilling registered establishment that has entered into a written contract with the registrant to conduct the actual refilling on the site of the actual user (grower) of the pesticide product (provided the registrant and refiller meet all of the requirements at 40 CFR §165.67(b) and 40 CFR §165.70 (b), respectively, which includes that the pesticide product is repackaged only into refillable containers that meet the standards of 40 CFR 165 subpart C).
 - Some find “The pesticide is repackaged **by a refilling establishment registered with EPA at the site of a user who intends to use or apply the product ...**” is clearer.
 - Did EPA mean to exclude registrants from refilling at a farm? From the preamble discussion on continuing their policy in their Mar. 22, '95 “Bulk Pesticide Transfers” memo, it appears EPA did not mean to.

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Containment

- **Elevating stationary liquid containers – EPA needs to define how high container needs to be to prevent flotation. Also, for anchoring, EPA should consider weight of container as factor in minimizing or preventing flotation.**
 - **New regulations say, “You must either anchor or elevate each new [or existing] stationary liquid pesticide container protected by a secondary containment unit to prevent flotation in the event that the secondary containment unit fills with liquid”.**
- **Elevating stationary dry containers – EPA needs to clarify if the dry pesticide containers that must be placed on pallets or a raised concrete platform (to prevent the accumulation of water in or under the pesticide) includes a pallet of individual bags as well as a single container.**
 - **Only stationary pesticide containers designed to hold undivided quantities of agricultural pesticides equal to or greater than 4000 lb (1818 kg) of dry pesticide are subject to the containment regulations in 40 CFR Subpart E.**

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Containment

- **New or existing containment pads in a pesticide dispensing area which have a pesticide container or pesticide-holding equipment with a volume of ≥ 750 gal must have a holding capacity of at least 750 gal. Does “pesticide–holding equipment” include transport vehicles?**
 - **Believe intent of EPA is “No”, i.e., EPA intends to distinguish a transport vehicle from a pesticide container and pesticide-holding equipment and to recognize that transport trucks are only present infrequently or for short periods and that under the new regulations, all transfers must be attended.**
 - **Thus, the transport hose and any other equipment extending from the transport vehicle that holds pesticide product should be included in the capacity calculation but not the transport vehicle itself.**
 - **Should note that EPA is referring to “gravity capacity”. Also, that EPA actually recommends a capacity of 1,000 gal if the containment pad is unprotected from rain.**

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Containment

- **Request for clarification that a transfer vehicle such as a tank truck or railcar that is being used as a pesticide-holding stationary container (means a refillable container that hold ≥ 500 gal of liquid or $\geq 4,000$ lb of dry pesticide and remains at the facility for at least 30 consecutive days, and holds pesticide during the entire time) must comply with the secondary containment regulations.**
 - **EPA recognizes that most large pesticide containers at agrochemical facilities are stationary but some of these containers are actually transport vehicles, e.g., a tank truck) used for prolonged storage. In this case, the primary function of the vessel shifts from pesticide transport to pesticide storage, and therefore containment is required.**

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Containment

- **Spills in new or existing containment structures - EPA needs to clarify that cleanup of a spill needs to be initiated no later than the end of the day it occurs and completed within a reasonable time frame dependent on availability cleanup materials, trained staff, and equipment.**
 - **Regulations say “Ensure that pesticide spills and leaks on or in any containment structure [containment pad or secondary containment unit] are collected and recovered in a manner that ensures protection of human health and the environment (including surface water and ground water) and maximum practicable recovery of the pesticide spilled or leaked. Cleanup must occur no later than the end of each day on which pesticides have been spilled or leaked”.**
 - **Believe intent of EPA is to protect human health and the environment. Thus, spills and leaks, even small ones must be attended to when discovered.**

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Containment

- **Maintenance of new or existing containment structures - EPA needs to further define the definition of immediate as it refers to the repair of cracks, gaps, and damage. Also, EPA needs to define a crack or gap that would trigger the need for repair.**
 - **Regulations say “Immediately repair any areas showing visible signs of damage and seal any cracks and gaps in the containment structure or appurtenances with material compatible with the pesticide being stored or dispensed”.**
 - **Believe intent of EPA is to protect human health and the environment. Thus, immediate repairs must be made at least to the extent that there is no further danger of harm to human health or the environment, i.e., will not advance to a spill or leak.**

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Labeling

- **The regulations require all nonrefillable containers to have the following 4 items on the label or container: (1) The phrase “Nonrefillable container”; (2) A statement regarding reuse; (3) A statement about recycling or reconditioning; & (4) A batch code. If any of the first 3 items are placed on the label, they must be put under an appropriate heading under the “Storage and Disposal” heading. If these 3 items are placed on the container, an appropriate referral statement must be placed on the label under the heading “Storage and Disposal.” For the former case, can the required statements be placed in the Directions for Use booklet rather than on the container label assuming there is an appropriate referral statement?**
 - **For a booklet/stay behind label, this means the required statements would appear on the booklet label under an appropriate heading under the heading “Storage and Disposal”. Per the Label Review Manual, the stay behind label would also have the referral statement "Refer to booklet for directions for use, and storage and disposal instructions.”**

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Definitions

- **Flowable Concentrate (FC), which is defined in the final container/containment rule as “a stable suspension of active ingredients in a liquid intended for dilution with water before use” – can Suspension Concentrate (SC), the terminology normally used by formulators, be substituted for FC?**
 - IUPAC (*Pure Appl. Chem.*, Vol. 68, No.5, pp. 1167-1193, 1996) and GIFAP (1989) define a suspension concentrate (SC) as a “Formulation in which the active ingredient is in the form of a stable dispersion of fine particles in water or organic liquid”.

- **Agricultural pesticide – does this include turf uses?**
 - Per the definition of agricultural pesticide at 40 CFR §165.3, “Yes” if the pesticide is used in the production of turf by a farmer, rancher, orchardist, or other comparable person primarily for sale, consumption, propagation, or other use by man or animals.

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Other Items That Should be Clarified

- **Net Contents on the Labels Used with Repackaging**
 - EPA should clarify the Net Contents requirement for the EPA-approved label on the bulk storage tank at the refiller (also at bulk terminal).
 - “See tank meter” or the equivalent (depending on system used at facility) vs. updating the Net Contents each time product is added to the bulk storage tank should be allowable since it is more accurate.

- **EPA Est. Number on the Labels Used with Repackaging**
 - EPA should clarify the EPA Est. No. requirement for the label on the bulk storage tank at the refiller (also at bulk terminal), i.e., that it should be the EPA Est. No. of the formulation production site until the product is repackaged into a refillable container.

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